JUDGE SCHEINDLIN

13 CIV 1408

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MEDINOL LTD.,

Plaintiff,

v.

CORDIS CORPORATION AND JOHNSON & JOHNSON,

Defendants.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiff Medinol Ltd. ("Medinol" or "Plaintiff"), for its Complaint against Defendants Cordis Corporation ("Cordis") and Johnson & Johnson ("J&J") (collectively "Defendants"), upon knowledge as to its own acts and upon information and belief as to the acts of others, states and alleges as follows:

THE PARTIES

2. Plaintiff Medinol is an Israeli company with its principal place of business at Building #7, Entrance 1, 5th floor, Kiryat Atidim, Tel Aviv, 61581, Israel.

3. Upon information and belief, Defendant Cordis is a Florida corporation with its principal place of business at 430 Route 22 East, Bridgewater, New Jersey 08807.

4. Upon information and belief, Defendant J&J is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. §§ 271, 281, 284, and 285. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Cordis and J&J are subject to personal jurisdiction in the State of New York and this District because, upon information and belief, they conduct business in this District and have committed acts of patent infringement in this District including, *inter alia*, offering for sale and/or selling infringing products, including at least the Cypher Stent, in this District. In addition, Cordis and J&J regularly place their products, including the Cypher Stent, within the stream of commerce, with the knowledge and/or understanding that such products will be sold in this District.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and/or 1400(b) because a substantial part of the events giving rise to Medinol's claims occurred in this District, Cordis and J&J are resident in or otherwise subject to personal jurisdiction in this District, and Cordis and J&J have committed acts of infringement in this District.

THE PATENTS-IN-SUIT

8. Medinol owns all right, title and interest in U.S. Patent No. 5,980,552 (the "'552 patent"); U.S. Patent No. 6,059,811 (the "'811 patent"); U.S. Patent No. 6,589,276 (the "'276 patent"); and U.S. Patent No. 6,875,228 (the "'228 patent") (collectively, the "patents-in-suit").

9. The '552 patent, entitled "Articulated Stent," was duly and legally issued by the United States Patent and Trademark Office on November 9, 1999. A true and correct copy of the '552 patent is attached hereto as Exhibit A.

10. The '811 patent, entitled "Articulated Stent," was duly and legally issued by the United States Patent and Trademark Office on May 9, 2000. A true and correct copy of the '811 patent is attached hereto as Exhibit B.

11. The '276 patent, entitled "Articulated Stent," was duly and legally issued by the United States Patent and Trademark Office on July 8, 2003. A true and correct copy of the '276 patent is attached hereto as Exhibit C.

12. The '228 patent, entitled "Articulated Stent," was duly and legally issued by the United States Patent and Trademark Office on April 5, 2005. A true and correct copy of the '228 patent is attached hereto as Exhibit D.

13. Each of the four patents-in-suit claims priority to U.S. Application No. 08/213,272 (the "'272 application"), filed on March 17, 1994, which issued as U.S. Patent No. 5,449,373 (the "'373 patent") on September 12, 1995.

14. Upon information and belief, Cordis and J&J had knowledge of the '373 patent no later than when the '373 patent issued in 1995, and knowledge of the continuation applications that claim priority to the '373 patent and that led to the patents-in-suit on or about the time the applications were pending and publicly available for inspection in the United States Patent and Trademark Office. Upon information and belief, Cordis and J&J had knowledge of each of the patents-in-suit on or about the date each patent issued, but in no event later than 2006.

15. In an earlier case in this District before District Judge Scheindlin captioned as *Medinol Ltd. v. Guidant Corp. and Advanced Cardiovascular Systems, Inc.*, No. 03 Civ. 2604, Medinol asserted different but related patents that issued from a continuation-in-part application of the '272 application that is the parent application of the '552, '811, '276 and '228 patents. In the course of construing the patent claim language and ruling on motions for summary judgment

related to validity and other issues in the Guidant case, Judge Scheindlin considered the prosecution history of the '272 parent application, as well as certain prior art references that may also be relevant in this new case. *See, e.g.*, *Medinol Ltd. v. Guidant Corp.*, 341 F.Supp.2d 301 (S.D.N.Y. 2004); *Medinol Ltd. v. Guidant Corp.*, 2004 WL 2210290 (S.D.N.Y. Sept. 30, 2004); *Medinol Ltd. v. Guidant Corp.*, 412 F.Supp.2d 301 (S.D.N.Y. 2005); *Medinol Ltd. v. Guidant Corp.*, 417 F.Supp.2d 280 (S.D.N.Y. 2006).

COUNT I

INFRINGEMENT OF THE '552 PATENT

16. Medinol incorporates each of the preceding paragraphs 1-15 as if fully set forth herein.

17. Cordis and J&J have directly infringed the '552 patent, in violation of 35 U.S.C. § 271(a), by making, using, selling, offering for sale, and/or importing in or into the United States, without authority, products that embody the patented invention, including the Cypher Stent and the Cypher Select Stent.

18. Upon information and belief, Cordis and J&J's infringement of the '552 patent has been and is willful because Cordis and J&J have had knowledge of the '552 patent since on or about the date the '552 patent issued, November 9, 1999, but have nonetheless deliberately engaged in infringing conduct by making, using, selling, offering for sale, and/or importing the Cypher Stent and the Cypher Select Stent despite knowing that these products infringe the '552 patent.

19. As a direct and proximate result of the acts of patent infringement by Cordis and J&J, Medinol has been damaged and is entitled to damages in an amount adequate to compensate Medinol for this infringement of the '552 patent, but in no event less than a reasonable royalty

under 35 U.S.C. § 284.

20. Medinol has incurred and will incur attorneys' fees, costs, and expenses in the prosecution of this action. The circumstances of this dispute create an exceptional case within the meaning of 35 U.S.C. § 285, and Medinol is entitled to recover its reasonable and necessary fees and expenses.

COUNT II

INFRINGEMENT OF THE '811 PATENT

21. Medinol incorporates each of the preceding paragraphs 1-15 as if fully set forth herein.

22. Cordis and J&J have directly infringed the '811 patent, in violation of 35 U.S.C. § 271(a), by making, using, selling, offering for sale, and/or importing in or into the United States, without authority, products that embody the patented invention, including the Cypher Stent and the Cypher Select Stent.

23. Upon information and belief, Cordis and J&J's infringement of the '811 patent has been and is willful because Cordis and J&J have had knowledge of the '811 patent since on or about the date the '811 patent issued, May 9, 2000, but have nonetheless deliberately engaged in infringing conduct by making, using, selling, offering for sale, and/or importing the Cypher Stent and the Cypher Select Stent despite knowing that these products infringe the '811 patent.

24. As a direct and proximate result of the acts of patent infringement by Cordis and J&J, Medinol has been damaged and is entitled to damages in an amount adequate to compensate Medinol for this infringement of the '811 patent, but in no event less than a reasonable royalty under 35 U.S.C. § 284.

25. Medinol has incurred and will incur attorneys' fees, costs, and expenses in the

prosecution of this action. The circumstances of this dispute create an exceptional case within the meaning of 35 U.S.C. § 285, and Medinol is entitled to recover its reasonable and necessary fees and expenses.

COUNT III

INFRINGEMENT OF THE '276 PATENT

26. Medinol incorporates each of the preceding paragraphs 1-15 as if fully set forth herein.

27. Cordis and J&J have directly infringed the '276 patent, in violation of 35 U.S.C. § 271(a), by making, using, selling, offering for sale, and/or importing in or into the United States, without authority, products that embody the patented invention, including the Cypher Stent.

28. Upon information and belief, Cordis and J&J's infringement of the '276 patent has been and is willful because Cordis and J&J have had knowledge of the '276 patent since on or about the date the '276 patent issued, July 8, 2003, but have nonetheless deliberately engaged in infringing conduct by making, using, selling, offering for sale, and/or importing the Cypher Stent despite knowing that these products infringe the '276 patent.

29. As a direct and proximate result of the acts of patent infringement by Cordis and J&J, Medinol has been damaged and is entitled to damages in an amount adequate to compensate Medinol for this infringement of the '276 patent, but in no event less than a reasonable royalty under 35 U.S.C. § 284.

30. Medinol has incurred and will incur attorneys' fees, costs, and expenses in the prosecution of this action. The circumstances of this dispute create an exceptional case within the meaning of 35 U.S.C. § 285, and Medinol is entitled to recover its reasonable and necessary fees and expenses.

COUNT IV

INFRINGEMENT OF THE '228 PATENT

31. Medinol incorporates each of the preceding paragraphs 1-15 as if fully set forth herein.

32. Cordis and J&J have directly infringed the '228 patent, in violation of 35 U.S.C. § 271(a), by making, using, selling, offering for sale, and/or importing in or into the United States, without authority, products that embody the patented invention, including the Cypher Stent.

33. Upon information and belief, Cordis and J&J's infringement of the '228 patent has been and is willful because Cordis and J&J have had knowledge of the '228 patent since on or about the date the '228 patent issued, April 5, 2005, but have nonetheless deliberately engaged in infringing conduct by making, using, selling, offering for sale, and/or importing the Cypher Stent despite knowing that these products infringe the '228 patent.

34. As a direct and proximate result of the acts of patent infringement by Cordis and J&J, Medinol has been damaged and is entitled to damages in an amount adequate to compensate Medinol for infringement of the '228 patent, but in no event less than a reasonable royalty under 35 U.S.C. § 284.

35. Medinol has incurred and will incur attorneys' fees, costs, and expenses in the prosecution of this action. The circumstances of this dispute create an exceptional case within the meaning of 35 U.S.C. § 285, and Medinol is entitled to recover its reasonable and necessary fees and expenses.

PRAYER FOR RELIEF

Medinol requests that judgment be entered in its favor and against Cordis and J&J, and that the Court award the following relief to Medinol:

(a) damages in an amount adequate to compensate Medinol for infringement of the patents-in-suit, and in no event less than a reasonable royalty;

(b) increased damages in an amount three times the damages found by the jury or assessed by the Court for the willful infringement of the patents-in-suit pursuant to 35 U.S.C. § 284;

(c) expenses, costs, and reasonable attorneys' fees pursuant to 35 U.S.C. § 285 and Federal Rule of Civil Procedure 54;

(d) prejudgment and post-judgment interest on all damages; and

(e) such other and further relief as the Court deems just and proper.

JURY DEMAND

In accordance with Federal Rules of Civil Procedure 38 and 39, Medinol asserts its rights under the Seventh Amendment to the United States Constitution and demands a trial by jury on all issues triable by a jury.

Dated: March 1, 2013

Respectfully submitted,

Richard L. Delucia
Elizabeth A. Gardner
Antony A. Pfeffer
Mark A. Chapman
KENYON & KENYON LLP
One Broadway
New York, New York 10004
(212) 425-7200 (main)
(212) 425-5288 (fax)

Counsel for Plaintiff Medinol Ltd.

EXHIBIT A

US005980552A

United States Patent [19]

Pinchasik et al.

[11] **Patent Number: 5,980,552**

[45] **Date of Patent: *Nov. 9, 1999**

[54] **ARTICULATED STENT**

[75] Inventors: **Gregory Pinchasik; Jacob Richter,** both of Ramat Hasharon, Israel

[73] Assignee: **Medinol Ltd.,** Tel Aviv, Israel

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

This patent is subject to a terminal disclaimer.

[21] Appl. No.: **08/760,359**

[22] Filed: **Dec. 4, 1996**

Related U.S. Application Data

[63] Continuation of application No. 08/455,462, May 31, 1995, abandoned, which is a continuation of application No. 08/213,272, Mar. 17, 1994, Pat. No. 5,449,373.

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **606/198**; 623/1; 623/12

[58] **Field of Search** 606/1, 108, 191, 606/194, 195, 198, 200; 623/1, 11, 12; 128/898, 899

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,733,665	3/1988	Palmaz .
4,762,128	8/1988	Rosenbluth .
4,800,882	1/1989	Gianturco .
4,830,003	5/1989	Wolff et al. .
4,856,516	8/1989	Hillstead .
4,886,062	12/1989	Wiktor .
4,922,905	5/1990	Strecker .
4,950,227	8/1990	Savin et al. .
4,969,458	11/1990	Wiktor .
4,994,071	2/1991	MacGregor .
5,019,085	5/1991	Hillstead .
5,019,090	5/1991	Pinchuk .
5,035,706	7/1991	Giantureo .
5,102,417	4/1992	Palmaz .
5,104,404	4/1992	Wolff .
5,116,365	5/1992	Hillstead .
5,133,732	7/1992	Wiktor .
5,158,548	10/1992	MacGregor .
5,161,547	11/1992	Tower .
5,195,984	3/1993	Schatz .
5,282,824	2/1994	Gianturco .
5,314,472	5/1994	Fontaine .
5,330,500	7/1994	Song .
5,354,308	10/1994	Simon et al. .
5,354,309	10/1994	Schepp et al. .
5,383,892	1/1995	Cardon et al. .
5,405,377	4/1995	Cragg .
5,441,515	8/1995	Khosravi et al. .
5,443,496	8/1995	Schwartz et al. .
5,449,373	9/1995	Pinchasik et al. .
5,507,767	4/1996	Maeda et al. .
5,540,712	7/1996	Kleshinski et al. .
5,554,181	9/1996	Das .
5,643,312	7/1997	Fischell et al. .
5,649,952	7/1997	Lam .
5,651,174	7/1997	Schwartz et al. .
5,653,727	8/1997	Wiktor .

FOREIGN PATENT DOCUMENTS

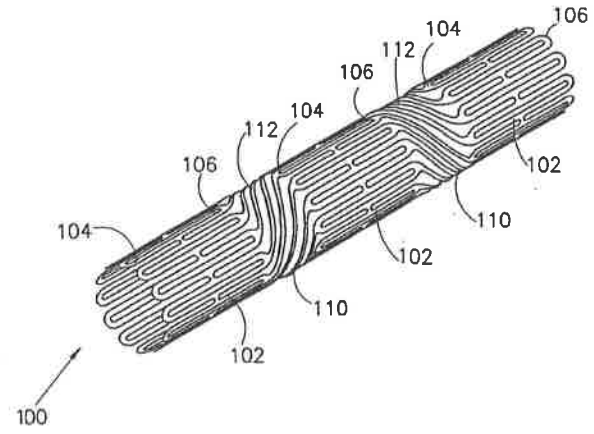
0 335 341	4/1989	European Pat. Off. .
0 514 443 A1	5/1993	European Pat. Off. .
0 540 290	5/1993	European Pat. Off. .
0 541 443	5/1993	European Pat. Off. .
0 566 807	10/1993	European Pat. Off. .
0 606 165	7/1994	European Pat. Off. .
WO 95/31945	11/1995	WIPO .
WO 96/03092	2/1996	WIPO .

Primary Examiner—Michael Buiz
Assistant Examiner—William Lewis
Attorney, Agent, or Firm—Kenyon & Kenyon

[57] **ABSTRACT**

An articulated stent for delivering through a bodily conduit, for example, a peripheral or coronary artery, which has one or more curved portions and for implantation therein. The articulated stent includes at least two substantially rigid segments and a flexible connector for connecting adjacent segments. The connector assumes a cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

14 Claims, 5 Drawing Sheets



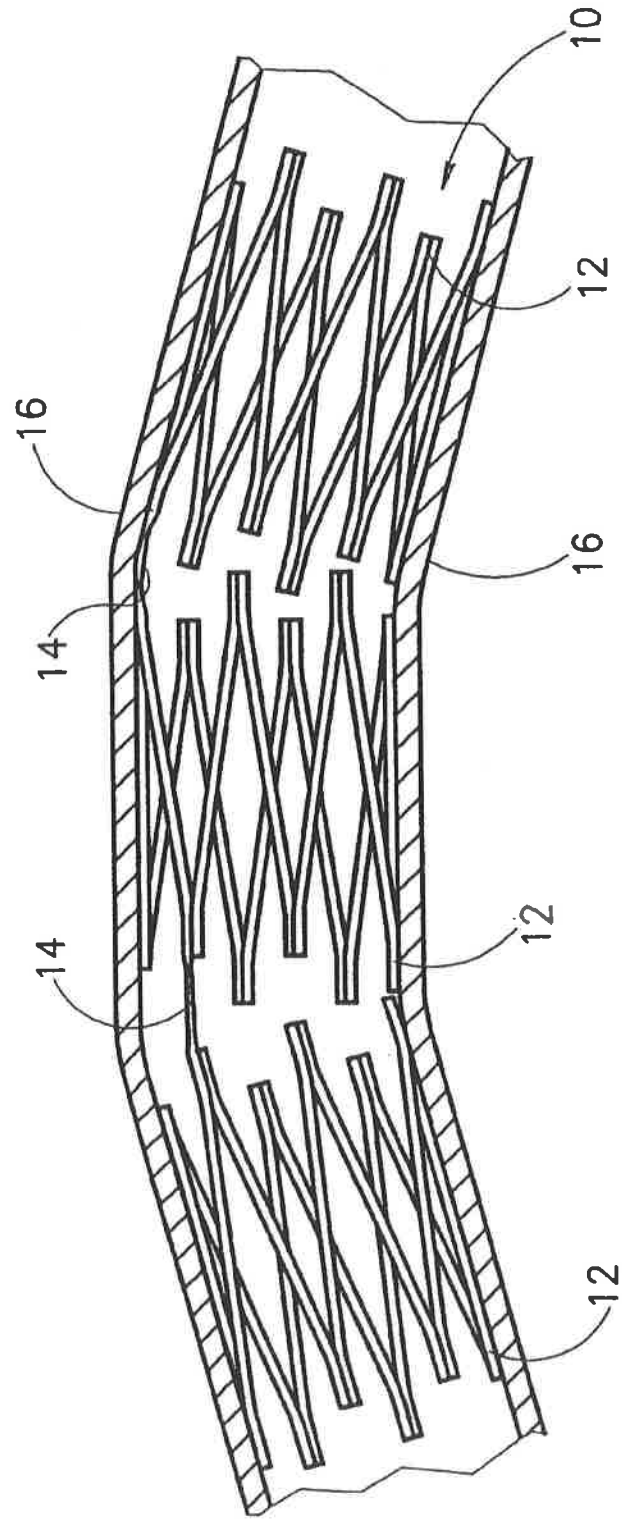


FIG. 1
PRIOR ART

FIG.2A

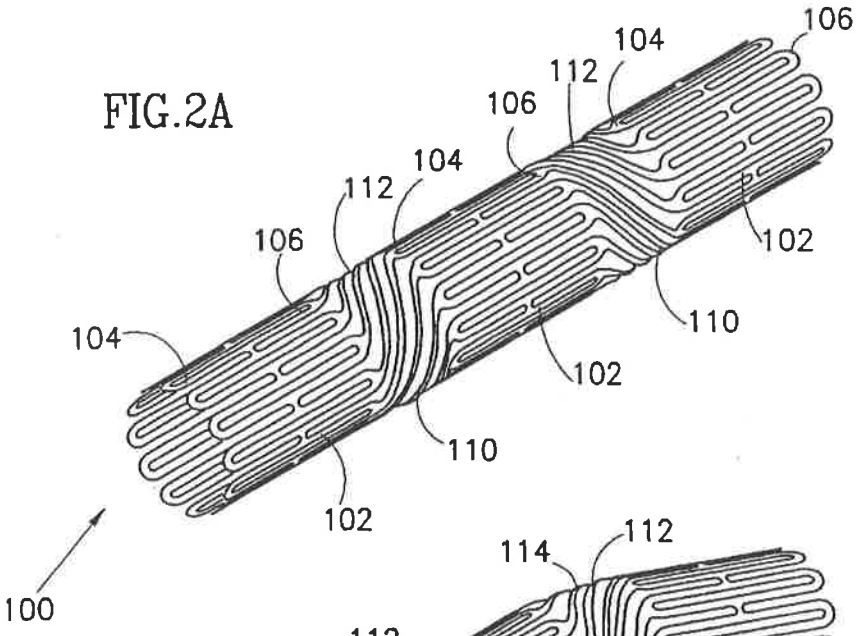


FIG.2B

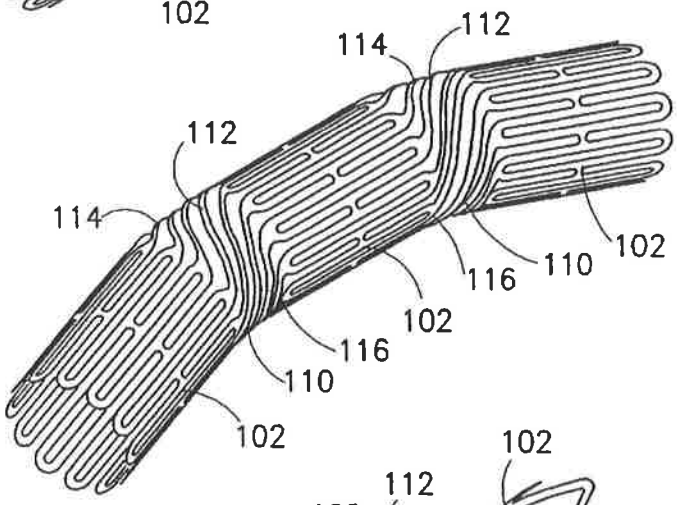
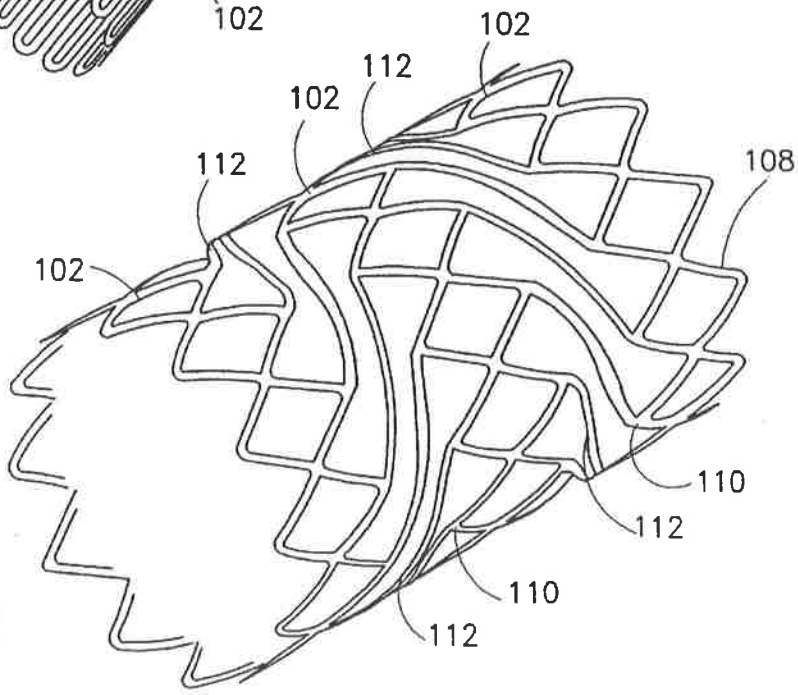


FIG.2C



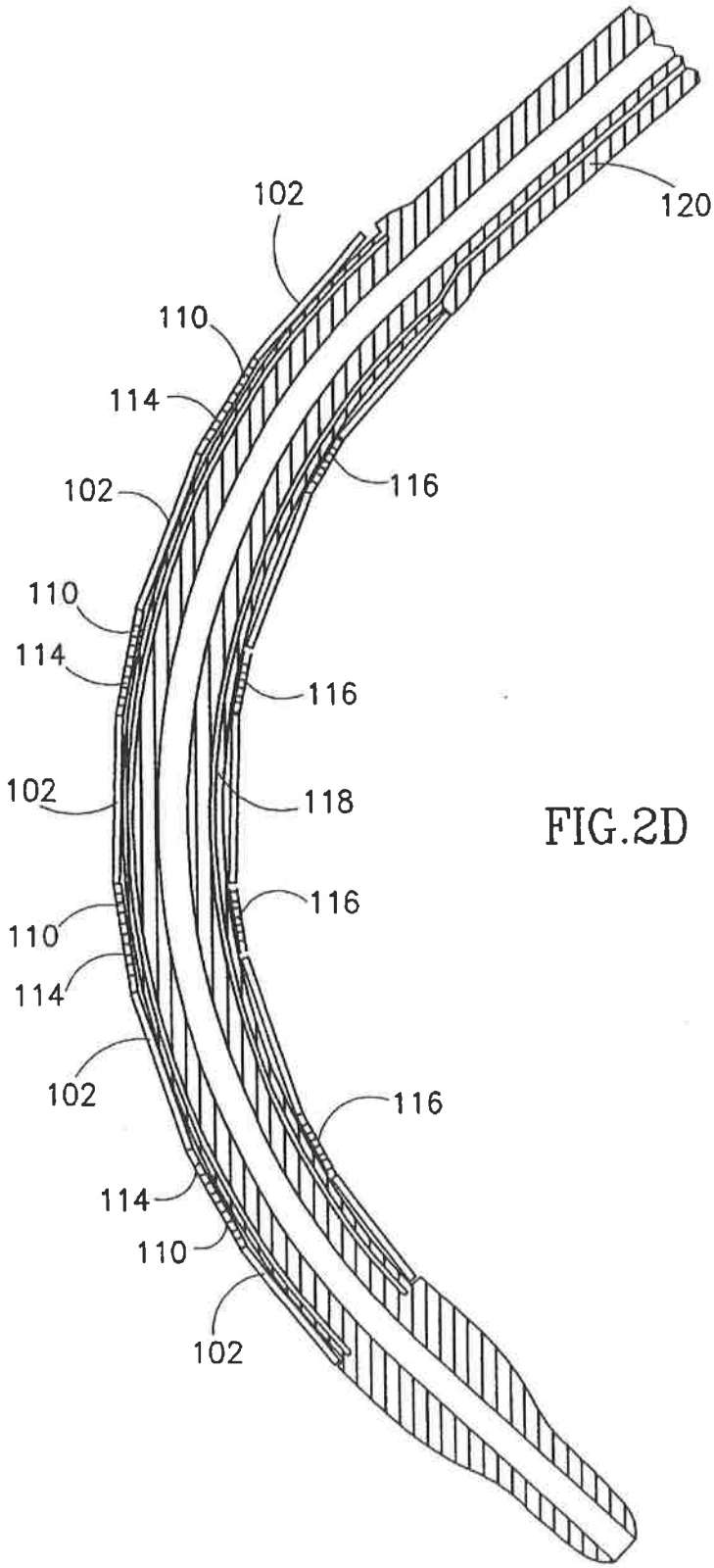

102
120
110
114
102
116
110
114
116
102
118
116
110
114
102
116
114
110
102

FIG.2D

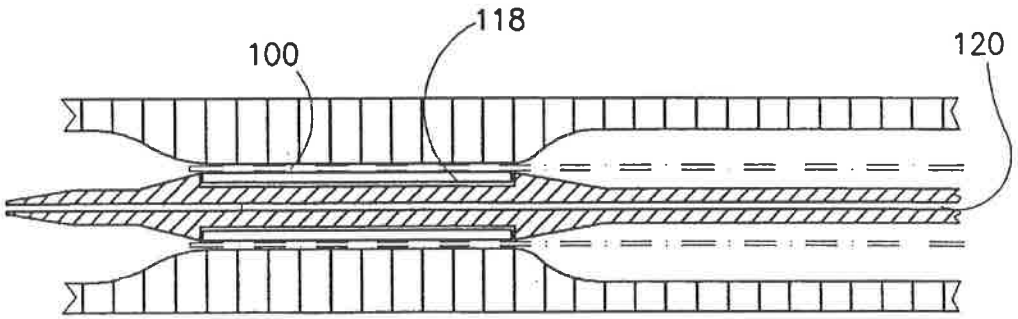


FIG.2E

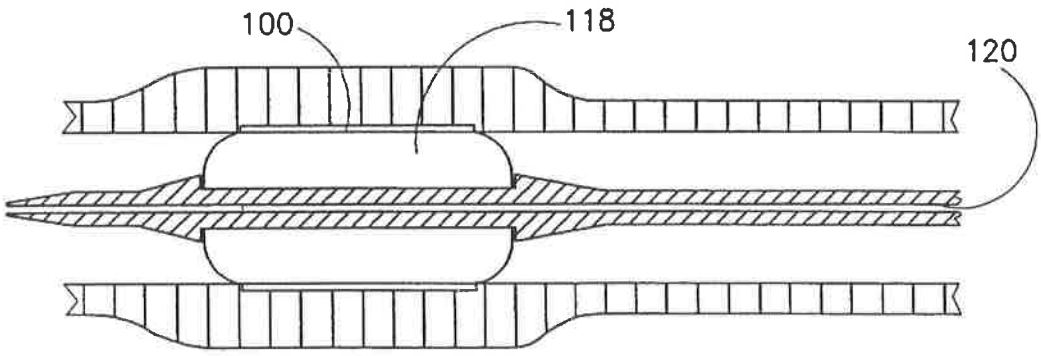


FIG.2F

FIG.3A

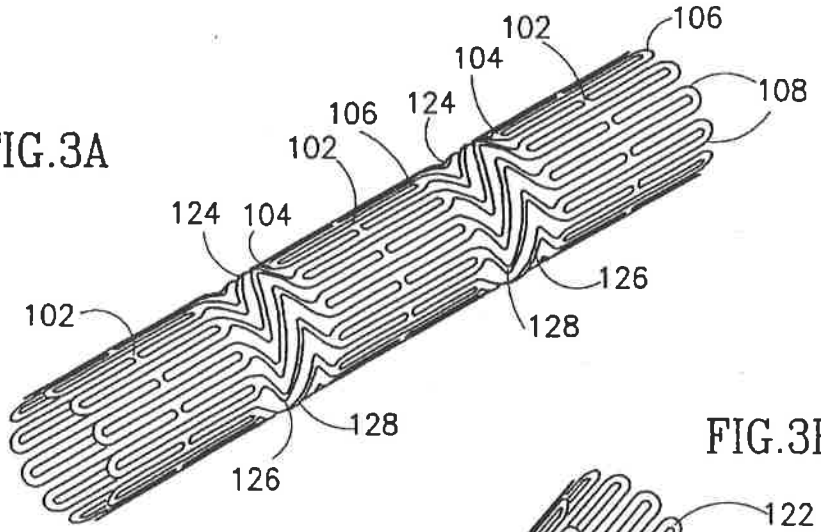


FIG.3B

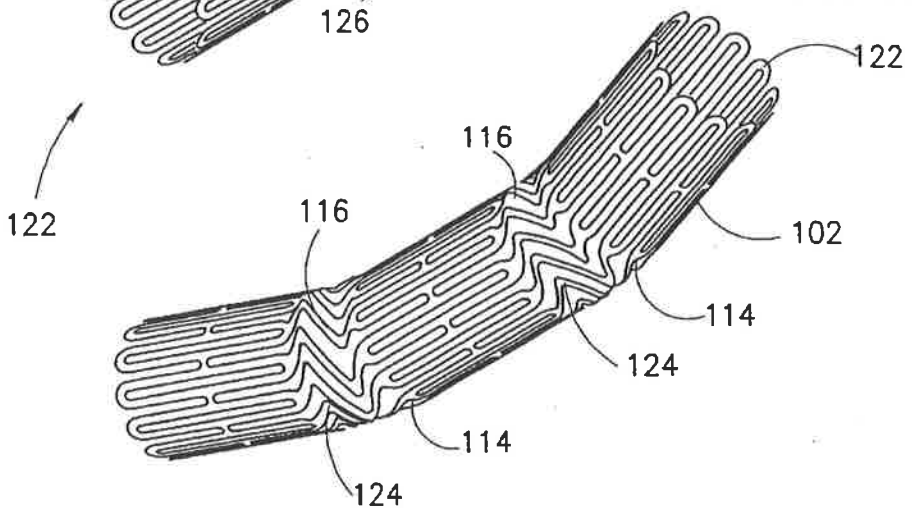
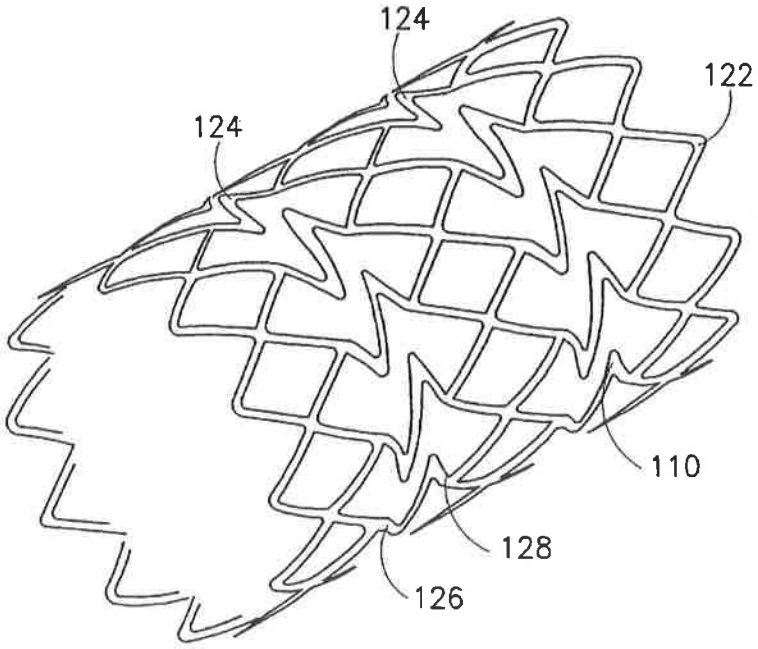


FIG.3C



ARTICULATED STENT

This application is a continuation of application Ser. No. 08/455,462, filed on May 31, 1995, now abandoned, which is a continuation of Ser. No. 08/213,272 filed Mar. 17, 1994 now U.S. Pat. No. 5,449,373.

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to stents which are implanted as part of a balloon angioplasty procedure within a bodily conduit of a living animal or a human to maintain patency. In particular, the present invention relates to articulated intravascular stents for delivery through or implantation in a blood vessel having a curved portion.

Intravascular stents having a constricted diameter for delivery through a blood vessel and an expanded diameter for applying a radially outwardly extending force for supporting the blood vessel are known in the art. Articulated intravascular stents for either delivery through a curved blood vessel or implanted therein are also known in the art.

Self-expandable articulated stents are described, for example, in U.S. Pat. No. 5,104,404 entitled "Articulated Stent" to Wolff. Balloon expandable articulated stents are commercially available under the trade name Palmaz-Schatz Balloon-Expandable Stents from Johnson & Johnson Intervention Systems Co.

A prior art self-expandable articulated intravascular stent **10** deployed in a curved blood vessel **16** is now described with reference to FIG. **1** which is, in actual fact, FIG. **2** of the above referenced U.S. Pat. No. 5,104,404. Stent **10** is made up of a number of individual segments **12** articulated by hinges **14** connected at each end to segments **12**. Stent **10** is preferably fabricated from memory shape material, for example, nitinol, and as such is self expandable after delivery from a delivery system described in U.S. Pat. No. 4,830,003 to Wolff et al. However, these prior art articulated intravascular stents suffer from a number of disadvantages both during delivery through a curved blood vessel and when implanted therein as will now described.

The delivery of stent **10** through curved blood vessel **16** is more complicated than the delivery of a non-articulated stent in that stent **10** has to be angularly oriented such that its hinges **14** are located towards the convex portion of blood vessel **16** so that stent **10** can be flexed inward. In the present example, it will be noted that hinges **14** are located on the same side of segments **12** because blood vessel **16** has only a simple curve in one plane. It can be readily appreciated that delivery of stents through blood vessels which have one or more curved portions which are not in the same plane is even more complicated and generally requires specially constructed stents.

Even when implanted in a curved blood vessel **16**, stents **10** are shown to be lacking in that the gaps between segments **12** render the curved portion of blood vessel **16** without support. Furthermore, the gaps at the convex portion of blood vessel **16** are substantially greater than the gaps at the concave portion thereof, thereby inducing non-uniform and therefore undesirable stresses on blood vessel **16**.

Therefore, it would be highly desirable to have an articulated stent which does not require any particular angular orientation when being delivered through a curved bodily conduit and provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted.

It would also be highly desirable the structure of a stent does not depend on the particular orientations of curved portions of a blood vessel.

SUMMARY OF THE INVENTION

The object of the present invention is for an articulated stent which can be delivered through a curved bodily conduit using a routine medical procedure and a conventional stent delivery system. Furthermore, the stent provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted. Still further, the structure of a stent and its support of a bodily conduit do not depend on the orientations of the curved portions of the conduit.

The objective of the present invention is achieved by an articulated stent, comprising: (a) at least two substantially rigid segments; and (b) a flexible connector for connecting adjacent segments, wherein the connector assumes a substantially cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

After expansion, the rigid segments of the stent preferably present a fine diamond shaped mesh having I mm long sides to provide continuous and uniform support for straight portions of a bodily conduit.

The connectors can be implemented as a plurality of substantially helical links connecting adjacent segments. Alternatively, the connectors can be implemented as links each having at least one kink. The connectors typically have between 8–24 links to provide continuous and uniform support for both straight and curved portions of a bodily conduit.

The stents have constricted diameters for intraluminal delivery and are then deformed, by the inflation of a balloon forming part of their catheter delivery system, to expanded diameters for applying radially outwardly extending forces for supporting the lumen of bodily conduits. The constricted and expanded diameters of the stents typically fall in the ranges of 1.0–3.5 mm and 3.5–10.0 mm, respectively.

The stents are preferably fabricated from low memory, more plastic than elastic, bio-compatible materials, for example, stainless steel 316L, gold, tantalum, etc. which enables them to be plastically deformed from their constricted diameters to their expanded diameters.

A typical stent for implantation in a human coronary artery is 9–21 mm long comprising three to seven 2.2 mm long stent segments connected by two to six 1 mm long connectors such that the ends of the stent subtend between a 45° to 135° angle at a radius of curvature of approximately 9 mm when flexed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. **1** shows a close-up view of a prior art articulated stent of deployed in a curved blood vessel;

FIGS. **2***a* and **2***b* show a preferred embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation;

FIG. **2***c* shows the expanded stent of FIG. **2** after plastic deformation;

FIG. **2***d* shows the stent of FIG. **2** mounted on a catheter in its flexed state;

FIGS. **2***e* and **2***f* show the stent of FIG. **2** before and after expansion by a balloon forming part of its catheter delivery system;

FIGS. 3*a* and 3*b* show a second embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation; and

FIG. 3*c* shows the expanded stent of FIG. 3 after plastic deformation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an articulated stent for delivering through a curved bodily conduit, for example, a peripheral or coronary artery of a living animal or a human and implantation therein as part of a balloon angioplasty procedure to maintain patency.

The principles and operation of the articulated stent of the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, FIGS. 2*a*–2*c* show an articulated stent, generally designated **100**, constructed and operative according to the teachings of the present invention, generally comprising a number of substantially rigid segments **102** connected by connectors **110**.

Segments **102** are preferably made up to present a fine diamond mesh of interconnected diamond shaped cells **108** having 1 mm sides on expansion as best seen in FIG. 2*c*. Depending on the intended diameter of stent **100**, segments **102** typically comprise between 8–24 diamond shaped cells **108**.

Connectors **110** comprise links **112** connecting a front end **104** to a tail end **106** of adjacent segments **102**. Links **112** preferably extend in a substantially helical fashion between apexes of diamond shaped cells **108** at front and rear ends **104** and **106** of adjacent segments **102** such that the number of links **112** equals the number of cells **108**. Links **112** are preferably evenly deployed around perimeters of segments **102** such that connectors **110** can be equally flexed in any direction and to provide continuous and uniform support to both straight and curved portions of a bodily conduit.

Alternate connectors **110** at front and rear ends **104** and **106**, respectively, of a segment **102** preferably have links **112** wound in clockwise and counter clockwise directions. Alternately winding connectors **110** ensures that the rotational displacement of links **112** and adjacent segments **102** relative to the walls of a blood vessel and more importantly the balloon of its delivery system is minimized when stent **100** is expanded.

It is particular feature of the present invention that connectors **110** have a generally cylindrical configuration when stent **100** is relaxed as best seen in FIG. 2*a* and a differentially stretched and compressed curved configuration when stent **100** is flexed as best seen in FIG. 2*b*. The flexed configuration is brought about by two relatively opposing displacements of links **112**. First, the differential stretching of connectors **110** occurs at the convex portion thereof denoted **114** by links **112** being displaced away from one another. Second, the differential compressing of connectors **110** occurs at the concave portion thereof denoted **116** by links **112** being displaced towards one another.

Stent **100** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 2*a* and 2*b* and an expanded diameter as shown in FIG. 2*c* for supporting a bodily conduit. Stent **100** is preferably fabricated from low memory, more plastic than elastic, biocompatible material, for example, stainless steel 316L, gold, tantalum, etc. which enables it to be plastically deformed from its constricted diameter to its expanded diameter. The constricted and expanded diameters of stent **100** typically fall in the ranges of 1.0–3.5 mm and 3.5–10.0 mm, respectively.

With reference now to FIGS. 2*d*–2*f*, stent **100** is shown overlying a balloon **118** forming part of its catheter delivery system **120**. Stent **100** is mounted on its catheter delivery system **120** in its constricted diameter state shown in FIG. 2*e* for plastic deformation through inflation of balloon **118** to its expanded diameter shown in FIG. 2*f* for supporting the walls of a bodily conduit. An exemplary stent for implantation in a human coronary artery, is typically 15 mm long made up of five 2.2 mm long segments **102** connected by four 1 mm long connectors **110** and capable of flexion such that its ends subtend a 90° angle at a radius of curvature of approximately 9 mm.

The delivery of articulated stent **100** is considerably simpler than the delivery of prior art articulated stent **10** because stent **100** is equally flexible in all direction and therefore does not require a dedicated angular orientation to pass a particular curved portion. This advantage is particularly important for delivery through blood vessels having multiple curved portions. It is a further advantage of stent **100** over prior art stents **10**, that stent **100** provides continuous and uniform support along the entire length of a blood vessel by means of segments **102** and unflexed connectors **110** supporting straight portions thereof while connector portions **114** and **116** supporting convex and concave curved portions thereof, respectively.

With reference now to FIGS. 3*a* and 3*b*, an articulated stent **122** is shown in which connectors **124** comprise links **126** having one or more kinks **128**. The design of connectors **124** is preferred to that of connector **110** because stent **100** may have a tendency to rupture balloon **118** due to two reasons. First, links **112** overlying the convex portion of balloon **118** have a tendency to be biased inward when stent **100** is flexed. Second, segments **102** display a rotational displacement relative to balloon **118** when stent **100** is expanded.

In this case, the differentially stretched and compressed curved configuration of connector **124** is brought about by two relatively opposing displacements of links **112** as before except that the differential stretching of connectors **124** at convex portion **114** occurs by kinks **128** being somewhat straightened out while the differential compressing of connectors **24** at concave portion **116** occurs by kinks **128** being more acutely bent.

In a similar fashion to stent **100**, stent **122** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 3*a* and 3*b* and an expanded diameter as shown in FIG. 3*c* for supporting a bodily conduit when implanted therein.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

What is claimed is:

1. A connector for connecting adjacent areas of adjacent substantially tubular and substantially rigid segments of an articulated stent, the connector comprising:

a plurality of flexible links,

wherein each of said flexible links includes a plurality of portions with each pair of neighboring portions when viewed laterally having an area of inflection therebetween.

2. A connector according to claim **1** and wherein, during expansion of said stent, said area of inflection of each flexible link remains inflected.

3. A connector for connecting adjacent substantially tubular and substantially rigid segments of an expandable articulated stent, comprising:

a flexible link having at least a first portion and a second portion and when viewed laterally an area of inflection disposed between said first portion and said second portion.

4. The connector according to claim 3, wherein said area of inflection remains inflected after the expansion of said stent.

5. The connector of claim 4, wherein said portions are of different lengths and wherein the length of the longer of said portions is not greater than twice the length of the shorter of said portions.

6. The connector of claim 1 or 3, in which the area of inflection enlarges during the expansion of the stent.

7. The connector of claim 1 or 3, in which said portions are generally straight.

8. A connector for connecting adjacent substantially tubular and substantially rigid segments of an expandable articulated stent, comprising:

a flexible link having at least a first portion, a second portion and a third portion, said link when viewed laterally having;

a first area of inflection disposed between said first portion and said second portion; and

a second area of inflection disposed between said second portion and said third portion.

9. The connector of claim 8, wherein said first area of inflection and said second area of inflection remain inflected after the expansion of said stent.

10. The connector of claim 8, wherein said portions are of different lengths and wherein the length of the longer of said portions is not greater than twice the length of the shorter of said portions.

11. The connector of claim 8 in which said first area of inflection and said second area of inflection enlarge during the expansion of said stent.

12. The connector of claim 8, in which said portions are generally straight.

13. A connector for connecting segments of an expandable articulated stent, comprising:

a flexible link having at least a first portion, a second portion and a third portion; said link when viewed laterally having an area of inflection disposed between each of said portions, said areas of inflection disposed in substantially opposed directions.

14. The connector according to claim 13, wherein said areas of inflection enlarge during the expansion of said stent.

* * * * *

EXHIBIT B

US006059811A

United States Patent [19]

Pinchasik et al.

[11] Patent Number: 6,059,811

[45] Date of Patent: *May 9, 2000

[54] **ARTICULATED STENT**

[75] Inventors: **Gregory Pinchasik; Jacob Richter,** both of Ramat Hasharon, Israel

[73] Assignee: **Medinol Ltd.,** Tel Aviv, Israel

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **09/026,750**

[22] Filed: **Feb. 20, 1998**

Related U.S. Application Data

[63] Continuation of application No. 08/760,359, Dec. 4, 1996, which is a continuation of application No. 08/455,462, May 31, 1995, abandoned, which is a continuation of application No. 08/213,272, Mar. 17, 1994, Pat. No. 5,449,373.

[51] **Int. Cl.**[7] **A61M 29/00**

[52] **U.S. Cl.** **606/198**; 606/194; 623/1; 623/12

[58] **Field of Search** 606/1, 108, 151, 606/154, 155, 158, 200; 623/1, 12

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,733,665	3/1988	Palmaz	128/343
4,762,128	8/1988	Rosenbluth	128/343
4,800,882	1/1989	Gianturco	128/343
4,830,003	5/1989	Wolff et al.	128/343
4,856,516	8/1989	Hillstead	128/343
4,886,062	12/1989	Wiktor	128/343
4,922,905	5/1990	Strecker	606/195
4,950,227	8/1990	Savin et al.	604/8
4,969,458	11/1990	Wiktor	606/194
4,994,071	2/1991	MacGregor	606/194
5,019,085	5/1991	Hillstead	606/108
5,019,090	5/1991	Pinchuk	606/194
5,035,706	7/1991	Gianturco	606/108
5,102,417	4/1992	Palmaz	606/195
5,104,404	4/1992	Wolff	623/1
5,116,365	5/1992	Hillstead	623/1
5,133,732	7/1992	Wiktor	606/195
5,158,548	10/1992	MacGregor	604/96
5,161,547	11/1992	Tower	128/898
5,195,984	3/1993	Schatz	606/195
5,282,824	2/1994	Gianturco	606/198
5,314,472	5/1994	Fontaine	623/12
5,330,500	7/1994	Song	606/198
5,354,308	10/1994	Simon et al.	606/198
5,354,309	10/1994	Schepp et al.	606/198
5,383,892	1/1995	Cardon et al.	606/198
5,405,377	4/1995	Cragg	623/1
5,441,515	8/1995	Khosravi et al.	606/194
5,443,496	8/1995	Schwartz et al.	623/1
5,449,373	9/1995	Pinchasik et al.	606/198
5,507,767	4/1996	Maeda et al.	606/198
5,540,712	7/1996	Kleshinski et al.	606/198
5,554,181	9/1996	Das	623/1
5,643,312	7/1997	Fischell et al.	606/198
5,649,952	7/1997	Lam	606/198
5,651,174	7/1997	Schwartz et al.	29/527.2
5,653,727	8/1997	Wiktor	606/195

FOREIGN PATENT DOCUMENTS

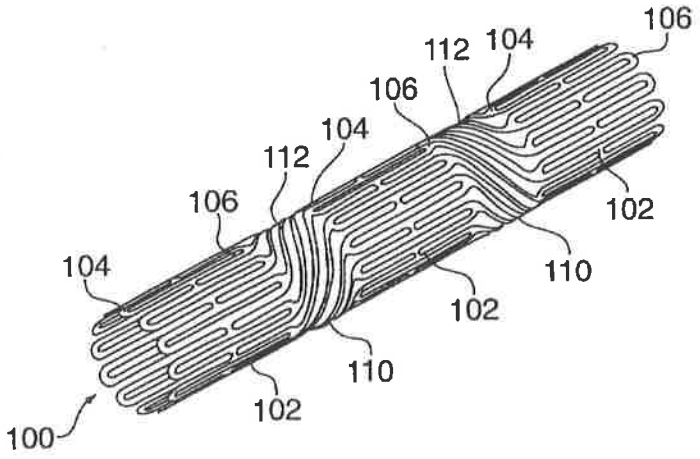
0 335 341	4/1989	European Pat. Off. .
0 514 443 A1	5/1993	European Pat. Off. .
0 540 290	5/1993	European Pat. Off. .
0 541 443	5/1993	European Pat. Off. .
0 566 807	10/1993	European Pat. Off. .
0 606 165	7/1994	European Pat. Off. .
WO 95/31945	11/1995	WIPO .
WO 96/03092	2/1996	WIPO .

Primary Examiner—Michael Buiz
Assistant Examiner—William W. Lewis
Attorney, Agent, or Firm—Kenyon & Kenyon

[57] **ABSTRACT**

An articulated stent for delivering through a bodily conduit, for example, a peripheral or coronary artery, which has one or more curved portions and for implantation therein. The articulated stent includes at least two substantially rigid segments and a flexible connector for connecting adjacent segments. The connector assumes a cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

20 Claims, 5 Drawing Sheets



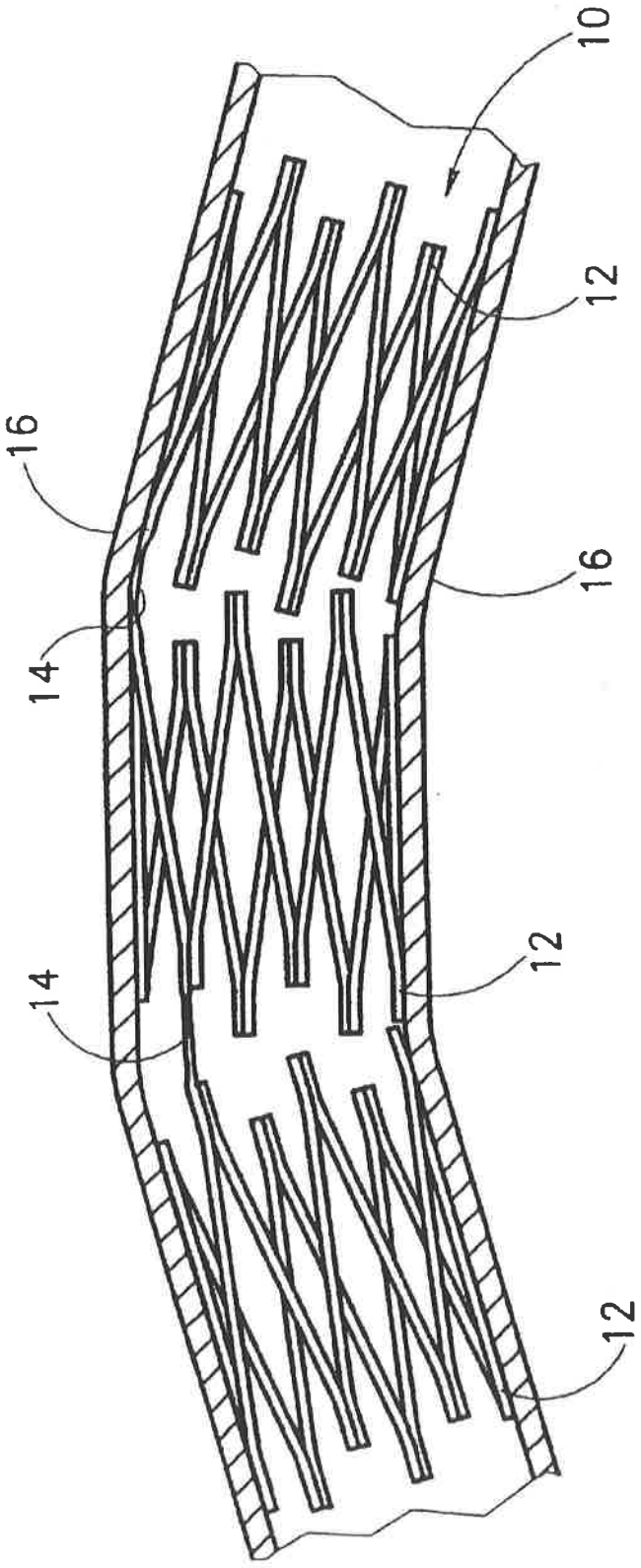


FIG. 1
PRIOR ART

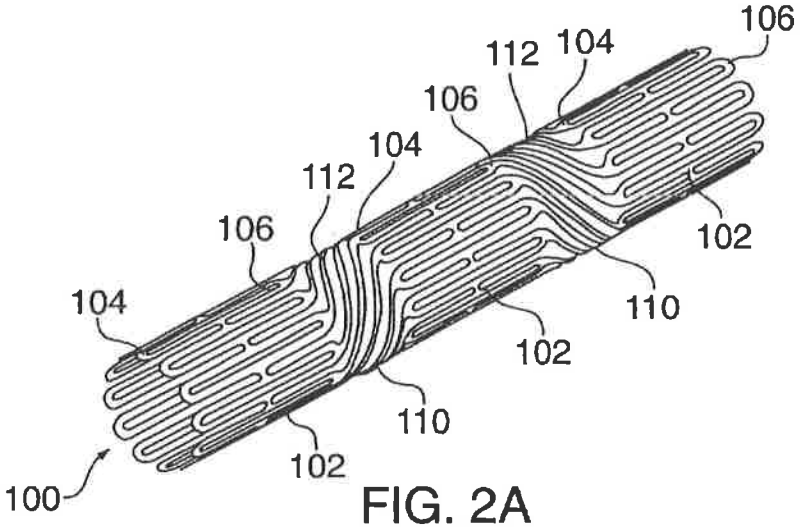


FIG. 2A

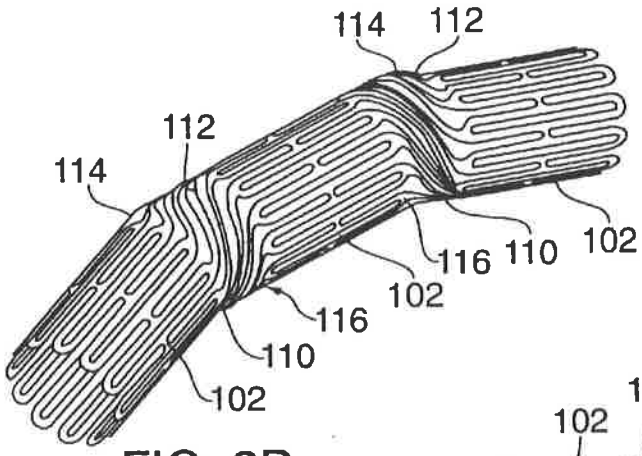


FIG. 2B

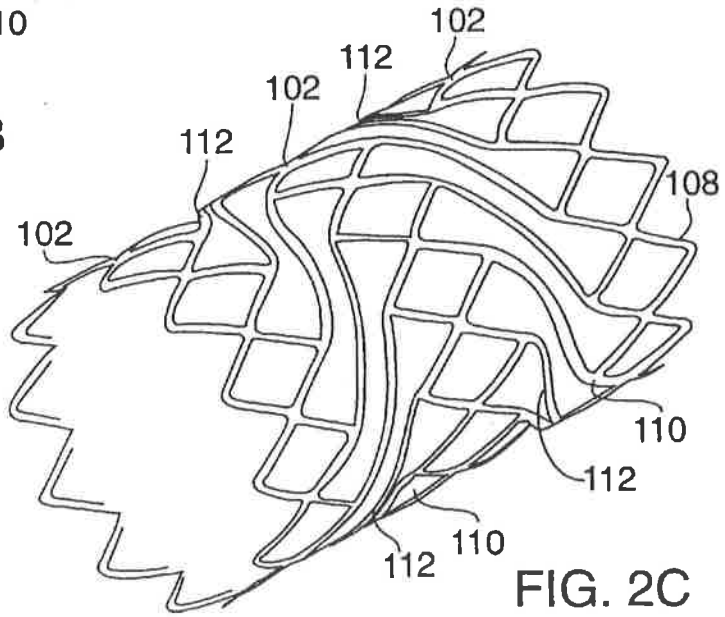


FIG. 2C

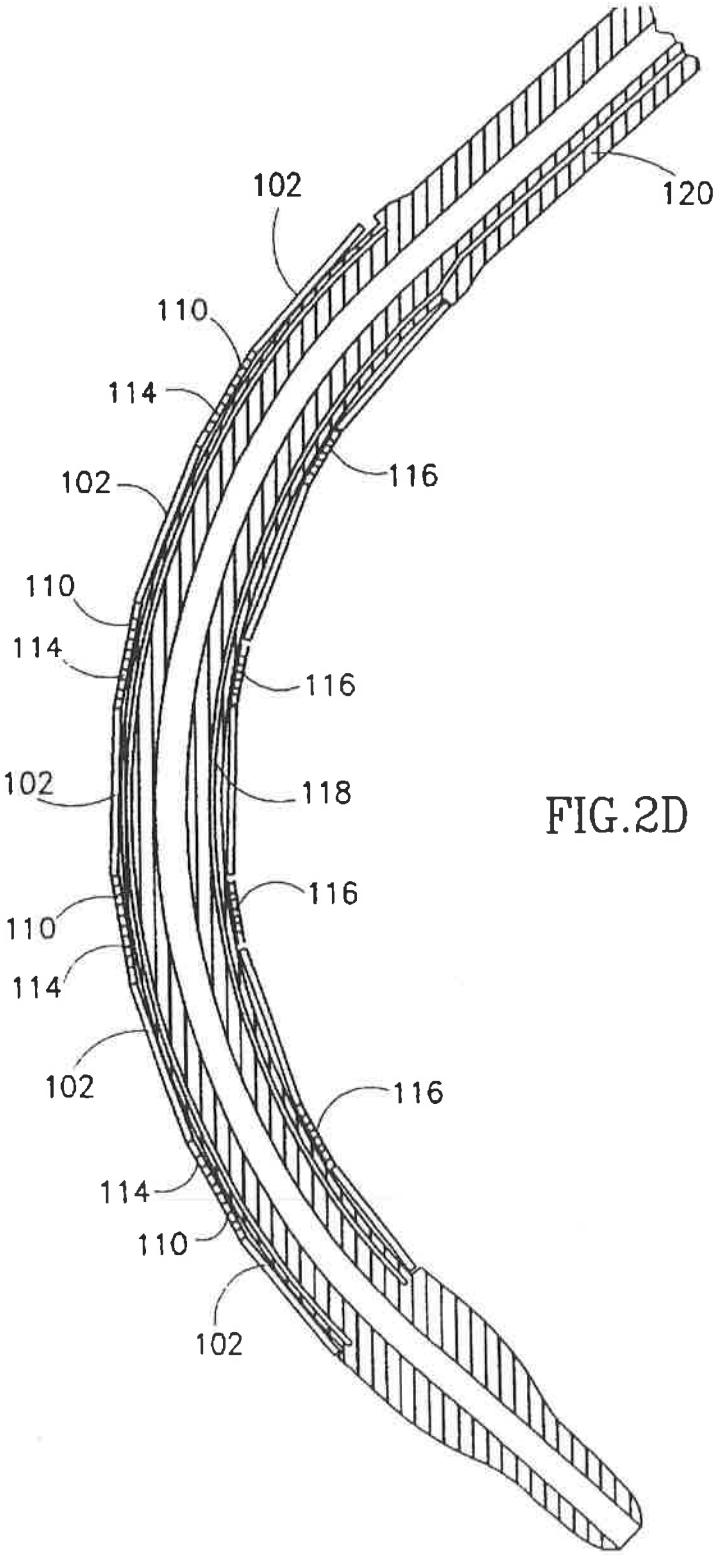

102
120
110
114
116
102
110
114
116
118
102
116
110
114
102
116
114
110
102

FIG.2D

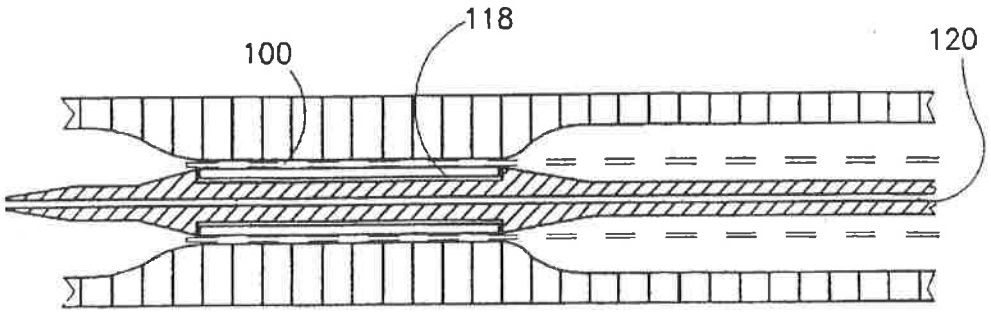


FIG.2E

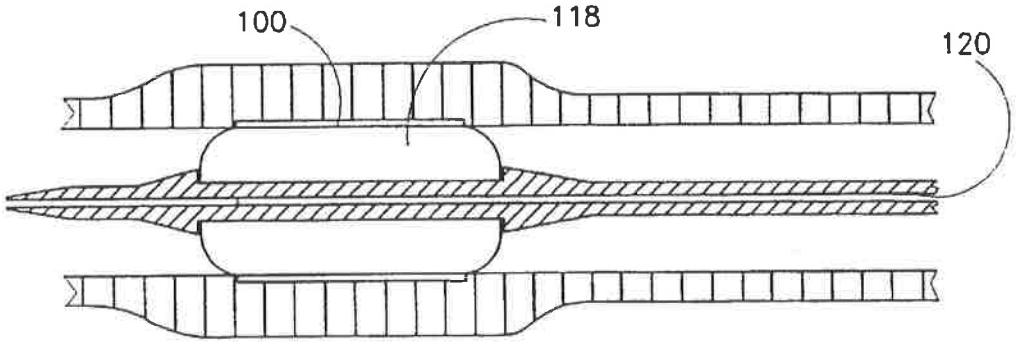


FIG.2F

FIG.3A

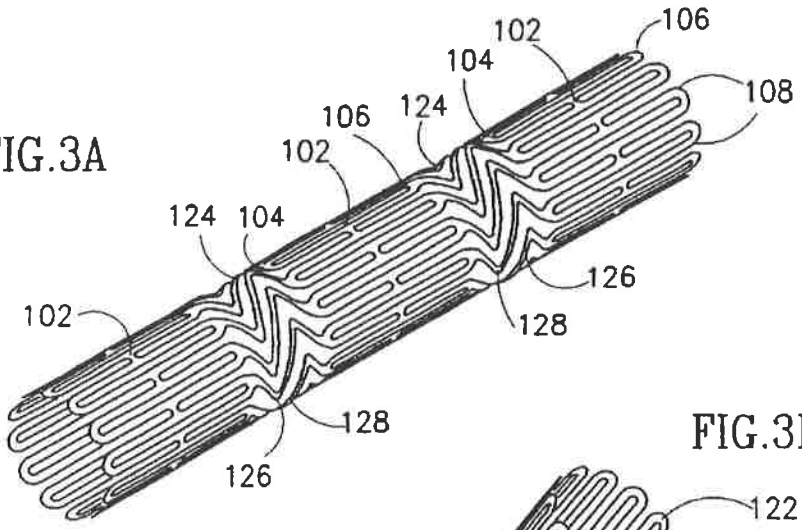


FIG.3B

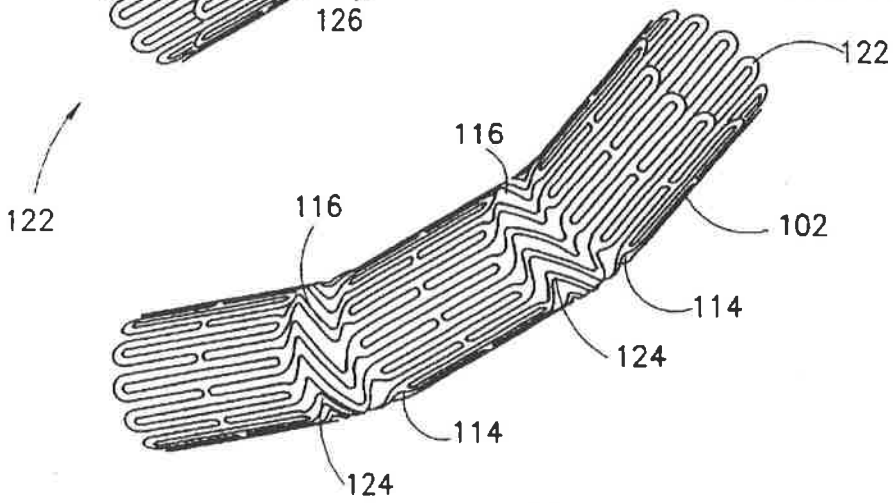
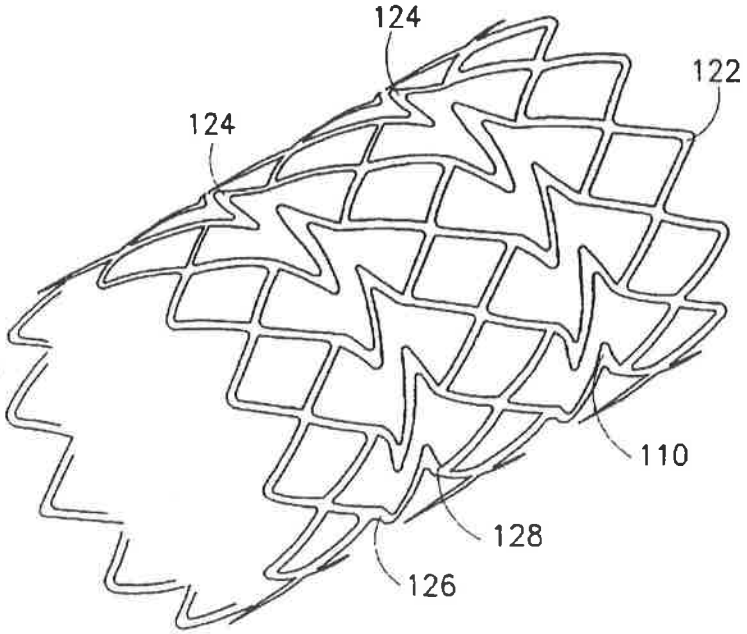


FIG.3C



ARTICULATED STENT

This application is a continuation of Ser. No. 08/760,359 filed Dec. 4, 1996 which is a continuation of Ser. No. 08/455,462 filed May 31, 1995 abandoned, which is a continuation of Ser. No. 08/213,272 filed Mar. 17. 1994 U.S. Pat. No. 5,449,373.

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to stents which are implanted as part of a balloon angioplasty procedure within a bodily conduit of a living animal or a human to maintain patency. In particular, the present invention relates to articulated intravascular stents for delivery through or implantation in a blood vessel having a curved portion.

Intravascular stents having a constricted diameter for delivery through a blood vessel and an expanded diameter for applying a radially outwardly extending force for supporting the blood vessel are known in the art. Articulated intravascular stents for either delivery through a curved blood vessel or implanted therein are also known in the art.

Self-expandable articulated stents are described, for example, in U.S. Pat. No. 5,104,404 entitled "Articulated Stent" to Wolff. Balloon expandable articulated stents are commercially available under the trade name Palmaz-Schatz Balloon-Expandable Stents from Johnson & Johnson Intervention Systems Co.

A prior art self-expandable articulated intravascular stent **10** deployed in a curved blood vessel **16** is now described with reference to FIG. **1** which is, in actual fact, FIG. **2** of the above referenced U.S. Pat. No. 5,104,404. Stent **10** is made up of a number of individual segments **12** articulated by hinges **14** connected at each end to segments **12**. Stent **10** is preferably fabricated from memory shape material, for example, nitinol, and as such is self expandable after delivery from a delivery system described in U.S Pat. No. 4,830,003 to Wolff et al. However, these prior art articulated intravascular stents suffer from a number of disadvantages both during delivery through a curved blood vessel and when implanted therein as will now described.

The delivery of stent **10** through curved blood vessel **16** is more complicated than the delivery of a non-articulated stent in that stent **10** has to be angularly oriented such that its hinges **14** are located towards the convex portion of blood vessel **16** so that stent **10** can be flexed inward. In the present example, it will be noted that hinges **14** are located on the same side of segments **12** because blood vessel **16** has only a simple curve in one plane. It can be readily appreciated that delivery of stents through blood vessels which have one or more curved portions which are not in the same plane is even more complicated and generally requires specially constructed stents.

Even when implanted in a curved blood vessel **16**, stents **10** are shown to be lacking in that the gaps between segments **12** render the curved portion of blood vessel **16** without support. Furthermore, the gaps at the convex portion of blood vessel **16** are substantially greater than the gaps at the concave portion thereof, thereby inducing non-uniform and therefore undesirable stresses on blood vessel **16**.

Therefore, it would be highly desirable to have an articulated stent which does not require any particular angular orientation when being delivered through a curved bodily conduit and provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted.

It would also be highly desirable the structure of a stent does not depend on the particular orientations of curved portions of a blood vessel.

SUMMARY OF THE INVENTION

The object of the present invention is for an articulated stent which can be delivered through a curved bodily conduit using a routine medical procedure and a conventional stent delivery system. Furthermore, the stent provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted. Still Further, the structure of a stent and its support of a bodily conduit do not depend on the orientations of the curved portions of the conduit.

The objective of the present invention is achieved by an articulated stent, comprising: (a) at least two substantially rigid segments; and (b) a flexible connector for connecting adjacent segments, wherein the connector assumes a substantially cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

After expansion, the rigid segments of the stent preferably present a fine diamond shaped mesh having 1 mm long sides to provide continuous and uniform support for straight portions of a bodily conduit.

The connectors can be implemented as a plurality of substantially helical links connecting adjacent segments. Alternatively, the connectors can be implemented as links each having at least one kink. The connectors typically have between 8–24 links to provide continuous and uniform support for both straight and curved portions of a bodily conduit.

The stents have constricted diameters for intraluminal delivery and are then deformed, by the inflation of a balloon forming part of their catheter delivery system, to expanded diameters for applying radially outwardly extending forces for supporting the lumen of bodily conduits. The constricted and expanded diameters of the stents typically fall in the ranges of 1.0–3.5 mm and 3.5–10.0 mm, respectively.

The stents are preferably fabricated from low memory, more plastic than elastic, bio-compatible materials, for example, stainless steel 316L, gold, tantalum, etc. which enables them to be plastically deformed from their constricted diameters to their expanded diameters.

A typical stent for implantation in a human coronary artery is 9–21 mm long comprising three to seven 2.2 mm long stent segments connected by two to six 1 mm long connectors such that the ends of the stent subtend between a 45° to 135° angle at a radius of curvature of approximately 9 mm when flexed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. **1** shows a close-up view of a prior art articulated stent of deployed in a curved blood vessel;

FIGS. **2***a* and **2***b* show a preferred embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation;

FIG. **2***c* shows the expanded stent of FIG. **2** after plastic deformation;

FIG. **2***d* shows the stent of FIG. **2** mounted on a catheter in its flexed state;

FIGS. 2*e* and 2*f* show the stent of FIG. 2 before and after expansion by a balloon forming part of its catheter delivery system;

FIGS. 3*a* and 3*b* show a second embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation; and

FIG. 3*c* shows the expanded stent of FIG. 3 after plastic deformation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an articulated stent for delivering through a curved bodily conduit, for example, a peripheral or coronary artery of a living animal or a human and implantation therein as part of a balloon angioplasty procedure to maintain patency.

The principles and operation of the articulated stent of the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, FIGS. 2*a*–2*c* show an articulated stent, generally designated **100**, constructed and operative according to the teachings of the present invention, generally comprising a number of substantially rigid segments **102** connected by connectors **110**.

Segments **102** are preferably made up to present a fine diamond mesh of interconnected diamond shaped cells **108** having 1 mm sides on expansion as best seen in FIG. 2*c*. Depending on the intended diameter of stent **100**, segments **102** typically comprise between 8–24 diamond shaped cells **108**.

Connectors **110** comprise links **112** connecting a front end **104** to a tail end **106** of adjacent segments **102**. Links **112** preferably extend in a substantially helical fashion between apexes of diamond shaped cells **108** at front and rear ends **104** and **106** of adjacent segments **102** such that the number of links **112** equals the number of cells **108**. Links **112** are preferably evenly deployed around perimeters of segments **102** such that connectors **110** can be equally flexed in any direction and to provide continuous and uniform support to both straight and curved portions of a bodily conduit.

Alternate connectors **110** at front and rear ends **104** and **106**, respectively, of a segment **102** preferably have links **112** wound in clockwise and counter clockwise directions. Alternately winding connectors **110** ensures that the rotational displacement of links **112** and adjacent segments **102** relative to the walls of a blood vessel and more importantly the balloon of its delivery system is minimized when stent **100** is expanded.

It is particular feature of the present invention that connectors **110** have a generally cylindrical configuration when stent **100** is relaxed as best seen in FIG. 2*a* and a differentially stretched and compressed curved configuration when stent **100** is flexed as best seen in FIG. 2*b*. The flexed configuration is brought about by two relatively opposing displacements of links **112**. First, the differential stretching of connectors **110** occurs at the convex portion thereof denoted **114** by links **112** being displaced away from one another. Second, the differential compressing of connectors **110** occurs at the concave portion thereof denoted **116** by links **112** being displaced towards one another.

Stent **100** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 2*a* and 2*b* and an expanded diameter as shown in FIG. 2*c* for supporting a bodily conduit. Stent **100** is preferably fabricated from low memory, more plastic than elastic, biocompatible material, for example, stainless steel 316L, gold, tantalum, etc. which enables it to be plastically deformed from its constricted diameter to its expanded diameter. The constricted and expanded diameters of stent **100** typically fall in the ranges of 1.0–3.5 mm and 3.5–10.0 mm, respectively.

With reference now to FIGS. 2*d*–2*f*, stent **100** is shown overlying a balloon **118** forming part of its catheter delivery system **120**. Stent **100** is mounted on its catheter delivery system **120** in its constricted diameter state shown in FIG. 2*e* for plastic deformation through inflation of balloon **118** to its expanded diameter shown in FIG. 2*f* for supporting the walls of a bodily conduit. An exemplary stent for implantation in a human coronary artery, is typically 15 mm long made up of five 2.2 mm long segments **102** connected by four 1 mm long connectors **110** and capable of flexion such that its ends subtend a 90° angle at a radius of curvature of approximately 9 mm.

The delivery of articulated stent **100** is considerably simpler than the delivery of prior art articulated stent **10** because stent **100** is equally flexible in all direction and therefore does not require a dedicated angular orientation to pass a particular curved portion. This advantage is particularly important for delivery through blood vessels having multiple curved portions. It is a further advantage of stent **100** over prior art stents **10**, that stent **100** provides continuous and uniform support along the entire length of a blood vessel by means of segments **102** and unflexed connectors **110** supporting straight portions thereof while connector portions **114** and **116** supporting convex and concave curved portions thereof, respectively.

With reference now to FIGS. 3*a* and 3*b*, an articulated stent **122** is shown in which connectors **124** comprise links **126** having one or more kinks **128**. The design of connectors **124** is preferred to that of connector **110** because stent **100** may have a tendency to rupture balloon **118** due to two reasons. First, links **112** overlying the convex portion of balloon **118** have a tendency to be biased inward when stent **100** is flexed. Second, segments **102** display a rotational displacement relative to balloon **118** when stent **100** is expanded.

In this case, the differentially stretched and compressed curved configuration of connector **124** is brought about by two relatively opposing displacements of links **112** as before except that the differential stretching of connectors **124** at convex portion **114** occurs by kinks **128** being somewhat straightened out while the differential compressing of connectors **124** at concave portion **116** occurs by kinks **128** being more acutely bent.

In a similar fashion to stent **100**, stent **122** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 3*a* and 3*b* and an expanded diameter as shown in FIG. 3*c* for supporting a bodily conduit when implanted therein.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

What is claimed is:

1. An expandable articulated stent having a longitudinal axis and a circumferential axis, including:

a) a plurality of substantially tubular and substantially rigid segments defining a longitudinal aperture, and

b) a plurality of flexible connecting links connecting said rigid segments, each of said flexible links having a first portion and a second portion, each of said links when

viewed laterally having an area of inflection disposed between said portions.

2. The stent of claim 1, wherein each of said flexible connecting links extends between and connects two of said plurality of segments.

3. The stent of claim 2, wherein said plurality of flexible links are provided with end points at which said links are joined to said segments.

4. The stent of claim 3, wherein said end points of said flexible connecting links are aligned substantially longitudinally with said longitudinally extending aperture.

5. The stent of claims 1, 2, 3, or 4 wherein said flexible connecting links are adapted to substantially compensate for the tendency of said segments to foreshorten when said stent is expanded.

6. The stent of claims 1, 2, 3, or 4 wherein said stent is expanded as by an inflatable balloon inflated within said longitudinal aperture.

7. The stent of claims 1, 2, 3, or 4 wherein said flexible connecting links open to longitudinally lengthen and substantially compensate for the longitudinal movement away from each other of the adjacent ends of said connected rigid segments when said stent is expanded.

8. The stent of claims 1, 2, 3, or 4 wherein said segments do not tend to rotate relative to each other when said stent is expanded.

9. The stent of claim 6, wherein at the juncture of said links with said segments there is substantially no component of force from said links in a direction about the circumferential axis of the stent when said stent is expanded.

10. The stent of claim 6, wherein at the juncture of said links with said segments there is substantially no component of force from said links in a direction radial to said longitudinal axis of said longitudinal aperture when said stent is expanded.

11. The stent of claim 10, wherein at the juncture of said links with said segments the only component of force from said links is substantially longitudinal when said stent is expanded.

12. The stent of claims 1, 2, 3, or 4 wherein said links do not tend to project into or outside of said longitudinal aperture of said stent when said stent is expanded.

13. The stent of claims 1, 2, 3, or 4, wherein said links do not tend to project into or outside of said longitudinal aperture of said stent when said stent is flexed.

14. The stent of claim 1, 2, 3, or 4, wherein each of said flexible connecting links has a first end and a second end, said area of inflection is disposed between said first end and said second end, and said area of inflection is provided with a width smaller than the width of said first end and said second end.

15. The stent of claim 1, 2, 3, or 4, wherein each of said segments is provided with apexes to which said flexible connecting links are attached, said flexible connecting links having a first end and a second end, said area of inflection disposed between said first end and said second end, said area of inflection provided with a width smaller than the width of said apexes of said segments to which said first end and said second end are connected.

16. The stent of claim 1, 2, 3, or 4, wherein said segments display substantially no rotational displacement relative to a balloon disposed in said longitudinal bore when said stent is expanded by said balloon.

17. An expandable articulated stent having a longitudinal axis and a circumferential axis, including:

a) a plurality of substantially tubular and substantially rigid segments defining a longitudinal aperture, and

b) a plurality of flexible connecting links connecting said rigid segments, each of said flexible links having a first portion and a second portion, each of said links when viewed laterally having an area of inflection disposed between said portions, wherein each of said flexible connecting links extends between and connects two of said plurality of segments, wherein said plurality of flexible links are provided with end points at which said links are joined to said segments, wherein said end points of said flexible connecting links are aligned substantially longitudinally with said longitudinally extending aperture,

wherein said flexible connecting links are adapted to substantially compensate for the tendency of said segments to foreshorten when said stent is expanded, and wherein said stent is expanded as by an inflatable balloon inflated within said longitudinal aperture.

18. An expandable articulated stent having a longitudinal axis and a circumferential axis, including:

a) a plurality of substantially tubular and substantially rigid segments defining a longitudinal aperture, and

b) a plurality of flexible connecting links connecting said rigid segments, each of said flexible links having a first portion and a second portion, said link when viewed laterally having an area of inflection disposed between said portions, wherein said stent is expanded as by an inflatable balloon inflated within said longitudinal aperture, wherein said end points of said flexible connecting links are aligned substantially longitudinally with said longitudinally extending aperture, wherein at the juncture of said links with said segments there is substantially no component of force from said links in a direction about the circumferential axis of the stent when said stent is expanded, and wherein at the juncture of said links with said segments there is substantially no component of force from said links in a direction radial to said longitudinal axis of said longitudinal aperture when said stent is expanded.

19. An expandable articulated stent having a longitudinal axis and a circumferential axis, including:

a) a plurality of substantially tubular and substantially rigid segments defining a longitudinal aperture, and

b) a plurality of flexible connecting links connecting said rigid segments, each of said flexible links having a first portion and a second portion, each of said links when viewed laterally having an area of inflection disposed between said portions,

wherein said stent is expanded as by an inflatable balloon inflated within said longitudinal aperture, wherein said links do not tend to project into or outside of said longitudinal aperture of said stent when said stent is expanded, and wherein said links do not tend to project into or outside of said longitudinal aperture of said stent when said stent is flexed.

20. An expandable articulated stent having a longitudinal axis and a circumferential axis, including:

a) a plurality of substantially tubular and substantially rigid segments defining a longitudinal aperture, and

b) a plurality of flexible connecting links connecting said rigid segments, each of said flexible links having a first portion and a second portion, each of said links when viewed laterally having an area of inflection disposed between said portions, wherein said stent is expanded as by an inflatable balloon inflated within said longitudinal aperture, wherein each of said flexible connecting links has a first end and a second end, said area of

inflection is disposed between said first end and said second end, and said area of inflection is provided with a width smaller than the width of said first end and said second end,

wherein each of said segments is provided with apexes to which said flexible connecting links are attached, said flexible connecting links having a first end and a second end, said area of inflection disposed between said first end and said second end, said area of inflection provided with a width smaller than the width of said apexes of said segments to which said first end and said second end are connected, and wherein said segments display substantially no rotational displacement relative to a balloon disposed in said longitudinal bore when said stent is expanded by said balloon.

* * * * *

EXHIBIT C

US006589276B2

(12) **United States Patent**
Pinchasik et al.

(10) **Patent No.: US 6,589,276 B2**
(45) **Date of Patent: Jul. 8, 2003**

(54) **ARTICULATED STENT**

(75) Inventors: **Gregory Pinchasik**, Ramat Hasbaron (IL); **Jacob Richter**, Ramat Hasbaron (IL)

(73) Assignee: **Medinol Ltd.**, Tel Aviv (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/292,759**

(22) Filed: **Nov. 13, 2002**

(65) **Prior Publication Data**

US 2003/0065384 A1 Apr. 3, 2003

Related U.S. Application Data

(63) Continuation of application No. 09/483,082, filed on Jan. 14, 2000, now Pat. No. 6,508,834, which is a continuation of application No. 09/026,750, filed on Feb. 20, 1998, now Pat. No. 6,059,811, which is a continuation of application No. 08/760,359, filed on Dec. 4, 1996, now Pat. No. 5,980,552, which is a continuation of application No. 08/455,462, filed on May 31, 1995, now abandoned, which is a continuation of application No. 08/213,272, filed on Mar. 17, 1994, now Pat. No. 5,449,373.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.16**
(58) **Field of Search** 623/1.15, 1.16, 623/1.17, 1.18, 1.11; 606/108, 194, 195

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,733,665	A	3/1988	Palmaz	128/343
4,762,128	A	8/1988	Rosenbluth	128/343
4,800,882	A	1/1989	Gianturco	128/343
4,830,003	A	5/1989	Wolff et al.	128/343
4,856,516	A	8/1989	Hillstead	128/343
4,886,062	A	12/1989	Wiktor	128/343
4,922,905	A	5/1990	Strecker	606/195
4,950,227	A	8/1990	Savin et al.	604/8
4,969,458	A	11/1990	Wiktor	606/194
4,994,071	A	2/1991	MacGregor	606/194
5,019,085	A	5/1991	Hillstead	606/108
5,019,090	A	5/1991	Pinchuk	606/194
5,035,706	A	7/1991	Giantureo	606/108
5,102,417	A	4/1992	Palmaz	606/195

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

EP	0 335 341	4/1989
EP	0 540 290	5/1993
EP	0 541 443	5/1993
EP	0 566 807	10/1993
EP	0 606 165	7/1994
WO	WO 95/31945	11/1995
WO	WO 96/03092	2/1996

OTHER PUBLICATIONS

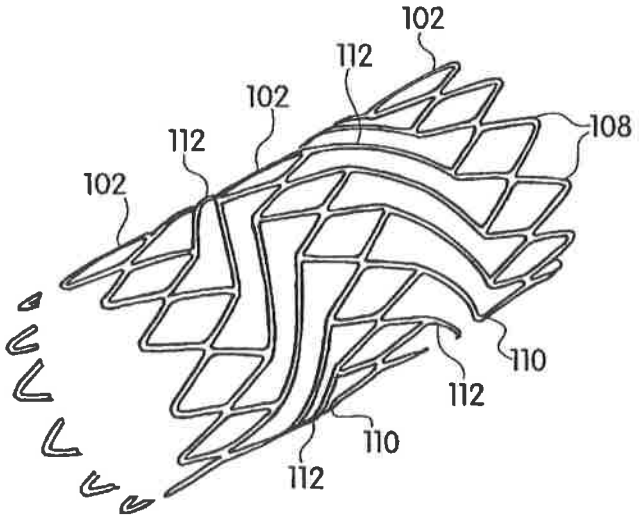
U.S. patent application Ser. No. 08/246,320, Burmeister et al., filed May 1994.

Primary Examiner—David H. Willse
Assistant Examiner—Suzette J. Jackson
(74) *Attorney, Agent, or Firm*—Kenyon & Kenyon

(57) **ABSTRACT**

An articulated stent for delivering through a bodily conduit, for example, a peripheral or coronary artery, which has one or more curved portions and for implantation therein. The articulated stent includes at least two substantially rigid segments and a flexible connector for connecting adjacent segments. The connector assumes a cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

16 Claims, 5 Drawing Sheets



U.S. PATENT DOCUMENTS

5,104,404	A		4/1992	Wolff 623/1
5,116,365	A		5/1992	Hillstead 623/1
5,133,732	A		7/1992	Wiktor 606/195
5,158,548	A		10/1992	MacGregor 604/96
5,161,547	A		11/1992	Tower 128/898
5,195,984	A		3/1993	Schatz 606/195
5,282,824	A		2/1994	Gianturco 606/198
5,314,472	A		5/1994	Fontaine 623/12
5,330,500	A		7/1994	Song 606/198
5,354,308	A		10/1994	Simon et al. 606/198
5,354,309	A		10/1994	Schnepp et al. 606/198
5,383,892	A		1/1995	Cardon et al. 606/198
5,405,377	A		4/1995	Cragg 623/1
5,441,515	A		8/1995	Khosravi et al. 606/194
5,443,496	A		8/1995	Schwartz et al. 623/1
5,449,373	A	*	9/1995	Pinchasik et al. 623/1.16
5,507,767	A		4/1996	Maeda et al. 606/198
5,540,712	A		7/1996	Kleshinski et al. 606/198
5,554,181	A		9/1996	Das 623/1
5,643,312	A		7/1997	Fischell et al. 606/198
5,649,952	A		7/1997	Lam 606/198
5,651,174	A		7/1997	Schwartz et al. 29/527.2
5,653,727	A		8/1997	Wiktor 606/195
5,980,552	A	*	11/1999	Pinchasik et al. 606/198
6,059,811	A	*	5/2000	Pinchasik et al. 606/108
6,348,065	B1	*	2/2002	Brown et al. 623/1.16
6,508,834	B1	*	1/2003	Pinchasik et al. 623/1.16

* cited by examiner

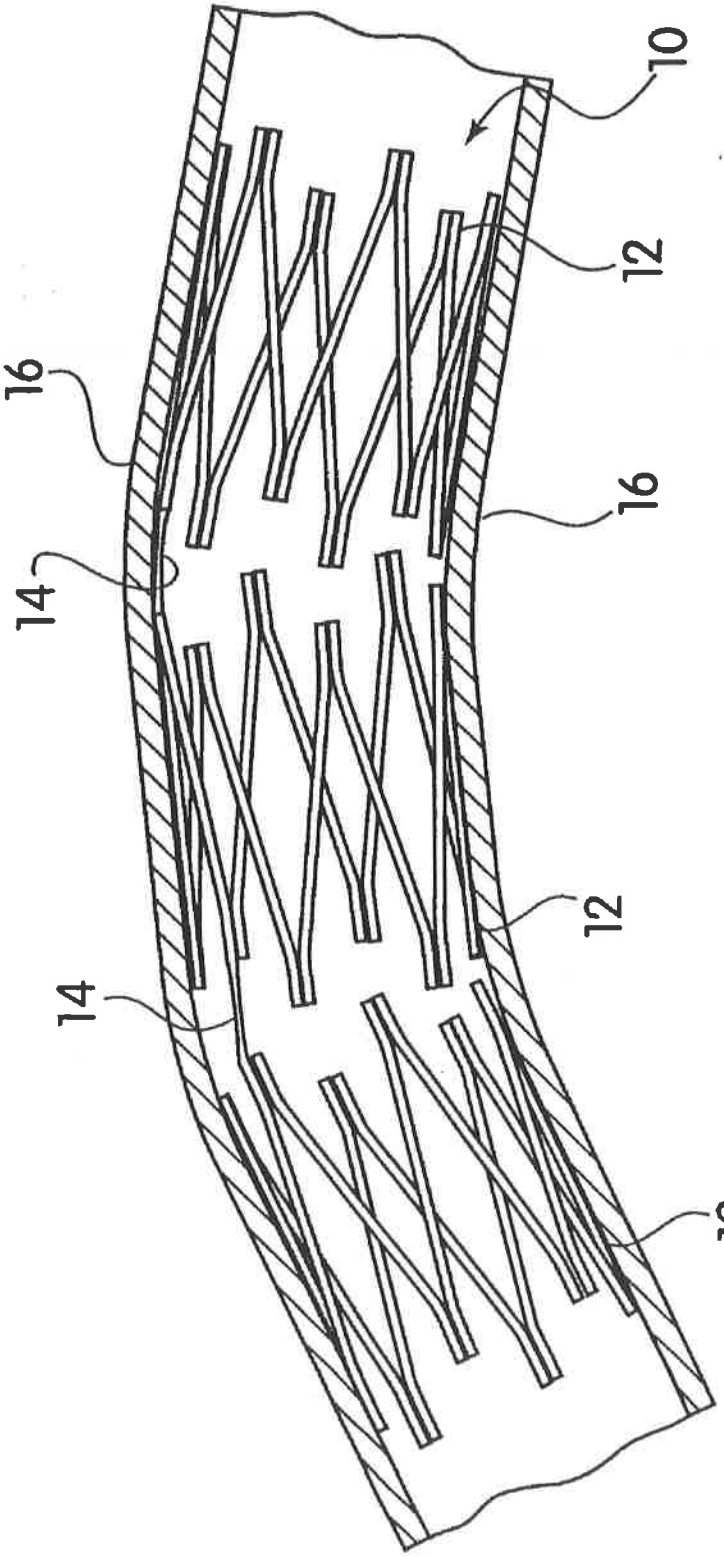


FIG. 1 (Prior Art)

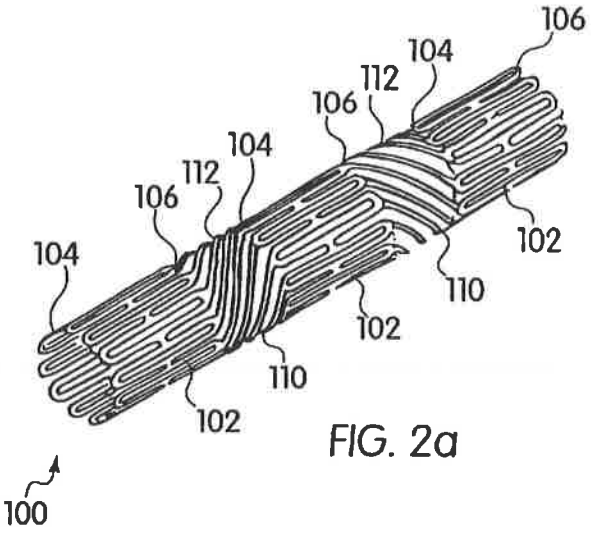


FIG. 2a

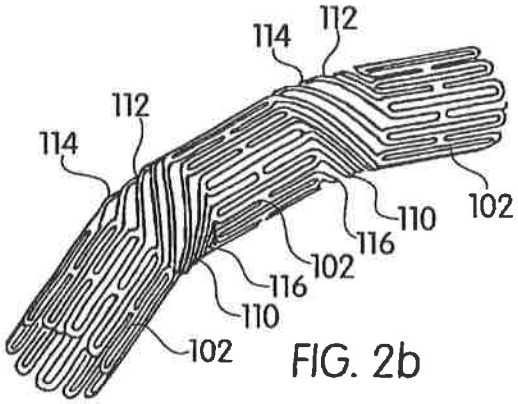


FIG. 2b

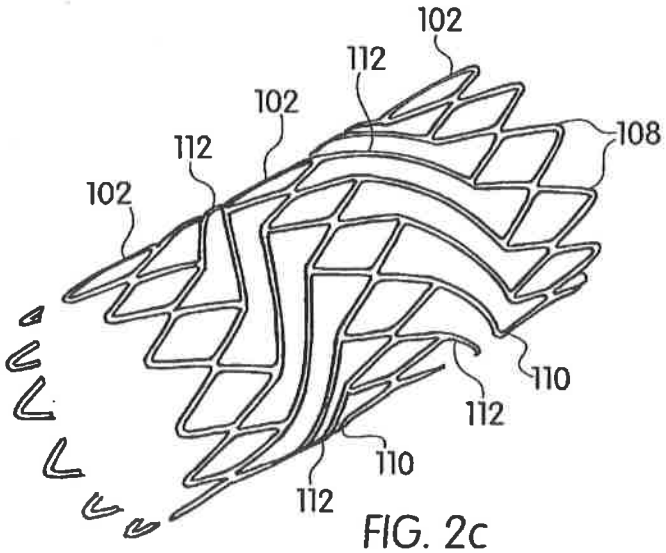


FIG. 2c

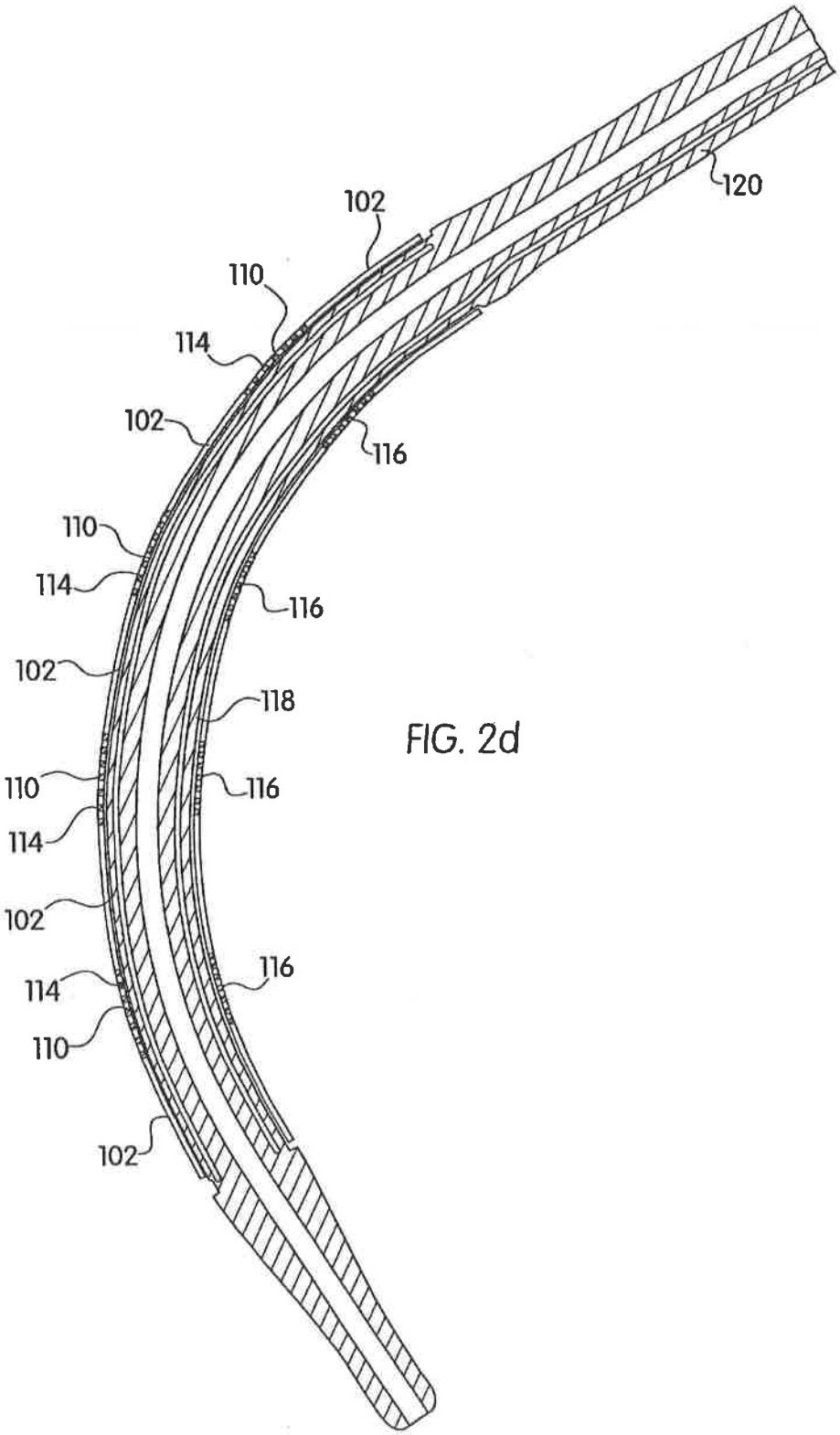

102
110
114
102
110
114
102
110
114
102
110
114
102
120
116
116
118
116
116
116

FIG. 2d

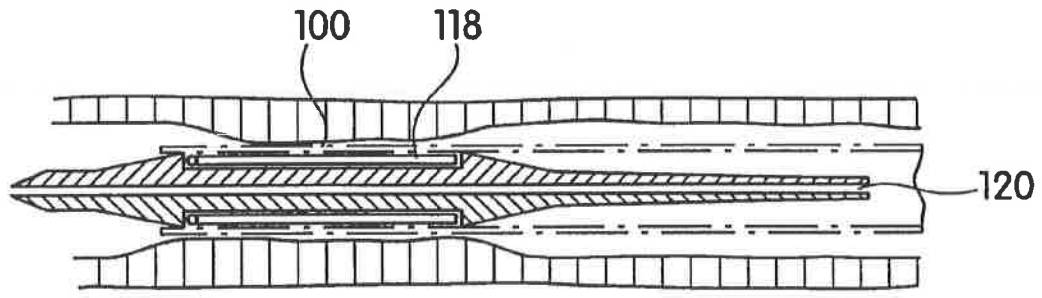


FIG. 2e

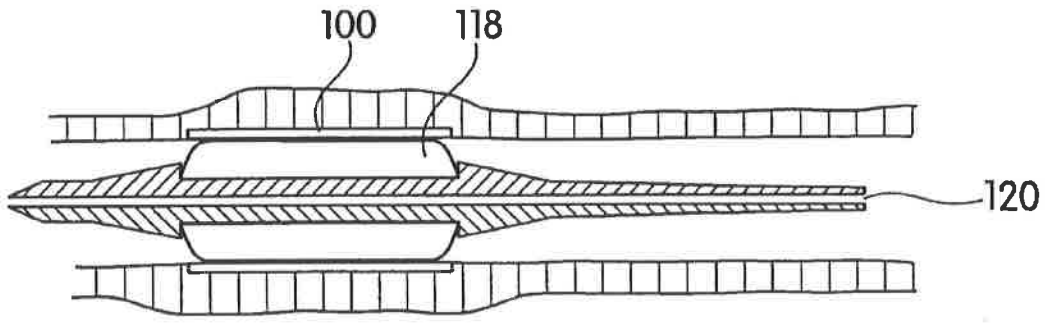


FIG. 2f

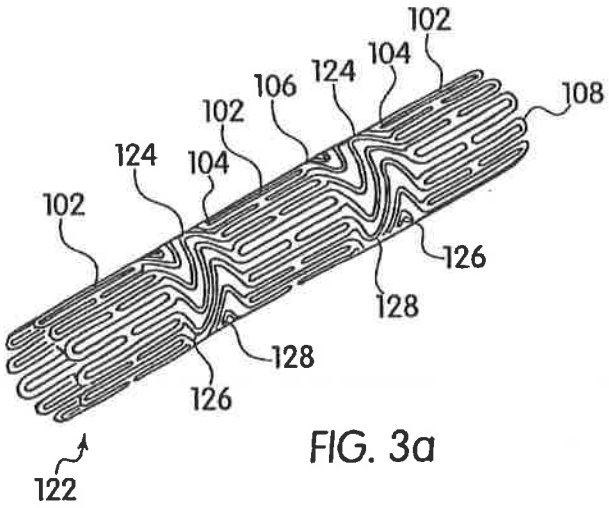


FIG. 3a

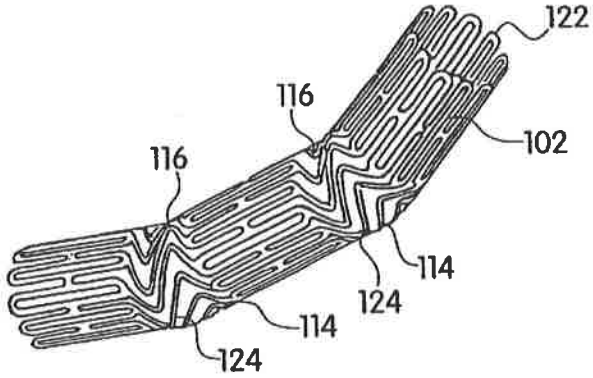


FIG. 3b

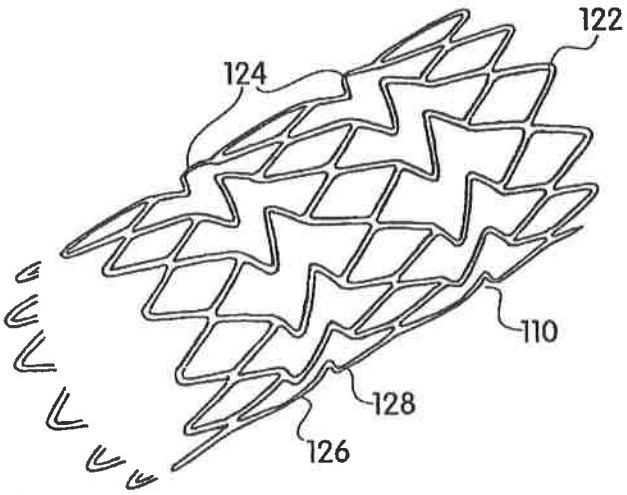


FIG. 3c

ARTICULATED STENT

RELATED PATENT APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 09/483,082 filed on Jan. 14, 2000 now U.S. Pat. No. 6,508,834 which is a continuation of U.S. patent application Ser. No. 09/026,750 filed Feb. 20, 1998 (now U.S. Pat. No. 6,059,811), which is a continuation of U.S. patent application Ser. No. 08/760,359 filed Dec. 4, 1996 (now U.S. Pat. No. 5,980,552), which is a continuation of U.S. patent application Ser. No. 08/455,462 filed May 31, 1995 (abandoned), which is a continuation of U.S. patent application Ser. No. 08/213,272 filed Mar. 17, 1994 (now U.S. Pat. No. 5,449,373).

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to stents which are implanted as part of a balloon angioplasty procedure within a bodily conduit of a living animal or a human to maintain patency. In particular, the present invention relates to articulated intravascular stunts for delivery through or implantation in a blood vessel having a curved portion.

Intravascular stents having a constricted diameter for delivery through a blood vessel and an expanded diameter for applying a radially outwardly extending force for supporting the blood vessel are known in the art. Articulated intravascular stents for either delivery through a curved blood vessel or implanted therein are also known in the art.

Self-expandable articulated stents are described, for example, in U.S. Pat. No. 5,104,404 entitled "Articulated Stent" to Wolff. Balloon expandable articulated stents are commercially available under the trade name Palmaz-Schatz Balloon-Expandable Stents from Johnson & Johnson Intervention Systems Co.

A prior art self-expandable articulated intravascular stent **10** deployed in a curved blood vessel **16** is now described with reference to FIG. **1** which is, in actual fact, FIG. **2** of the above referenced U.S. Pat. No. 5,104,404. Stent **10** is made up of a number of individual segments **12** articulated by hinges **14** connected at each end to segments **12**. Stent **10** is preferably fabricated from memory shape material, for example, nitinol, and as such is self expandable after delivery from a delivery system described in U.S Pat. No. 4,830,003 to Wolff et al. However, these prior art articulated intravascular stents suffer from a number of disadvantages both during delivery through a curved blood vessel and when implanted therein as will now described.

The delivery of stent **10** through: curved blood vessel **16** is more complicated than the delivery of a non-articulated stent in that stent **10** has to be angularly oriented such that its hinges **14** are located towards the convex portion of blood vessel **16** so that stent **10** can be flexed inward. In the present example, it will be noted that hinges **14** are located on the same side of segments **12** because blood vessel **16** has only a simple curve in one plane. It can be readily appreciated that delivery of stents through blood vessels which have one or more curved portions which are not in the same plane is even more complicated and generally requires specially constructed stents.

Even when implanted in a curved blood vessel **16**, stents **10** are shown to be lacking in that the gaps between segments **12** render the curved portion of blood vessel **16** without support. Furthermore, the gaps at the convex portion of blood vessel **16** are substantially greater than the gaps at the concave portion thereof, thereby inducing non-uniform and therefore undesirable stresses on blood vessel **16**.

Therefore, it would be highly desirable to have an articulated stent which does not require any particular angular orientation when being delivered through a curved bodily conduit and provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted.

It would also be highly desirable, the structure of a stent does not depend on the particular orientations of curved portions of a blood vessel.

SUMMARY OF THE INVENTION

The object of the present invention is for an articulated stent which can be delivered through a curved bodily conduit using a routine medical procedure and a conventional stent delivery system. Furthermore, the stent provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted. Still further, the structure of a stent and its support of a bodily conduit do not depend on the orientations of the curved portions of the conduit.

The objective of the present invention is achieved by an articulated stent, comprising: (a) at least two substantially rigid segments; and (b) a flexible connector for connecting adjacent segments, wherein the connector assumes a substantially cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

After expansion the rigid segments of the stent preferably present a fine diamond shaped mesh having 1 mm long sides to provide continuous and uniform support for straight portions of a bodily conduit.

The connectors can be implemented as a plurality of substantially helical links connecting adjacent segments. Alternatively, the connectors can be implemented as links each having at least one kink. The connectors typically have between 8–24 links to provide continuous and uniform support for both straight and curved portions of a bodily conduit.

The stents have constricted diameters for intraluminal delivery and are then deformed, by the inflation of a balloon forming part of their catheter delivery system, to expanded diameters for applying radially outwardly extending forces for supporting the lumen of bodily conduits. The constricted and expanded diameters of the stents typically fall in the ranges of 10–3.5 mm and 3.5–10.0 mm, respectively.

The stents are preferably fabricated from low memory, more plastic than elastic, bio-compatible materials, for, example, stainless steel 316L, gold, tantalum, etc. which enables them to be plastically deformed from their constricted diameters to their expanded diameters.

A typical stent for implantation in a human coronary artery is 9–21 mm long comprising three to seven 2.2 mm long stent segments connected by two to six 1 mm long connectors such that the ends of the stent subtend between a 45° to 135° angle at a radius of curvature of approximately 9 mm when flexed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. **1** shows a close-up view of a prior art articulated stent of deployed in a curved blood vessel;

FIGS. 2*a* and 2*b* show a preferred embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation;

FIG. 2*c* shows the expanded stent of FIG. 2 after plastic deformation;

FIG. 2*d* shows the stent of FIG. 2 mounted on a catheter in its flexed state;

FIGS. 2*e* and 2*f* show the stent of FIG. 2 before and after expansion by a balloon forming part of its catheter delivery system;

FIGS 3*a* and 3*b* show a second embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation; and

FIG. 3*c* shows the expanded stent of FIG. 3 after plastic deformation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an articulated stent for delivering through a curved bodily conduit, for example, a peripheral or coronary artery of a living animal or a human and implantation therein as part of a balloon angioplasty procedure to maintain patency.

The principles and operation of the articulated stent of the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, FIGS. 2*a*–2*c* show an articulated tent, Generally designated **100**, constructed and operative according to the teachings of the present invention, generally comprising a number of substantially rigid segments **102** connected by connectors **110**.

Segments **102** are preferably made up to present a fine diamond mesh of interconnected diamond shaped cells **108** having 1 mm sides on expansion as best seen in FIG. 2*c*. Depending on the intended diameter of stent **100**, segments **102** typically comprise between 8–24 diamond shaped cells **108**.

Connectors **110** comprise links **112** connecting a front end **104** to tail end **106** of adjacent segments **102**. Links **112** preferably extend in a substantially helical fashion between apexes of diamond shaped cells **108** at front and rear ends **104** and **106** of adjacent segments **102** such that the number of links **112** equals the number of cells **108**. Links **112** are preferably evenly deployed around perimeters of segments **102** such that connectors **110** can be equally flexed in any direction and to provide continuous and uniform support to both straight and curved portions of a bodily conduit.

Alternate connectors **110** at front and rear ends **104** and **106**, respectively, of a segment **102** preferably have links **112** wound in clockwise and counter clockwise directions. Alternately winding connectors **110** ensures that the rotational displacement of links **112** and adjacent segments **102** relative to the walls of a blood vessel and more importantly the balloon of its delivery system is minimized when stent **100** is expanded.

It is particular feature of the present invention that connectors **110** have a generally cylindrical configuration when stent **100** is relaxed as best seen in FIG. 2*a* and a differentially stretched and compressed curved configuration when stent **100** is flexed as best seen in FIG. 2*b*. The flexed configuration is brought about by two relatively opposing displacements of links **112**. First, the differential stretching of connectors **110** occurs at the convex portion thereof denoted **114** by links **112** being displaced away from one another. Second, the differential compressing of

connectors **110** occurs at the concave portion thereof denoted **116** by links **112** being displaced towards one another.

Stent **100** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 2*a* and 2*b* and an expanded diameter as shown in FIG. 2*c* for supporting a bodily conduit. Stent **100** is preferably fabricated from low memory, more plastic than elastic, bio-compatible material, for example, stainless steel 316L, gold, tantalum, etc. which enables it to be plastically deformed from its constricted diameter to its expanded diameter. The constricted and expanded diameters of stent **100** typically fall in the ranges of 1:0–3.5 mm and 3.5–10.0 mm, respectively.

With reference now to FIGS. 2*d*–2*f*, stent **100** is shown overlying a balloon **118** forming part of its catheter delivery system **120**. Stent **100** is mounted on its catheter delivery system **120** in its constricted diameter state shown in FIG. 2*e* for plastic deformation through inflation of balloon **118** to its expanded diameter shown in FIG. 2*f* for supporting the walls of a bodily conduit. An exemplary stent for implantation in a human coronary artery, is typically 15 mm long, made up of five 2.2 mm long segments **102** connected by four 1 mm long connectors **110** and capable of flexion such that its ends subtend a 90° angle at a radius of curvature of approximately 9 mm.

The delivery of articulated stent **100** is considerably simpler than the delivery of prior art articulated stent **10** because stent **100** is equally flexible in all direction and therefore does not require a dedicated angular orientation to pass a particular curved portion. This advantage is particularly important for delivery through blood vessels having multiple curved portions. It is a further advantage of stent **100** over prior art stents **10**, that stent **100** provides continuous and uniform support along the entire length of a blood vessel by means of segments **102** and unflexed connectors **110** supporting straight portions thereof while connector portions **114** and **116** supporting convex and concave curved portions thereof, respectively.

With reference now to FIGS. 3*a* and 3*b*, an articulated stent **122** is shown in which connectors **124** comprise links **126** having one or more kinks **128**. The design of connectors **124** is preferred to that of connector **110** because stent **100** may have a tendency to rupture balloon **118** due to two reasons. First, links **112** overlying the convex portion of balloon **118** have a tendency to be biased inward when stent **100** is flexed. Second, segments **102** display a rotational displacement relative to balloon **118** when stent **100** is expanded.

In this case, the differentially stretched and compressed curved configuration of connector **124** is brought about by two relatively opposing displacements of links **112** as before except that the differential stretching of connectors **124** at convex portion **114** occurs by kinks **128** being somewhat straightened out while the differential compressing of connectors **124** at concave portion **116** occurs by kinks **128** being more acutely bent.

In a similar fashion to stent **100**, stent **122** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. 3*a* and 3*b* and an expanded diameter as shown in FIG. 3*c* for supporting a bodily conduit when implanted therein.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

What is claimed is:

1. An expandable stent comprising:

(a) at least two substantially rigid segments,

(i) each of said substantially rigid segments having a plurality of U or V-shaped regions in both the expanded and unexpanded configuration, the U or V-shaped regions being more open in the expanded configuration than in the unexpanded configuration,

(ii) each of said substantially rigid segments presenting a substantially cylindrical structure defining a longitudinal passageway therethrough in both the expanded and unexpanded configurations, the cylindrical structure being shorter in length and wider in diameter in the expanded configuration than in the unexpanded configuration,

(b) a flexible connector comprising a plurality of flexible links disposed between and connecting adjacent substantially rigid segments,

(i) each of said flexible links connecting a U or V-shaped region of a substantially rigid segment with the nearest U or V-shaped region of the adjacent substantially rigid segment,

(ii) each of said flexible links, when viewed laterally, having a first portion, a second portion and at least one area of inflection disposed between the first portion and the second portion, and

(iii) none of said flexible links projecting into said longitudinal passageway in the unexpanded configuration.

2. An expandable stent in accordance with claim 1, wherein each of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent, is connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

3. An expandable stent in accordance with claim 1, wherein substantially all of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent, are connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

4. An expandable stent in accordance with claim 1, wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

5. An expandable stent in accordance with claim 1 wherein the first portion and second portion are substantially straight.

6. An expandable stent in accordance with claim 1 wherein said stent is expanded by an inflatable balloon inflated within said longitudinal aperture.

7. An expandable stent comprising:

(a) at least two substantially rigid segments,

(i) each of said substantially rigid segments having a plurality of U or V-shaped regions in both the expanded and unexpanded configuration, the U or V-shaped regions being more open in the expanded configuration than in the unexpanded configuration,

(ii) each of said substantially rigid segments presenting a substantially cylindrical structure defining a longitudinal passageway therethrough in both the expanded and unexpanded configurations, the cylindrical structure being shorter in length and wider in diameter in the expanded configuration than in the unexpanded configuration,

(b) a flexible connector comprising a plurality of flexible links disposed between and connecting adjacent substantially rigid segments,

(i) each of said flexible links having end points which are aligned substantially parallel to the longitudinal axis of the sent,

(ii) each of said flexible links, when viewed laterally, having a first portion, a second portion and at least one area of inflection disposed between the first portion and the second portion, and

(iii) none of said flexible links projecting into said longitudinal passageway in the unexpanded configuration.

8. An expandable stent in accordance with claim 7, wherein each of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent, is connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

9. An expandable stent in accordance with claim 7, wherein substantially all of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent, are connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

10. An expandable stent in accordance with claim 7, wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

11. An expandable stent in accordance with claim 7, wherein the first portion and second portion are substantially straight.

12. An expandable stent in accordance with claim 7, wherein said stent is expanded by an inflatable balloon inflated within said longitudinal aperture.

13. An expandable stent comprising:

(a) at least two substantially rigid segments,

(i) each of said substantially rigid segments having a plurality of U or V-shaped regions in both the expanded and unexpanded configuration, the U or V-shaped regions being more open in the expanded configuration than in the unexpanded configuration,

(ii) each of said substantially rigid segments presenting a substantially cylindrical structure defining a longitudinal passageway therethrough in both the expanded and unexpanded configurations, the cylindrical structure being wider in diameter in the expanded configuration than in the unexpanded configuration,

(b) a flexible connector comprising a plurality of flexible links disposed between and connecting adjacent substantially rigid segments,

(i) each of said flexible links connecting a U or V-shaped region of a substantially rigid segment with the nearest U or V-shaped region of the adjacent substantially rigid segment,

(ii) each of said flexible links, when viewed laterally, having a first portion, a second portion and at least one area of inflection disposed between the first portion and the second portion, and

(iii) none of said flexible links projecting into said longitudinal passageway in the unexpanded configuration.

14. An expandable stent in accordance with claim 13, wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

15. An expandable stent in accordance with claim 13, wherein the first portion and second portion are substantially straight.

16. An expandable stent in accordance with claim 13, wherein said stent is expanded by an inflatable balloon inflated within said longitudinal aperture.

* * * * *

EXHIBIT D

US006875228B2

(12) **United States Patent**
Pinchasik et al.

(10) **Patent No.: US 6,875,228 B2**
(45) **Date of Patent: *Apr. 5, 2005**

(54) **ARTICULATED STENT**

(75) Inventors: **Gregory Pinchasik**, Ramat Basharon (IL); **Jacob Richter**, Ramat Basharon (IL)

(73) Assignee: **Medinol, Ltd.**, Tel Aviv (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/442,171**

(22) Filed: **May 21, 2003**

(65) **Prior Publication Data**

US 2003/0195616 A1 Oct. 16, 2003

Related U.S. Application Data

(63) Continuation of application No. 10/292,759, filed on Nov. 13, 2002, now Pat. No. 6,589,276, which is a continuation of application No. 09/483,082, filed on Jan. 14, 2000, now Pat. No. 6,508,834, which is a continuation of application No. 09/026,750, filed on Feb. 20, 1998, now Pat. No. 6,059,811, which is a continuation of application No. 08/760,359, filed on Dec. 4, 1996, now Pat. No. 5,980,552, which is a continuation of application No. 08/455,462, filed on May 31, 1995, now abandoned, which is a continuation of application No. 08/213,272, filed on Mar. 17, 1994, now Pat. No. 5,449,373.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.16**
(58) **Field of Search** 623/1.11–1.22

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,733,665	A	3/1988	Palmaz	128/343
4,762,128	A	8/1988	Rosenbluth	128/343
4,800,882	A	1/1989	Gianturco	128/343
4,830,003	A	5/1989	Wolff et al.	128/343
4,856,516	A	8/1989	Hillstead	128/343
4,886,062	A	12/1989	Wiktor	128/343
4,922,905	A	5/1990	Strecker	606/195
4,950,227	A	8/1990	Savin et al.	604/8
4,969,458	A *	11/1990	Wiktor	623/1.11
4,994,071	A	2/1991	MacGregor	606/194
5,019,085	A	5/1991	Hillstead	606/108
5,019,090	A	5/1991	Pinchuk	606/194
5,035,706	A	7/1991	Giantureo	606/108

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0 335 341	4/1989
EP	0 540 290	5/1993
EP	0 541 443	5/1993
EP	0 566 807	10/1993
EP	0 606 165	7/1994
WO	WO 95/31945	11/1995
WO	WO 96/03092	2/1996

OTHER PUBLICATIONS

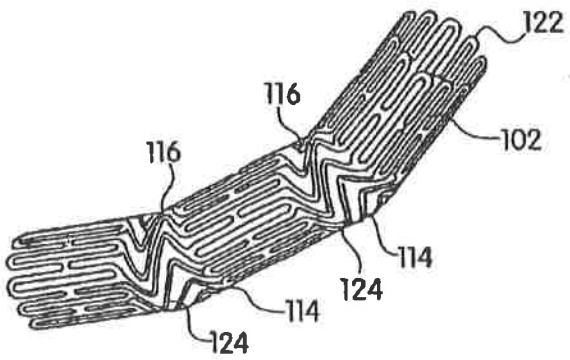
U.S. Appl. No. 08/246,320, filed May 1994, Burmeister et al.

Primary Examiner—David H. Willse
Assistant Examiner—Suzette J. Jackson
(74) *Attorney, Agent, or Firm*—Morgan & Finnegan, L.L.P.

(57) **ABSTRACT**

An articulated stent for delivering through a bodily conduit, for example, a peripheral or coronary artery, which has one or more curved portions and for implantation therein. The articulated stent includes at least two substantially rigid segments and a flexible connector for connecting adjacent segments. The connector assumes a cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

22 Claims, 5 Drawing Sheets



U.S. PATENT DOCUMENTS

5,102,417	A *	4/1992	Palmaz	606/195
5,104,404	A	4/1992	Wolff	623/1
5,116,365	A	5/1992	Hillstead	623/1
5,133,732	A	7/1992	Wiktor	606/195
5,158,548	A	10/1992	Lau et al.	604/96
5,161,547	A	11/1992	Tower	128/898
5,195,984	A	3/1993	Schatz	606/195
5,282,824	A	2/1994	Gianturco	606/198
5,314,472	A	5/1994	Fontaine	623/12
5,330,500	A	7/1994	Song	606/198
5,354,308	A	10/1994	Simon et al.	606/198
5,354,309	A	10/1994	Schnepp et al.	606/198
5,383,892	A	1/1995	Cardon et al.	606/198
5,405,377	A	4/1995	Cragg	623/1
5,441,515	A	8/1995	Khosravi et al.	606/194
5,443,496	A	8/1995	Schwartz et al.	623/1
5,449,373	A *	9/1995	Pinchasik et al.	606/198
5,507,767	A	4/1996	Maeda et al.	606/198
5,540,712	A	7/1996	Kleshinski et al.	606/198
5,554,181	A	9/1996	Das	623/1
5,643,312	A	7/1997	Fischell et al.	606/198
5,649,952	A	7/1997	Lam	606/198
5,651,174	A	7/1997	Schwartz et al.	29/527.2
5,653,727	A	8/1997	Wiktor	606/195
5,980,552	A *	11/1999	Pinchasik et al.	623/1.16
6,059,811	A *	5/2000	Pinchasik et al.	606/198
6,348,065	B1 *	2/2002	Brown et al.	623/1.16
6,508,834	B1 *	1/2003	Pinchasik et al.	623/1.16
6,589,276	B2 *	7/2003	Pinchasik et al.	623/1.16

* cited by examiner

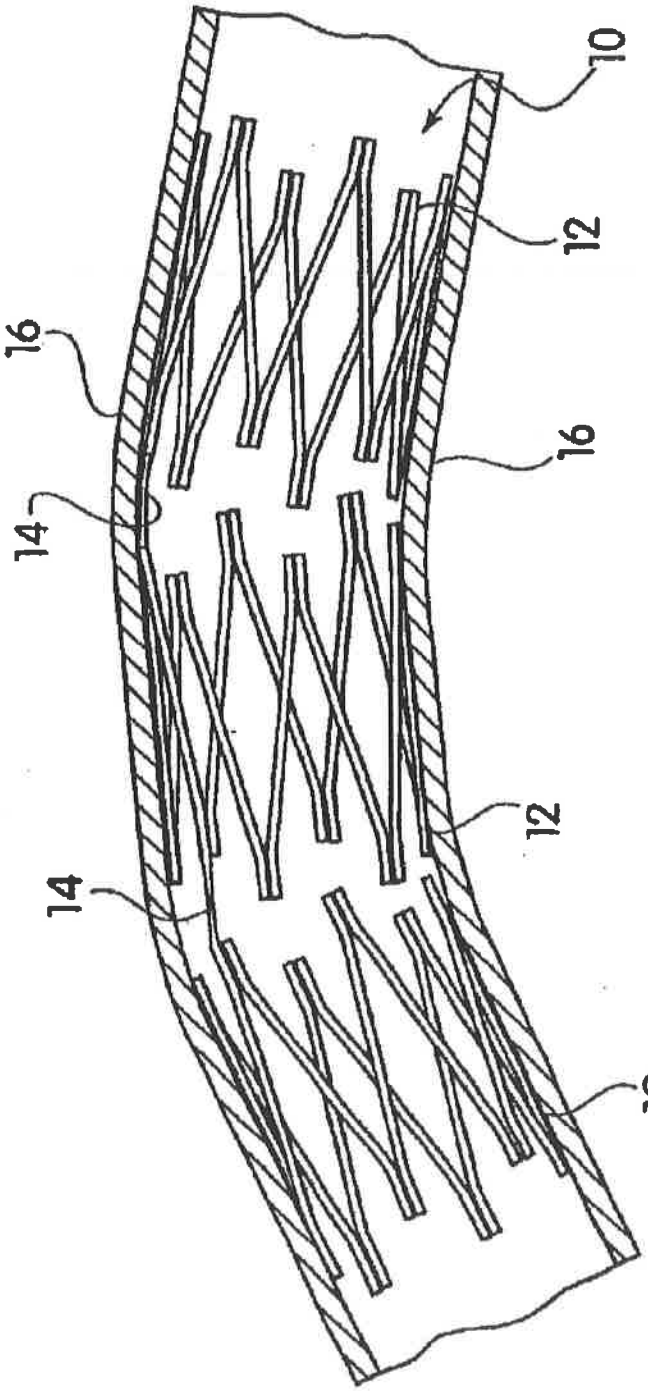


FIG. 1 (Prior Art)

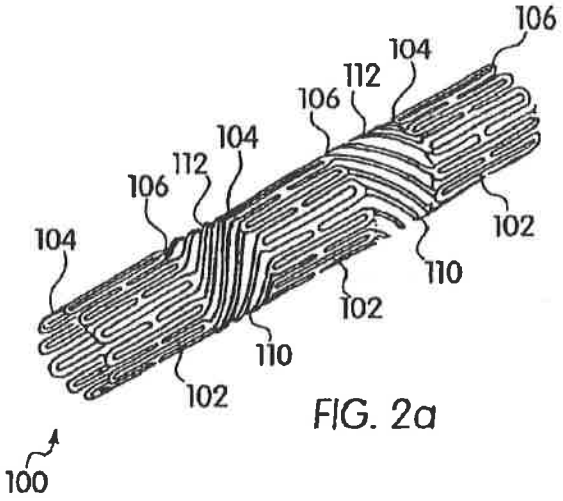


FIG. 2a

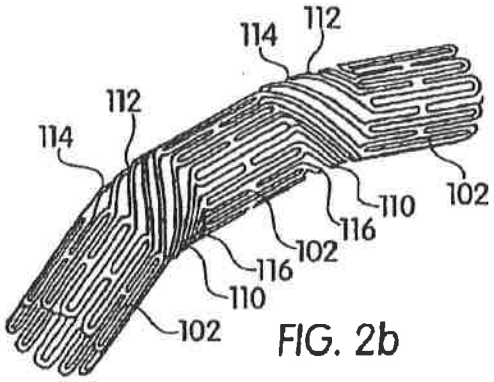


FIG. 2b

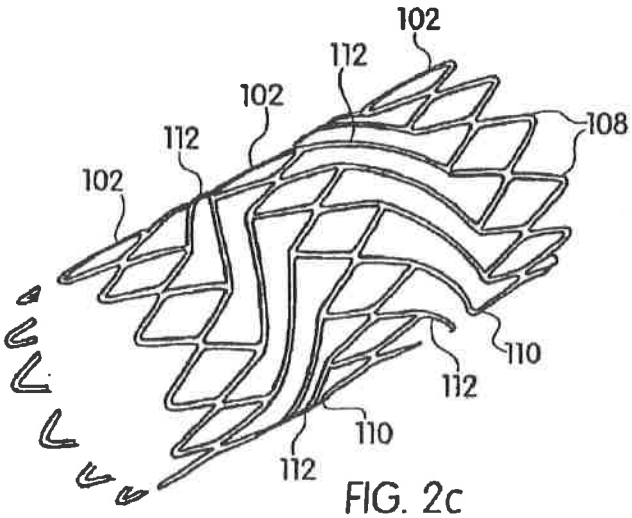


FIG. 2c

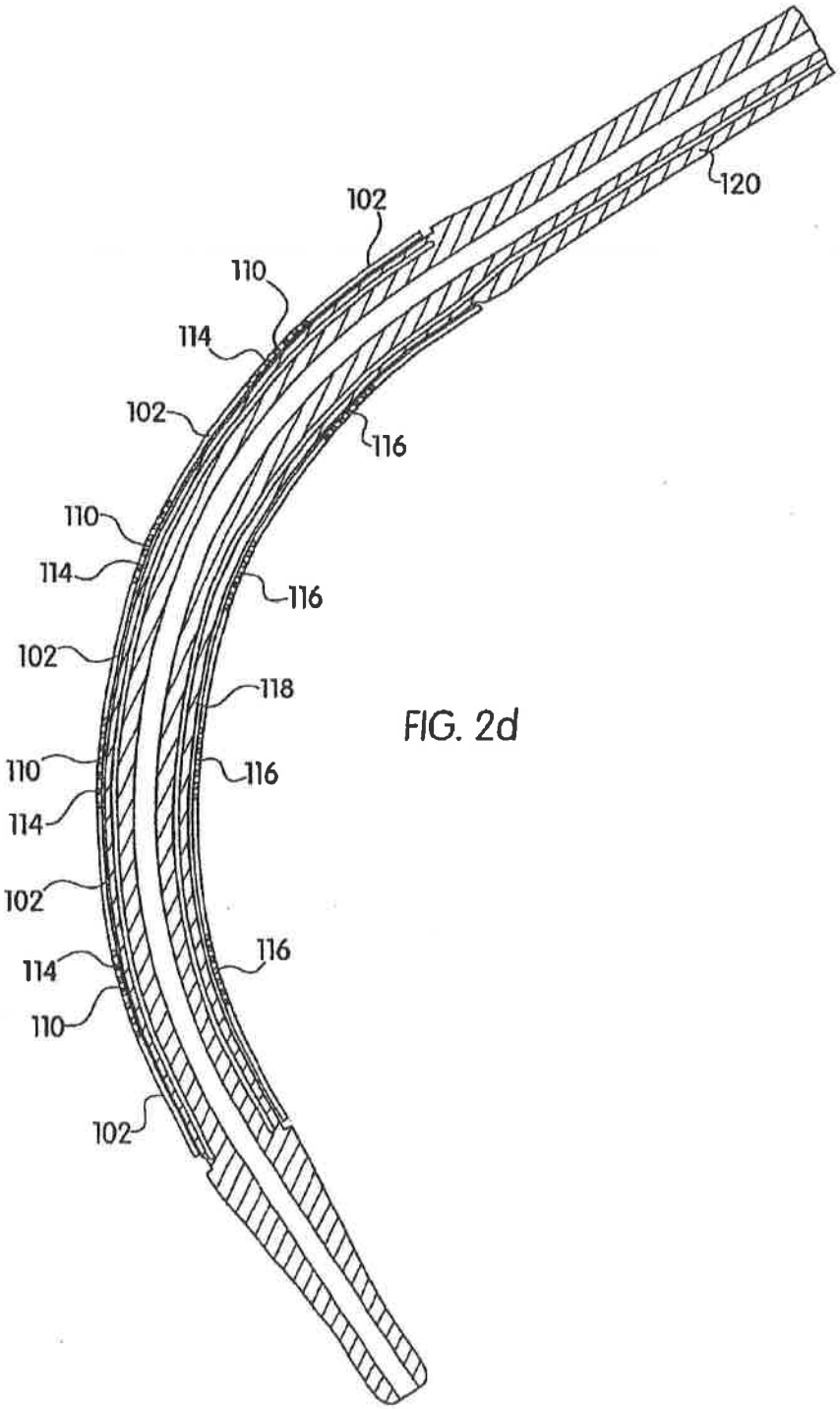

102
110
114
102
110
114
102
110
114
102
114
110
102
120
116
116
118
116
116

FIG. 2d

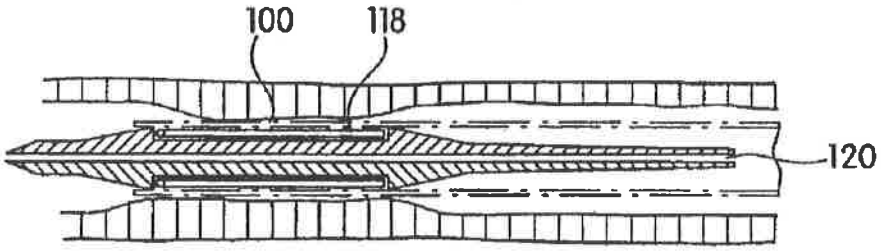


FIG. 2e

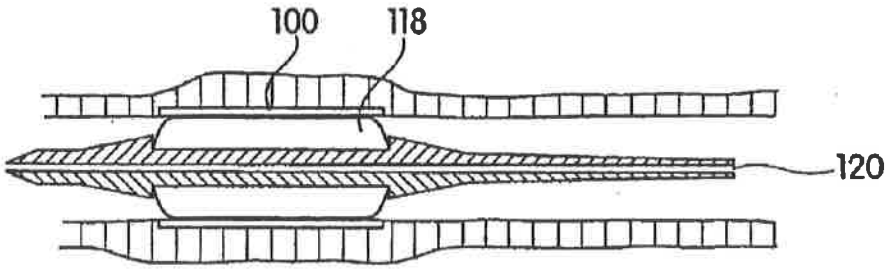


FIG. 2f

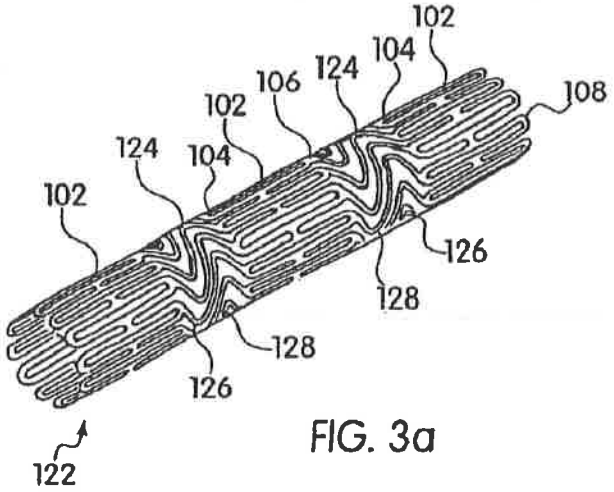


FIG. 3a

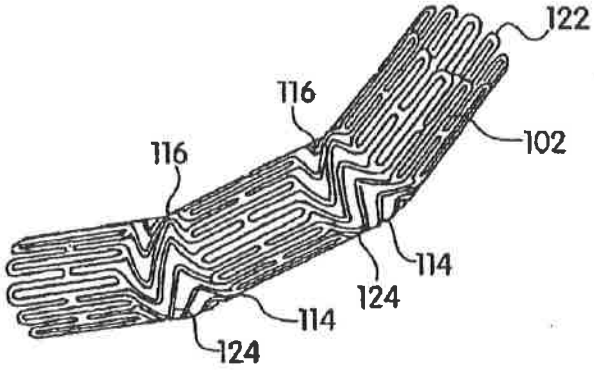


FIG. 3b

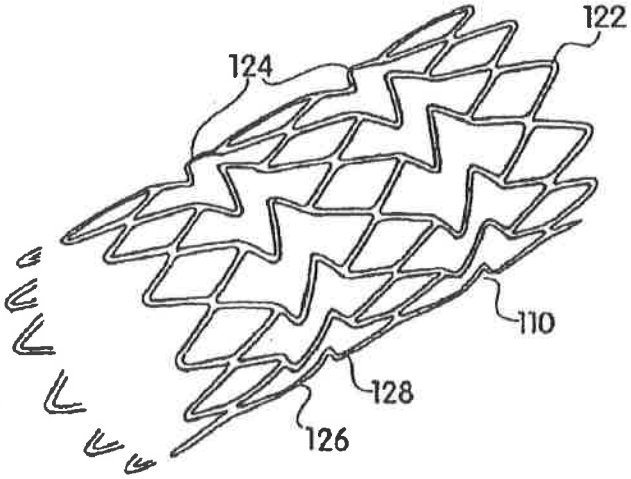


FIG. 3c

ARTICULATED STENT

RELATED PATENT APPLICATIONS

This application a continuation of U.S. patent application Ser. No. 10/292,759 filed Nov. 13, 2000 now U.S. Pat. No. 6,589,276, which is a continuation of U.S. patent application Ser. No. 09/483,082 filed on Jan. 14, 2000 now U.S. Pat. No. 6,508,834, which is a continuation of U.S. patent application Ser. No. 09/026,750 filed Feb. 20, 1998 (now U.S. Pat. No. 6,059,811), which is a continuation of U.S. patent application Ser. No. 08/760,359 filed Dec. 4, 1996 (now U.S. Pat. No. 5,980,552), which is a continuation of U.S. patent application Ser. No. 08/455,462 filed May 31, 1995 (abandoned), which is a continuation of U.S. patent application Ser. No. 08/213,272 filed Mar. 17, 1994 (now U.S. Pat. No. 5,449,373).

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to stents which are implanted as part of a balloon angioplasty procedure within a bodily conduit of a living animal or a human to maintain patency. In particular, the present invention relates to articulated intravascular stents for delivery through or implantation in a blood vessel having a curved portion.

Intravascular stents having a constricted diameter for delivery through a blood vessel and an expanded diameter for applying a radially outwardly extending force for supporting the blood vessel are known in the art. Articulated intravascular stents for either delivery through a curved blood vessel or implanted therein are also known in the art

Self-expandable articulated stents are described, for example, in U.S. Pat. No. 5,104,404 entitled "Articulated Stent" to Wolff. Balloon expandable articulated stents are commercially available under the trade name Palmaz-Schatz Balloon-Expandable Stents from Johnson & Johnson Intervention Systems Co.

A prior art self-expandable articulated intravascular stent **10** deployed in a curved blood vessel **16** is now described with reference to FIG. **1** which is, in actual fact, FIG. **2** of the above referenced U.S. Pat. No. 5,104,404. Stent **10** is made up of a number of individual segments **12** articulated by hinges **14** connected at each end to segments **12**. Stent **10** is preferably fabricated from memory shape material, for example, nitinol, and as such is self expandable after delivery from a delivery system described in U.S. Pat. No. 4,830,003 to Wolff et al. However, these prior art articulated intravascular stents suffer from a number of disadvantages both during delivery through a curved blood vessel and when implanted therein as will now described.

The delivery of stent **10** through curved blood vessel **16** is more complicated than the delivery of a non-articulated stent in that stent **10** has to be angularly oriented such that its hinges **14** are located towards the convex portion of blood vessel **16** so that stent **10** can be flexed inward. In the present example, it will be noted that hinges **14** are located on the same side of segments **12** because blood vessel **16** has only a simple curve in one plane. It can be readily appreciated that delivery of stents through blood vessels which have one or more curved portions which are not in the same plane is even more complicated and generally requires specially constructed stents.

Even when implanted in a curved blood vessel **16**, stents **10** are shown to be lacking in that the gaps between segments **12** render the curved portion of blood vessel **16** without support. Furthermore, the gaps at the convex portion of blood vessel **16** are substantially greater than the gaps at the concave portion thereof, thereby inducing non-uniform and therefore undesirable stresses on blood vessel **16**.

Therefore, it would be highly desirable to have an articulated stent which does not require any particular angular orientation when being delivered through a curved bodily conduit and provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted.

It would also be highly desirable the structure of a stent does not depend on the particular orientations of curved portions of a blood vessel.

SUMMARY OF THE INVENTION

The object of the present invention is for an articulated stent which can be delivered through a curved bodily conduit using a routine medical procedure and a conventional stent delivery system. Furthermore, the stent provides continuous and uniform support for both straight and curved portions of a bodily conduit when implanted. Still further, the structure of a stent and its support of a bodily conduit do not depend on the orientations of the curved portions of the conduit.

The objective of the present invention is achieved by an articulated stent, comprising: (a) at least two substantially rigid segments; and (b) a flexible connector for connecting adjacent segments, wherein the connector assumes a substantially cylindrical configuration when relaxed and a differentially stretched and compressed curved configuration when flexed.

After expansion, the rigid segments of the stent preferably present a fine diamond shaped mesh having 1 mm long sides to provide continuous and uniform support for straight portions of a bodily conduit.

The connectors can be implemented as a plurality of substantially helical links connecting adjacent segments. Alternatively, the connectors can be implemented as links each having at least one kink. The connectors typically have between 8–24 links to provide continuous and uniform support for both straight and curved portions of a bodily conduit.

The stents have constricted diameters for intraluminal delivery and are then deformed, by the inflation of a balloon forming part of their catheter delivery system, to expanded diameters for applying radially outwardly extending forces for supporting the lumen of bodily conduits. The constricted and expanded diameters of the stents typically fall in the ranges of 1.0–3.5 mm and 3.5–10.0 mm, respectively.

The stents are preferably fabricated from low memory, more plastic than elastic, bio-compatible materials, for example, stainless steel 316L, gold, tantalum, etc. which enables them to be plastically deformed from their constricted diameters to their expanded diameters.

A typical stent for implantation in a human coronary artery is 9–21 mm long comprising three to seven 2.2 mm long stent segments connected by two to six 1 mm long connectors such that the ends of the stent subtend between a 45° to 135° angle at a radius of curvature of approximately 9 mm when flexed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. **1** shows a close-up view of a prior art articulated stent of deployed in a curved blood vessel;

FIGS. **2***a* and **2***b* show a preferred embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation;

FIG. **2***c* shows the expanded stent of FIG. **2** after plastic deformation;

FIG. **2***d* shows the stent of FIG. **2** mounted on a catheter in its flexed state;

FIGS. **2***e* and **2***f* show the stent of FIG. **2** before and after expansion by a balloon forming part of its catheter delivery system;

FIGS. **3***a* and **3***b* show a second embodiment of an articulated stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation; and

FIG. **3***c* shows the expanded stent of FIG. **3** after plastic deformation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an articulated stent for delivering through a curved bodily conduit, for example, a peripheral or coronary artery of a living animal or a human and implantation therein as part of a balloon angioplasty procedure to maintain patency.

The principles and operation of the articulated stent of the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, FIGS. **2***a*–**2***c* show an articulated stent, generally designated **100**, constructed and operative according to the teachings of the present invention, generally comprising a number of substantially rigid segments **102** connected by connectors **110**.

Segments **102** are preferably made up to present a fine diamond mesh of interconnected diamond shaped cells **108** having 1 mm sides on expansion as best seen in FIG. **2***c*. Depending on the intended diameter of stent **100**, segments **102** typically comprise between 8–24 diamond shaped cells **108**.

Connectors **110** comprise links **112** connecting a front end **104** to a tail end **106** of adjacent segments **102**. Links **112** preferably extend in a substantially helical fashion between apexes of diamond shaped cells **108** at front and rear ends **104** and **106** of adjacent segments **102** such that the number of links **112** equals the number of cells **108**. Links **112** are preferably evenly deployed around perimeters of segments **102** such that connectors **110** can be equally flexed in any direction and to provide continuous and uniform support to both straight and curved portions of a bodily conduit.

Alternate connectors **110** at front and rear ends **104** and **106**, respectively, of a segment **102** preferably have links **112** wound in clockwise and counter clockwise directions. Alternately winding connectors **110** ensures that the rotational displacement of links **112** and adjacent segments **102** relative to the walls of a blood vessel and more importantly the balloon of its delivery system is minimized when stent **100** is expanded.

It is particular feature of the present invention that connectors **110** have a generally cylindrical configuration when stent **100** is relaxed as best seen in FIG. **2***a* and a differentially stretched and compressed curved configuration when stent **100** is flexed as best seen in FIG. **2***b*. The flexed configuration is brought about by two relatively opposing displacements of links **112**. First, the differential stretching of connectors **110** occurs at the convex portion thereof denoted **114** by links **112** being displaced away from one another. Second, the differential compressing of connectors **110** occurs at the concave portion thereof denoted **116** by links **112** being displaced towards one another.

Stent **100** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. **2***a* and **2***b* and an expanded diameter as shown in FIG. **2***c* for supporting a bodily conduit. Stent **100** is preferably fabricated from low memory, more plastic than elastic, bio-compatible material, for example, stainless steel 316L, gold, tantalum, etc. which enables it to be plastically deformed from its constricted diameter to its expanded diameter. The constricted and expanded diameters of stent **100** typically fall in the ranges of 1.0–3.5 mm and 3.5–10.0 mm, respectively.

With reference now to FIGS. **2***d*–**2***f*, stent **100** is shown overlying a balloon **118** forming part of its catheter delivery system **120**. Stent **100** is mounted on its catheter delivery system **120** in its constricted diameter state shown in FIG. **2***e* for plastic deformation through inflation of balloon **118** to its expanded diameter shown in FIG. **2***f* for supporting the walls of a bodily conduit. An exemplary stent for implantation in a human coronary artery, is typically 15 mm long made up of five 2.2 mm long segments **102** connected by four 1 mm long connectors **110** and capable of flexion such that its ends subtend a 90° angle at a radius of curvature of approximately 9 mm.

The delivery of articulated stent **100** is considerably simpler than the delivery of prior art articulated stent **10** because stent **100** is equally flexible in all direction and therefore does not require a dedicated angular orientation to pass a particular curved portion. This advantage is particularly important for delivery through blood vessels having multiple curved portions. It is a further advantage of stent **100** over prior art stents **10**, that stent **100** provides continuous and uniform support along the entire length of a blood vessel by means of segments **102** and unflexed connectors **110** supporting straight portions thereof while connector portions **114** and **116** supporting convex and concave curved portions thereof, respectively.

With reference now to FIGS. **3***a* and **3***b*, an articulated stent **122** is shown in which connectors **124** comprise links **126** having one or more kinks **128**. The design of connectors **124** is preferred to that of connector **110** because stent **100** may have a tendency to rupture balloon **118** due to two reasons. First, links **112** overlying the convex portion of balloon **118** have a tendency to be biased inward when stent **100** is flexed. Second, segments **102** display a rotational displacement relative to balloon **118** when stent **100** is expanded.

In this case, the differentially stretched and compressed curved configuration of connector **124** is brought about by two relatively opposing displacements of links **112** as before except that the differential stretching of connectors **124** at convex portion **114** occurs by kinks **128** being somewhat straightened out while the differential compressing of connectors **124** at concave portion **116** occurs by kinks **128** being more acutely bent.

In a similar fashion to stent **100**, stent **122** has a constricted diameter for delivery through a curved bodily conduit as shown in FIGS. **3***a* and **3***b* and an expanded diameter as shown in FIG. **3***c* for supporting a bodily conduit when implanted therein.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that

many variations, modifications and other applications of the invention may be made.

What is claimed is:

1. An expandable stent comprising:

(a) at least two substantially longitudinally rigid segments,

(i) each of said substantially rigid segments having a plurality of U or V-shaped regions in both the expanded and unexpanded configuration, the U or V-shaped regions being more open in the expanded configuration than in the unexpanded configuration,

(ii) each of said substantially rigid segments presenting a substantially cylindrical structure defining a longitudinal passageway therethrough in both the expanded and unexpanded configurations, the cylindrical structure being shorter in length and wider in diameter in the expanded configuration than in the unexpanded configuration,

(b) a flexible connector comprising a plurality of flexible links disposed between and connecting adjacent substantially longitudinally rigid segments,

(i) each of said flexible links connecting a U or V-shaped region of a substantially rigid segment with the nearest U or V-shaped region of the adjacent substantially rigid segment,

(ii) each of said flexible links, when viewed laterally, having a first portion, a second portion and at least one area of inflection disposed between the first portion and the second portion, and

(iii) none of said flexible links projecting into said longitudinal passageway in the unexpanded configuration.

2. An expandable stent in accordance with claim 1, wherein each of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent, is connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

3. An expandable stent in accordance with claim 2 wherein substantially all of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent, are connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

4. An expandable stent in accordance with claim 3, wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

5. An expandable stent in accordance with claim 3 wherein the average length of the flexible links, from each one's point of connection of said first portion to a substantially rigid segment to the point of connection of said second portion to a substantially rigid segment is greater in the expanded configuration than in the unexpanded configuration.

6. An expandable stent in accordance with claim 4 wherein the average length of the flexible links, from each one's point of connection of said first portion to a substantially rigid segment to the point of connection of said second portion to a substantially rigid segment is greater in the expanded configuration than in the unexpanded configuration.

7. An expandable stent in accordance with claim 2, wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

8. An expandable stent in accordance with claim 7 wherein the average length of the flexible links, from each one's point of connection of said first portion to a substantially rigid segment to the point of connection of said second portion to a substantially rigid segment is greater in the expanded configuration than in the unexpanded configuration.

9. An expandable stent in accordance with claim 2 wherein the average length of the flexible links, from each one's point of connection of said first portion to a substantially rigid segment to the point of connection of said second portion to a substantially rigid segment is greater in the expanded configuration than in the unexpanded configuration.

10. An expandable stent in accordance with claim 1, wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

11. An expandable stent in accordance with claim 10 wherein the average length of the flexible links, from each one's point of connection of said first portion to a substantially rigid segment to the point of connection of said second portion to a substantially rigid segment is greater in the expanded configuration than in the unexpanded configuration.

12. An expandable stent in accordance with claim 1 wherein the average length of the flexible links, from each one's point of connection of said first portion to a substantially rigid segment to the point of connection of said second portion to a substantially rigid segment is greater in the expanded configuration than in the unexpanded configuration.

13. An expandable stent in accordance with claim 1, wherein each of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent, is connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

14. An expandable stent in accordance with claim 13, wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

15. An expandable stent comprising:

(a) at least two substantially longitudinally rigid segments,

(i) each of said substantially rigid segments having a plurality of U or V-shaped regions in both the expanded and unexpanded configuration, the U or V-shaped regions being more open in the expanded configuration than in the unexpanded configuration,

(ii) each of said substantially rigid segments presenting a substantially cylindrical structure defining a longitudinal passageway therethrough in both the expanded and unexpanded configurations, the cylindrical structure being shorter in length and wider in diameter in the expanded configuration than in the unexpanded configuration,

(b) a flexible connector comprising a plurality of flexible links disposed between and connecting adjacent substantially longitudinally rigid segments,

(i) each of said flexible links having end points which are aligned substantially parallel to the longitudinal axis of the sent,

(ii) each of said flexible links, when viewed laterally, having a first portion, a second portion and at least one area of inflection disposed between the first portion and the second portion, and

(iii) none of said flexible links projecting into said longitudinal passageway in the unexpanded configuration.

16. An expandable stent in accordance with claim 15, wherein each of said U or V-shaped regions, other than the

U or V-shaped regions at the ends of the stent, is connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

17. An expandable stent in accordance with claim **16** wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

18. An expandable stent in accordance with claim **15**, wherein substantially all of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent, are connected by a flexible link to a U or V-shaped region of the adjacent substantially rigid segment.

19. An expandable stent in accordance with claim **18** wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

20. An expandable stent in accordance with claim **15** wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

21. An expandable stent comprising:

(a) at least two substantially rigid segments,

(i) each of said substantially rigid segments having a plurality of U or V-shaped regions in both the expanded and unexpanded configuration, the U or V-shaped regions being more open in the expanded configuration than in the unexpanded configuration,

(ii) each of said substantially rigid segments presenting a substantially cylindrical structure defining a longitudinal passageway therethrough in both the expanded and unexpanded configurations, the cylindrical structure being wider in diameter in the expanded configuration than in the unexpanded configuration,

(b) a flexible connector comprising a plurality of flexible links disposed between and connecting adjacent substantially rigid segments,

(i) each of said flexible links connecting a U or V-shaped region of a substantially rigid segment with the nearest U or V-shaped region of the adjacent substantially rigid segment, with substantially all of said U or V-shaped regions, other than the U or V-shaped regions at the ends of the stent being connected,

(ii) each of said flexible links, when viewed laterally, having a first portion, a second portion and at least one area of inflection disposed between the first portion and the second portion, and

(iii) none of said flexible links projecting into said longitudinal passageway in the unexpanded configuration.

22. An expandable stent in accordance with claim **21**, wherein said substantially rigid segments are substantially rigid particularly when compared to said flexible connectors disposed between said substantially rigid segments.

* * * * *