

APPLICATION FOR PATENT

Title: ARTICULATED STENT

FIELD AND BACKGROUND OF THE INVENTION

5 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.

10 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.

15 Self-expandable articulated stents are described, for example, in U.S. Patent 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.

20 A prior art self-expandable articulated intravascular stent 10 deployed in a curved blood vessel 16 is now described with reference to Figure 1 which is, in actual fact, Figure 2 of the above referenced U.S. Patent 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 Patent No. 4,830,003 to Wolff et al.
5 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
10 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
15 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
20 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
5 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.

10 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
15 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
20 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
5 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
10 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.
15 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
20 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

5 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. 2a and 2b show a preferred embodiment of an articulated
10 stent, constructed and operative according to the teachings of the present invention, in its relaxed and flexed states before plastic deformation;

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

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

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

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

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

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of an articulated stent for delivering through
5 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
10 accompanying description.

Referring now to the drawings, Figures 2a-2c 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.

15 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 Figure 2c. Depending on the intended diameter of stent 100, segments 102 typically comprise between 8-24 diamond shaped cells 108.

20 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 5 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 10 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.

15 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 Figure 2a and a differentially stretched and compressed curved configuration when stent 100 is flexed as best seen in Figure 2b. The flexed configuration is brought about by two relatively opposing 20 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 Figures 2a and 2b and an expanded diameter 5 as shown in Figure 2c 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 10 100 typically fall in the ranges of 1.0-3.5 mm and 3.5-10.0 mm, respectively.

With reference now to Figures 2d-2f, 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 15 state shown in Figure 2e for plastic deformation through inflation of balloon 118 to its expanded diameter shown in Figure 2f 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 20 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 Figures 3a and 3b, 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 5 for delivery through a curved bodily conduit as shown in Figures 3a and 3b and an expanded diameter as shown in Figure 3c for supporting a bodily conduit when implanted therein.

While the invention has been described with respect to a limited 10 number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

CLAIMS

1. A connector for connecting adjacent areas of adjacent segments of an articulated stent, the connector comprising:
- 5 a plurality of flexible links,
- wherein each of said flexible links includes a plurality of portions with each pair of neighboring portions having an area of inflection therebetween.
2. A connector according to claim 1 and wherein, during expansion of said stent,
- 10 said area of inflection of each flexible link remains inflected.
3. An articulated stent, comprising:
- (a) at least two substantially rigid segments having a plurality of connected cells each having apices, wherein, upon expansion, each of said rigid segments presents
- 15 a substantially cylindrical diamond mesh; and
- (b) a flexible connector, comprising a plurality of flexible links
- wherein each of said flexible links connects apices of adjacent cells on adjacent rigid segments;
- each of said flexible links includes a plurality of portions with each pair
- 20 of neighboring portions having an area of inflection therebetween, and during expansion of said stent, said area of inflection remains inflected.
4. The stent as in claim 3, wherein said plurality of links includes between 8-24 links.



This Sheet Has Been Replaced



THIS SHEET HAS BEEN
REPLACED

5. The stent as in claim 3 made from bio-compatible material capable of a more plastic than elastic deformation.

6. The stent as in claim 5, wherein said material is stainless steel.

5

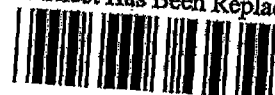
7. The stent as in claim 5, wherein said material is gold.

8. The stent as in claim 5, wherein said material is tantalum

10



This Sheet Has Been Replaced



THIS SHEET HAS BEEN
REPLACED

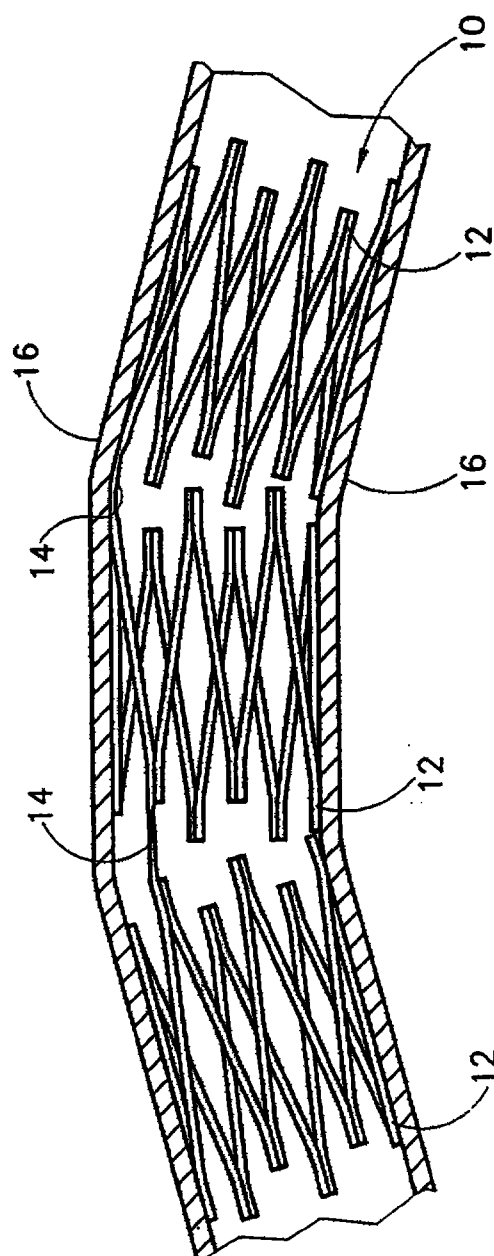


FIG. 1
PRIOR ART

2/5

FIG.2A

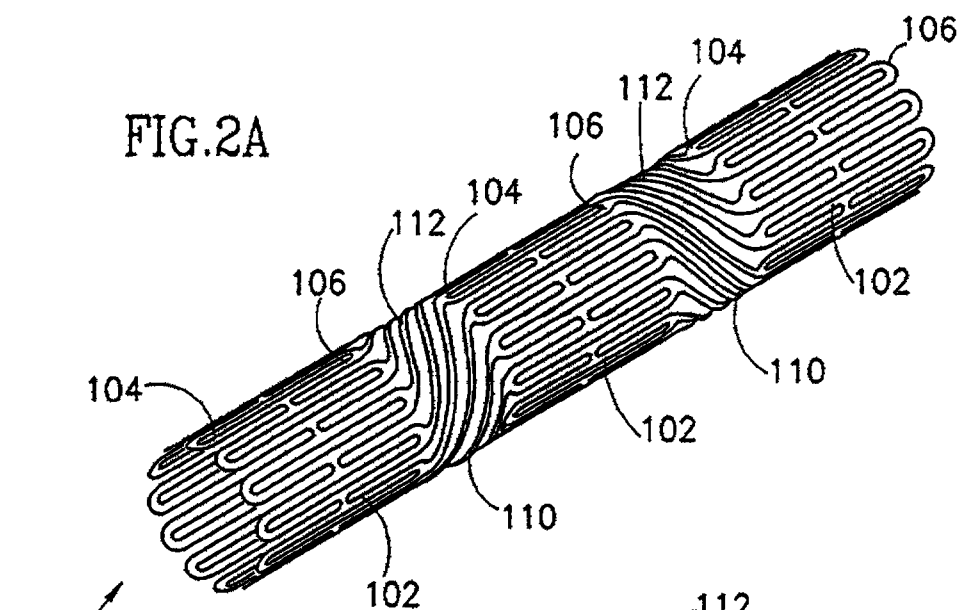


FIG.2B

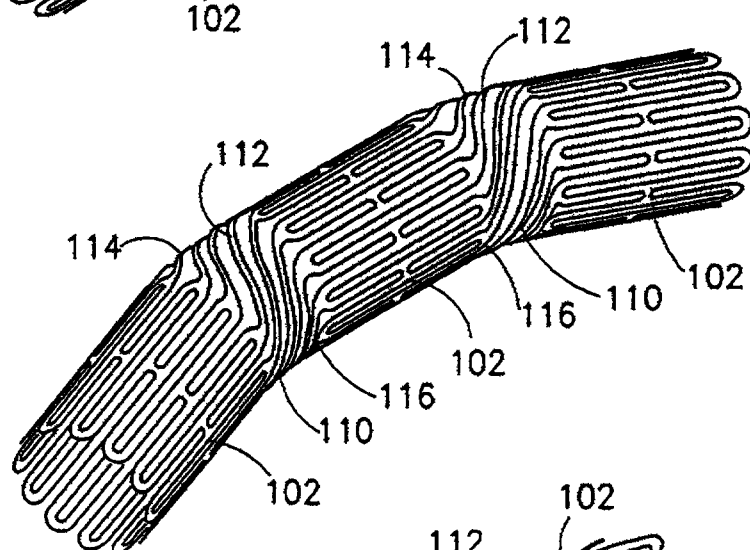
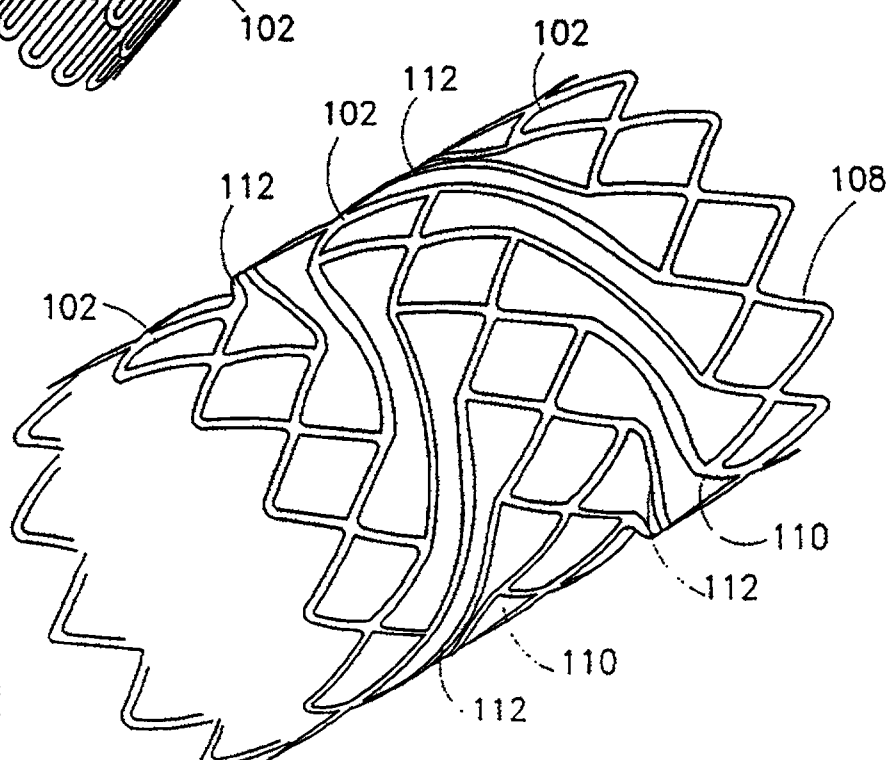
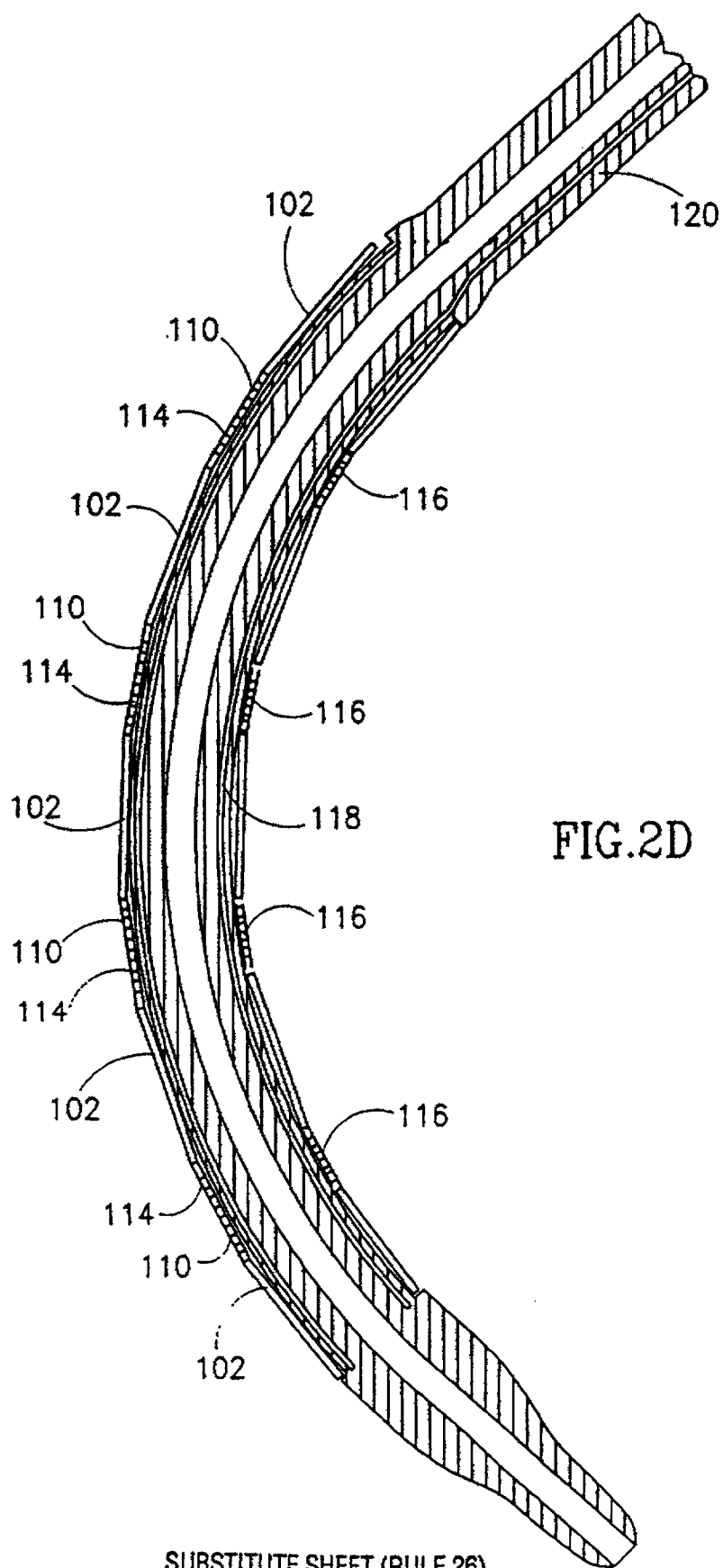


FIG.2C





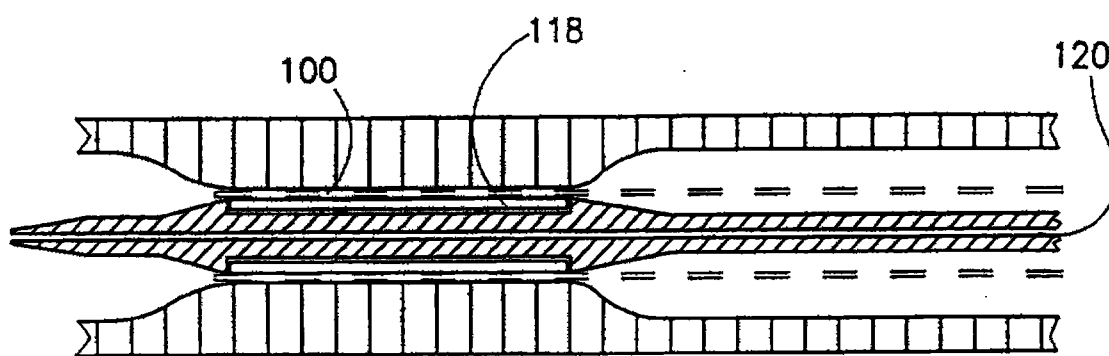


FIG. 2E

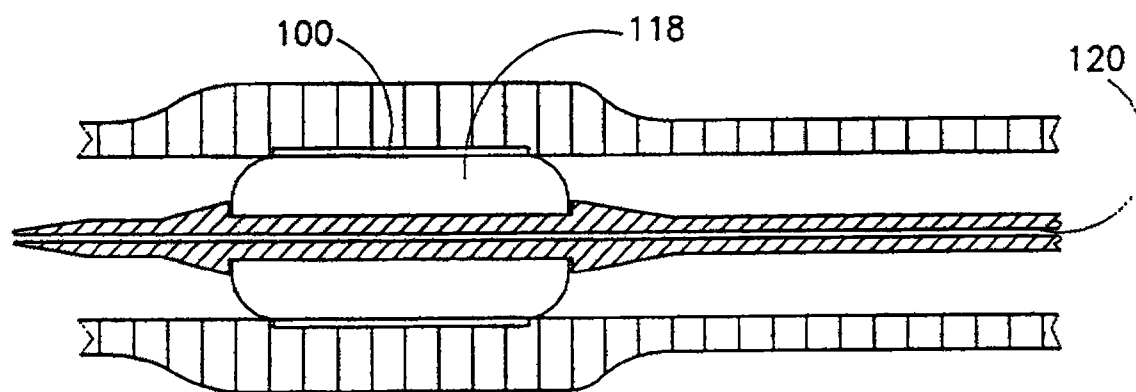
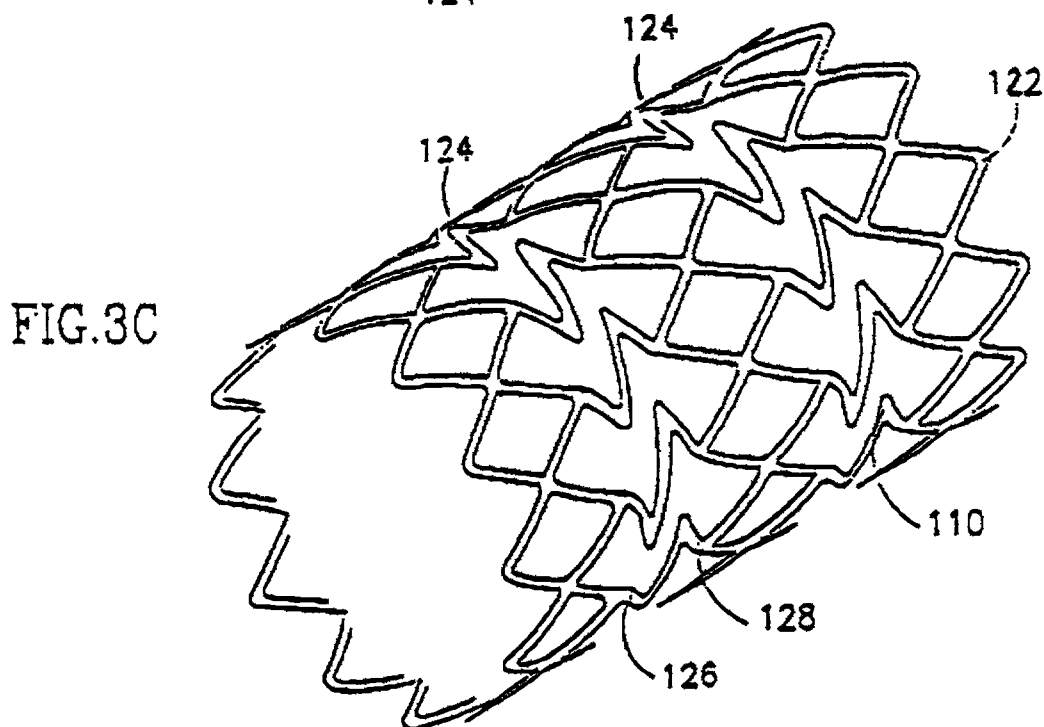
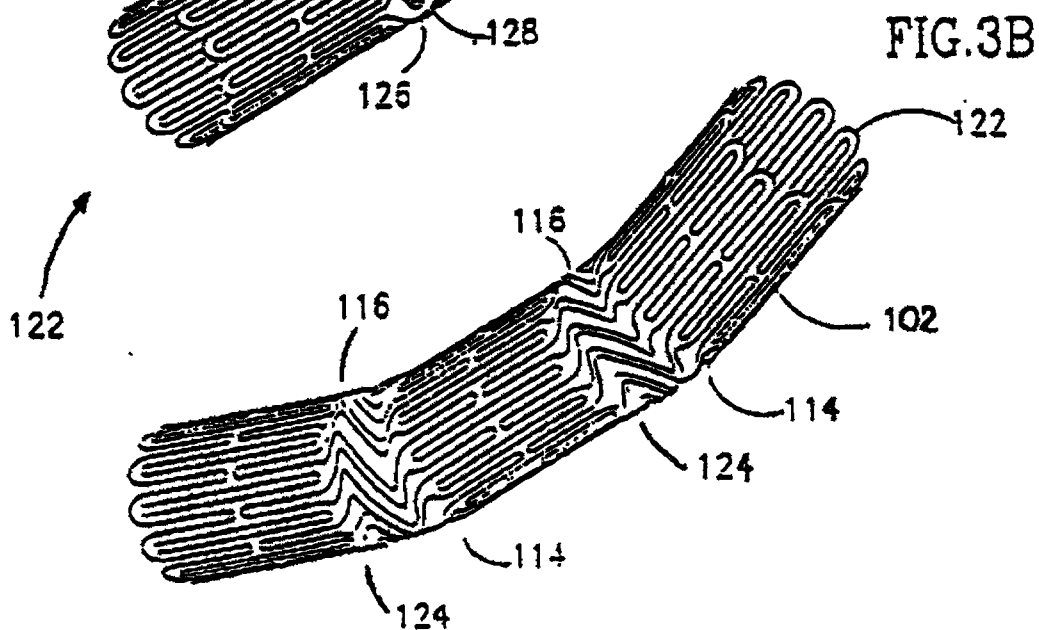
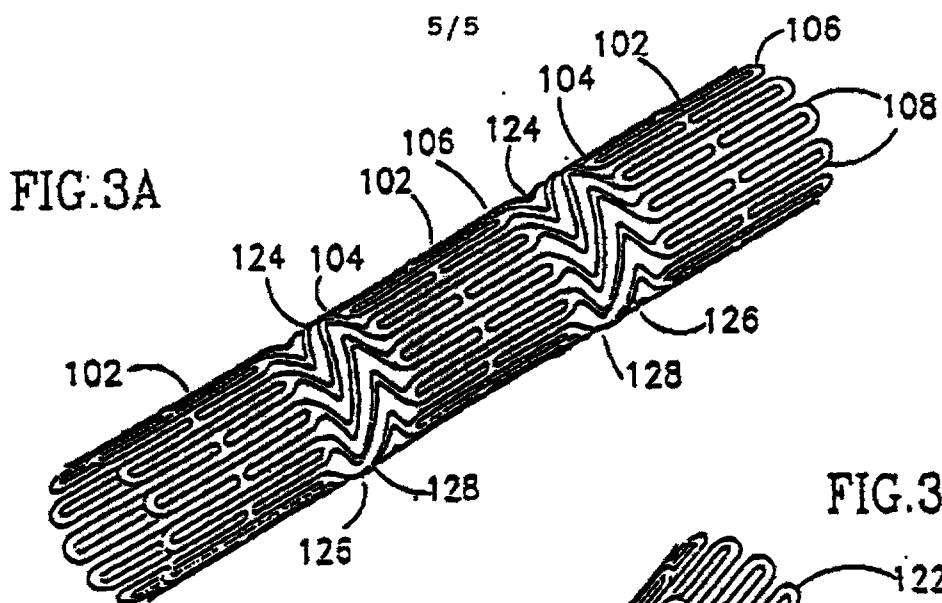


FIG. 2F



9705728-5

IPOS.

11

REPLACEMENT SHEET

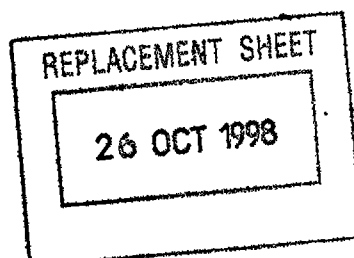
What is claimed is :

1. An articulated stent, comprising:

- (a) at least two substantially rigid segments having a plurality of connected cells each having apices, wherein, upon expansion, each of said rigid segments presents a substantially cylindrical diamond mesh; and
- (b) a flexible connector, comprising a plurality of flexible links wherein each of said flexible links connects apices of adjacent cells on adjacent rigid segments; each of said flexible links includes a plurality of portion with each pair of neighbouring portions having an area of inflection therebetween, and during expansion of said stent, said area of inflection remains inflected.

- 2. The stent as in claim 1, wherein said plurality of links includes between 8-24 links.
- 3. The stent as in claim 1 made from bio-compatible material capable of a more plastic than elastic deformation.
- 4. The stent as in claim 3, wherein said material is stainless steel.
- 5. The stent as in claim 3, wherein said material is gold.
- 6. The stent as in claim 3, wherein said material is tantalum.

REPLACEMENT SHEETS		SG
☐	Description : paged to paged	
☒	Claim(s) : paged ... to paged ...	30
☐	Drawing(s) : paged to paged	
☐	Abstract : paged to paged	
DATE OF RECEIPT		26 OCT 1998



7. 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.

8. The connector according to claim 9, wherein said area of inflection remains inflected after the expansion of said stent.

9.. The connector of claim 10, 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.

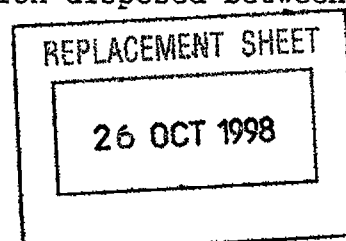
10. The connector of claim 1 or 9, in which the area of inflection enlarges during the expansion of the stent.

11. The connector of claim 1 or 9, in which said portions are generally straight.

12. 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.

13. The connector of claim 14, wherein said first area of inflection and said second area of inflection remain inflected after the expansion of said stent.

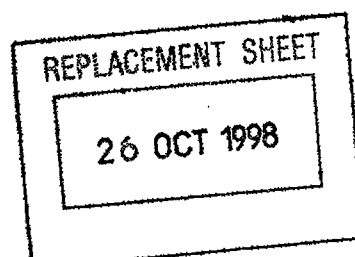
14. The connector of claim 14, wherein said portions are of different lengths and wherein the length of the longer of said portions is not greater than twice the length of the shorter of said portions.

15. The connector of claim 14 in which said first area of inflection and said second area of inflection enlarge during the expansion of said stent.

16. The connector of claim 14, in which said portions are generally straight.

17. 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.



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

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

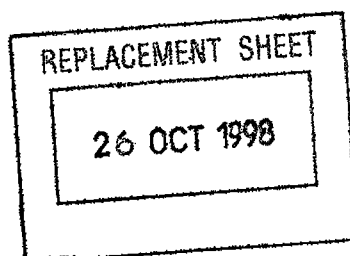
b) a plurality of flexible connecting links connecting said rigid segments, each of said flexible links having a first portion and a second portion, each of said links when viewed laterally having an area of inflection disposed between said portions.

20 The stent of claim 21, wherein each of said flexible connecting links extends between and connects two of said plurality of segments.

21. The stent of claim 22, wherein said plurality of flexible links are provided with end points at which said links are joined to said segments.

22. The stent of claim 23, wherein said end points of said flexible connecting links are aligned substantially longitudinally with said longitudinally extending aperture.

23. The stent of claims 21, 22, 23, or 24 wherein said flexible connecting links are adapted to substantially compensate for the



tendency of said segments to foreshorten when said stent is expanded.

24. The stent of claims 21, 22, 23, or 24 wherein said stent is expanded as by an inflatable balloon inflated within said longitudinal aperture.

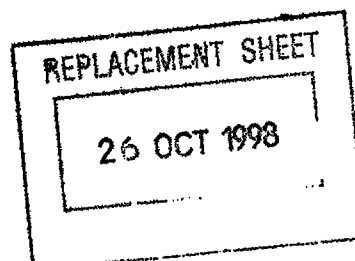
25. The stent of claims 21, 22, 23, or 24 wherein said flexible connecting links open to longitudinally lengthen and substantially compensate for the longitudinal movement away from each other of the adjacent ends of said connected rigid segments when said stent is expanded.

26. The stent of claims 21, 22, 23, or 24 wherein said segments do not tend to rotate relative to each other when said stent is expanded.

27. The stent of claim 28, 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.

28. The stent of claim 28, 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.

29. The stent of claim 30, 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.

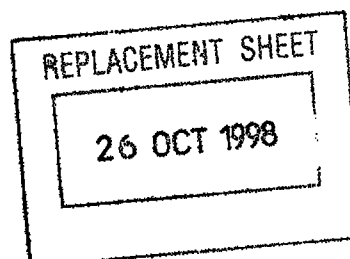
30.. The stent of claims 21, 22, 23, or 24 wherein said links do not tend to project into or outside of said longitudinal aperture of said stent when said stent is expanded.

31. The stent of claims 21, 22, 23, or 24, wherein said links do not tend to project into or outside of said longitudinal aperture of said stent when said stent is flexed.

32. The stent of claim 21, 22, 23, or 24, 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.

33. The stent of claim 21, 22, 23, or 24, 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.

34. The stent of claim 21, 22, 23, or 24, 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.

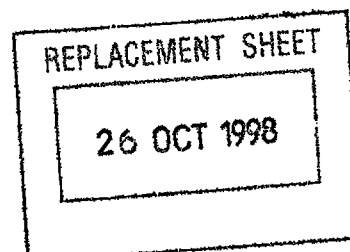
35. An expandable articulated stent having a longitudinal axis and a circumferential axis, including:

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.

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

a) a plurality of substantially tubular and



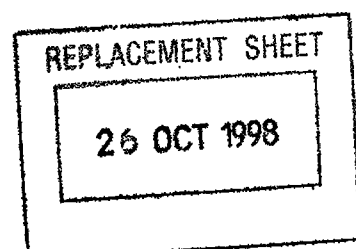
substantially rigid segments defining a longitudinal aperture,
and

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.

37 . 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,



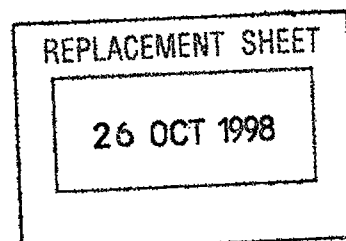
wherein said stent is expanded as by an inflatable balloon inflated within said longitudinal aperture, wherein said links do not tend to project into or outside of said longitudinal aperture of said stent when said stent is expanded, and wherein said links do not tend to project into or outside of said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

38. 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

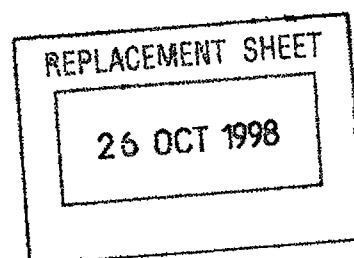


REPLACEMENT SHEET

20

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.

193812





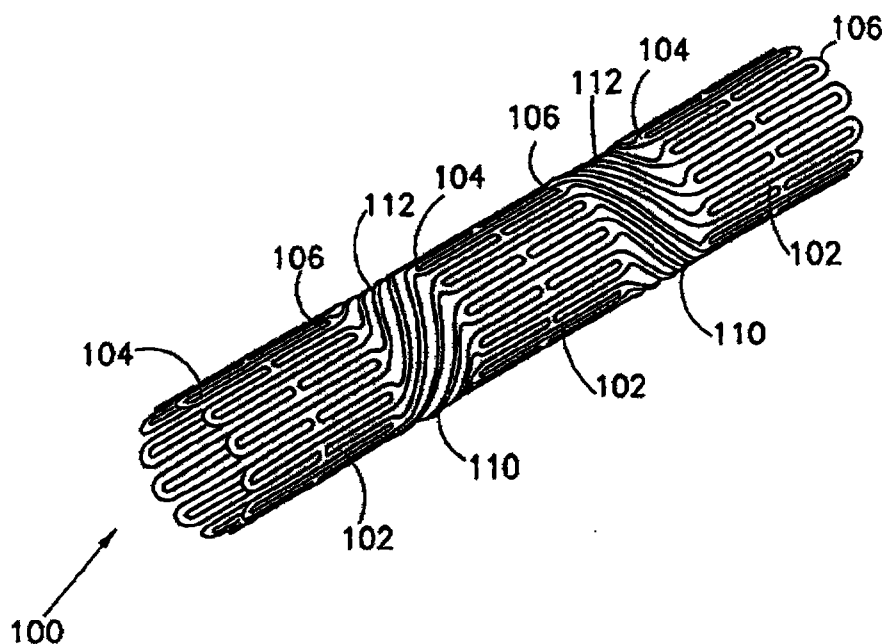
PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 2/06, A61M 29/02	A1	(11) International Publication Number: WO 96/33671 (43) International Publication Date: 31 October 1996 (31.10.96)
(21) International Application Number: PCT/US95/05095 ✓ (22) International Filing Date: 26 April 1995 (26.04.95) ✓ (71) Applicants: BRUN, Heidi, M. [US/IL]; 7 Halris Street, 99512 Bet Shemesh (IL); MEDINOL LTD. [IL/IL]; Kiryat Atidim, P.O. Box 58165, 61581 Tel Aviv (IL). ✓ (72) Inventors: PINCHASIK, Gregory; 23 Golomb Street, 47414 Ramat Hasharon (IL). ✓ RICHTER, Jacob; 8 Anafa Street, 47226 Ramat Hasharon (IL). ✓ (74) Agents: GUNNISON, Forrest, E. et al.; Skjerven, Morrill, MacPherson, Franklin & Friel, Suite 700, 25 Metro Drive, San Jose, CA 95110 (US). ✓	(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, ARIPO patent (KE, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report. NO PDOC 1 appl. 2 Invs. IPC = A61F 2/06 } IPER A61M 29/02 } 22/11/96	

(54) Title: ARTICULATED STENT ✓



(57) Abstract

A connector (110) for connecting adjacent areas of adjacent segments (102) of an articulated stent, the connector includes a plurality of flexible links (112), wherein each of the flexible links includes a plurality of portions with each pair of neighboring portions having an area of inflection therebetween and wherein during expansion of said stent, said area of inflection of each flexible link remains inflected.