



(43) International Publication Date
15 August 2013 (15.08.2013)

- (51) International Patent Classification:
A61F 2/958 (2013.01) *A61M 25/10* (2013.01)
- (21) International Application Number:
PCT/US2013/025032
- (22) International Filing Date:
7 February 2013 (07.02.2013)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/596,618 8 February 2012 (08.02.2012) US
- (72) Inventors; and
- (71) Applicants : **FELD, Tanhum** [IL/IL]; 19105 Moshav Merhavaya (IL). **KONSTANTINO, Eitan** [IL/US]; 29 Meadow Park Court, Orinda, CA 94563 (US).
- (74) Agent: **CHRISTENSEN, Michael, R.**; Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).
- (81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: CONSTRAINING STRUCTURE WITH NON-LINEAR AXIAL STRUTS

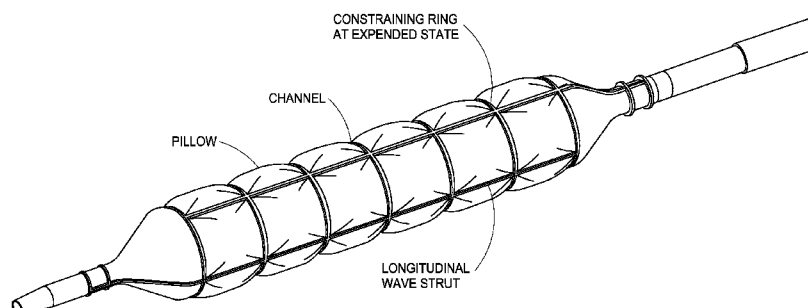


FIG. 2

(57) Abstract: A constraining structure for use with a balloon catheter can include multiple longitudinal struts and multiple, sinusoidal shaped radial rings. The constraining structure can expand to form a pattern of channels including substantially square windows. The constraining structure can modify, restrict, and control a shape and/or size of the balloon when inflated. Inflating the balloon catheter within the constraining structure can provide nonuniform pressure on a vessel wall adjacent the balloon.

CONSTRAINING STRUCTURE WITH NON-LINEAR AXIAL STRUTS

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention is a balloon catheter for angioplasty procedures, comprising an elastic constraining structure mounted over the balloon where the structure has a mechanism of expansion to control the balloon inflation.

[0002] Conventional angioplasty balloons expand in an artery lesion at the least resistant areas of the lesion causing “dog bone” effect at the lesion ends and overexpansion in the softer areas, resulting in trauma to the vessel wall. Conventional angioplasty is associated with vessel displacement and its main mechanism of action is plaque compression where the vessel is significantly displaced or “pushed out” before reaction force can be generated and plaque compression takes place. During this process the balloon may expand in the axial direction (in addition to radial), a phenomenon that accelerates propagation of “cracks” in the vessel wall (dissections). This elongation continues after the balloon engages the lesion and the vessel wall and cause longitudinal stretch

[0003] This mechanism of action causes a high rate of failure due to the vessel trauma (randomize studies in legs arteries document up to 40% acute failure rate and poor long term results with 20%-40% patency in one year). Attempts to modify the mechanism of action were mainly aimed at increasing the local force by adding cutting blades, wires or scoring elements that can penetrate into the vessel wall and create pre defined dissection plans. Those devices are used when encountering resistant lesions otherwise hard to crack open with conventional balloons. None of those technologies was designed to provide an alternative mechanism that leads to a gentler dilatation by minimizing vessel displacement and reducing the radial forces during balloon dilatation.

SUMMARY OF THE INVENTION

[0004] According to the present invention, a device that modifies the properties of an angioplasty balloon in order to provide uniform inflation and extraction

of longitudinal forces in order to facilitate plaque extrusion and minimize vessel trauma. In the device presented herein, a novel constraining structure prevents non-cylindrical expansion using constraining rings that are spaced apart along the balloon working length leading to creation of small balloon segments (pillows) separated by grooves that facilitate plaque extrusion. The constraining structure also prevents longitudinal elongation of the balloon since it has a structure that shortens during expansion and constrains the balloon in both longitudinal and radial directions.

[0005] Computer simulation shows a decrease in radial forces using a balloon with the constraining structure. The constraining structure causes reduction in the rate of vessel dissections and perforations thru formation of an array of balloon pillows that provide gentle contact with the vessel wall and thru the formation of channels between these pillows that allow plaque flow and strain relief areas in the vessel wall.

[0006] Conventional balloon angioplasty does not provide strain relief to the vessel wall and suffer from high rate of dissections.

[0007] Other devices, such as cutting balloons and scoring devices (for example US7691119 Farnan) made to address resistant lesions by adding elements that can cut or score into the vessel wall and significantly, increase the local force (“focus force angioplasty”), but do not provide strain relief and gentle contact with the vessel wall. On the contrary, these devices include aggressive metallic components that are made to break hard plaque and mark their metal footprint on the vessel wall.

[0008] The constraining structure of the present invention takes advantage of the fact that by forcing the balloon into pillows topography the excessive length of the balloon is directed into a three dimensional shape and the surface area of the balloon increases. This mechanism shortens the overall balloon length during inflation and minimized longitudinal vessel stretch. Other devices such as stents or scoring cages that have structures over a balloon are using the balloon as an “activator” or expandable shell designed to increase the diameter of the stent or scoring stent and allow the balloon to inflate in full both radially and longitudinally and are therefore designed to expand as big as the inflated balloon, while the design present herein is made smaller than the inflated balloon, specifically aimed to modify, restrict and control the balloon inflated shape and size.

[0009] The combination of the advantages of the device described herein result in controlled non aggressive and predictable lesion dilation that addresses a major health concern.

[0010] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0012] Fig 1 show the layout of the constraining structure design adjacent to the balloon scheme, where the distal and proximal ends of the constraining structure are placed over the balloon legs, the constraining rings are spaced apart along the balloon length over the working length of the balloon, and an array of longitudinal waved struts interconnect between the constraining rings and the ends.

[0013] Fig 2 shows a scheme of the inflated device with circumferential and longitudinal pattern of channels and pillows.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0014] A balloon catheter comprising a catheter shaft and an inflatable balloon at its distal end and an elastic constraining structure is mounted over the balloon. The constraining structure is made from an elastic material such as Nitinol, elastic polymers or high strength fibers or mesh.

[0015] The device natural configuration is collapsed. Unlike “self-expanding stents” it is not “self-expanding” but to the contrary “self-closing”: prior to expansion the constraining structure is tightly closed on the folded balloon. When the balloon is inflated the constraining structure is expanded by the balloon force up to a diameter smaller than the free inflated diameter of the balloon. The structure will self compressed back to a small diameter when the balloon is deflated. Typically the distal end and a proximal end

of the constraining structure are fixedly attached to the catheter at both sides of the balloon to prevent it from disengaging with the catheter. Attachment is made by means of adhesive or thermal bonding or other method known in the art.

[0016] The constraining structure comprises an array of sinusoidal constraining rings spaced apart along the balloon working length. Each ring has a sinus curve length defined by the length of the ring when fully straitened. For each ring the sinus curve length is smaller than the balloon expanded circumference. When expanded the rings expand to its maximal expansion resulting in a substantially circular ring shape that is smaller in diameter than the balloon diameter and force a substantially circular channel around the balloon outer surface.

[0017] Expansion of the constraining rings results in an array of channels along the balloon length and also results in shortening of the balloon. It is easier to understand the shortening caused by the rings as it is obvious that if the rings were removed from an inflated balloon the balloon would elongate.

[0018] The maximum expanded diameter of the constraining structure is mainly controlled by the length of the sinus curve rings. The maximum expanded diameter could be 0.15mm-0.3mm smaller than the balloon free inflated diameter but it could also be in the range of 0.1mm to 0.5mm or exceed this range depending on the material of choice and the specifics of the design. For example for 3mm balloon the maximum expanded diameter of the structure made of nitinol is in the range of 2.6mm-2.85mm. If the maximum expanded diameter is out of the desirable range the device will fail to perform. For example, if the maximum expanded diameter is similar or larger than the balloon free expanded diameter, the constraining structure would not be able to restrict the free expansion of the balloon and pillows will not form. If the structure is too small, the forces applied by the balloon would cause the structure to break and the device will fail, risking patient's safety.

[0019] The constraining rings are interconnected by a circumferential array of interlacing longitudinal waved struts. The number of struts is usually twice the number of the sine waves in the constraining ring. For example the structure scheme shows a two waves sine ring and therefore four longitudinal waved struts. Each strut begins near one end of the constraining structure and ends at the last constraining ring near the opposite end. It does not continue all the way to the opposite end in order to allow proper functionality and expansion. The following strut begins near the opposite end of the

constraining structure and ends at the last constraining rings near the first end of the balloon, such that the opposing ends are not interconnected by the longitudinal waved struts.

[0020] This construction result in the last ring being connected to the ends with half the number of struts only. If the struts were to continue all the way to the opposing end it would restrict the first ring from expanding homogeneously over the balloon as the intermediate rings expand.

[0021] The struts connect to the first constraining rings at the external peaks of the ring and thus forming a structure that shortens when expanded. If the struts were connected to the first constraining rings at the internal peaks of the ring than the structure would elongate when expanded.

[0022] It is particularly important not to have “spine” or struts that are connected to both proximal and distal end of the balloon. The current structure in figure 1 in which two (or more) longitudinal struts are connected to the distal end of the balloon and two (or more) other interlacing struts connected to the proximal end of the balloon create “push/pull” forces during inflation and longitudinal struts are moving in opposing directions during inflation in order to apply compressive forces on the balloon and allow it to shorten. This “tilt” function supports expansion of the pillows at lower pressure. The longitudinal waved struts form longitudinal channels over the balloon outer surface and together with the circular channels formed by the rings it results in substantially square pattern of channels (“windows”) and balloon pillows protruding in the windows.

WHAT IS CLAIMED IS:

1. A balloon catheter, comprising
an elongate tubular body;
an inflatable balloon at a distal end of the body;
a constraining structure positioned on the balloon, the constraining structure comprising a plurality of sinusoidal shaped radial rings connected by waved longitudinal struts, the constraining structure comprising an inflated diameter smaller than an inflated diameter of the balloon.
2. The balloon catheter of claim 1, wherein the constraining structure is attached to the catheter at a distal and/or proximal end of the balloon.
3. The balloon catheter of claim 1, wherein a diameter of the constraining structure when expanded is about 0.15-0.3 mm smaller than a diameter of the balloon when expanded.
4. The balloon catheter of claim 1, wherein the balloon comprises pillows protruding through the constraining structure when inflated.
5. A constraining structure, comprising
a plurality of radial rings spaced apart along a length of the constraining structure;
a plurality of longitudinal struts spaced along a circumference of the constraining structure,
wherein the constraining structure is configured to be positioned over a balloon catheter and wherein the constraining structure has an expanded and a collapsed state and is biased to be in the collapsed state.
6. The constraining structure of claim 5, wherein the radial rings comprise one or more first peaks extending towards a proximal end of the constraining structure and one or more second peaks extending towards a distal end of the constraining structure.
7. The constraining structure of claim 6, wherein the longitudinal struts extend from an end of the constraining structure to the radial ring positioned nearest an opposite end of the constraining structure.
8. The constraining structure of claim 7, wherein each longitudinal strut is attached to a peak of the radial ring closest to its point of attachment to the constraining structure.

9. The constraining structure of claim 5, wherein the rings comprise one or more sine waves.

10. The constraining structure of claim 9, wherein a number of struts is twice a number of sine waves in the rings.

11. The constraining structure of claim 5, wherein the longitudinal struts are waved struts.

12. A method of expanding a balloon catheter in a vessel of a patient, the method comprising:

positioning the balloon catheter so that the balloon is adjacent a treatment site in a vessel of a patient, the balloon catheter comprising a constraining structure positioned over the balloon, the constraining structure comprising a plurality of longitudinal struts connecting radial sinusoidal rings, the constraining structure biased to be in a collapsed state; and

inflating the balloon, thereby expanding the constraining structure and providing nonuniform pressure on the vessel wall adjacent the balloon.

13. The method of claim 12, wherein inflating the balloon and expanding the constraining structure produces a pattern of channels comprising a pattern of substantially square windows in the constraining structure.

14. The method of claim 13, wherein inflating the balloon and expanding the constraining structure causes balloon pillows to protrude through the windows.

15. The method of claim 12, wherein expanding the constraining structure comprises expanding the constraining structure in a radial direction.

16. The method of claim 12, wherein expanding the constraining structure comprises at least one of modifying, restricting, and controlling a shape and/or size of the balloon when inflated.

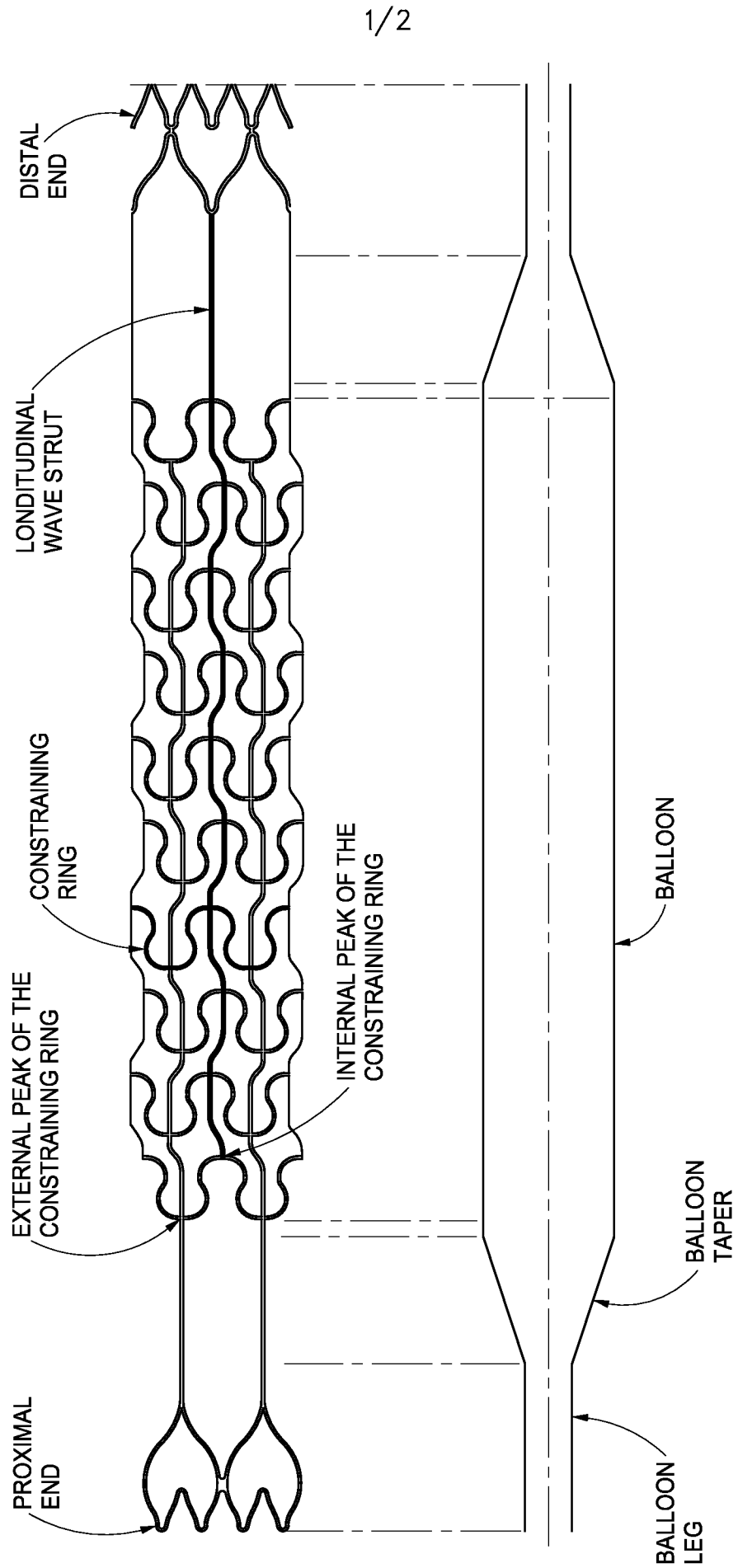


FIG. 1

2/2

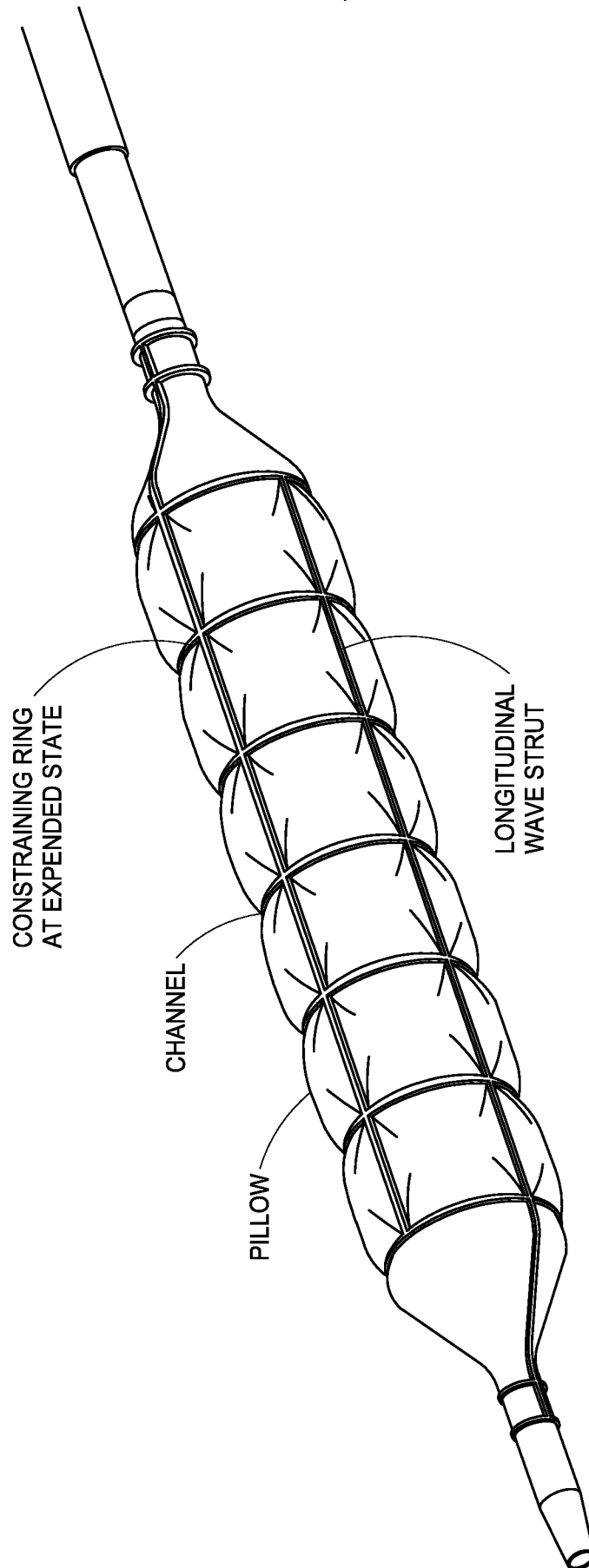


FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US13/25032

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/958; A61M 25/10 (2013.01)

USPC - 606/191; 623/1.1, 1.15

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61K 9/00, 31/00, 39/00 (2012.01)

USPC: 604/103.05, 103.09, 507, 509; 606/192, 194; 623/1.16, 1.35

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

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

MicroPatent (US-Granted, US-Applications, EP-A, EP-B, WO, JP, DE-G, DE-A, DE-T, DE-U, GB-A, FR-A); DialogPRO (Derwent, INSPEC, NTIS, PASCAL, Current Contents Search, Dissertation Abstracts Online, Inside Conferences); Google Scholar; Espacenet.com; balloon*, catheter*, tube*, tubular*, cylind*, constrain*, control*, ring*, strut*, band*, encircl*

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	WO 2011/112863 A1 (KONSTANTINO, E et al.) September 15, 2011; abstract; paragraphs [0008]-[0016], [0027]-[0032]; Claim 16; figures 2A-3A, 4A	1, 2, 4-8, 11-16 ----- 3, 9, 10
Y	US 2006/0085025 A1 (FARNAN, R et al.) April 20, 2006; figure 5; paragraphs [0020]-[0022], [0024], [0025]	3
Y	US 5133732 A (WILKOR, DM) July 28, 1992; column 3, lines 47-68	9, 10
Y	US 6217608 B1 (PENN, IM et al.) April 17, 2001; abstract; figure 7; column 9, lines 56-67	10

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

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

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

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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

02 April 2013 (02.04.2013)

Date of mailing of the international search report

19 APR 2013

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Shane Thomas

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774