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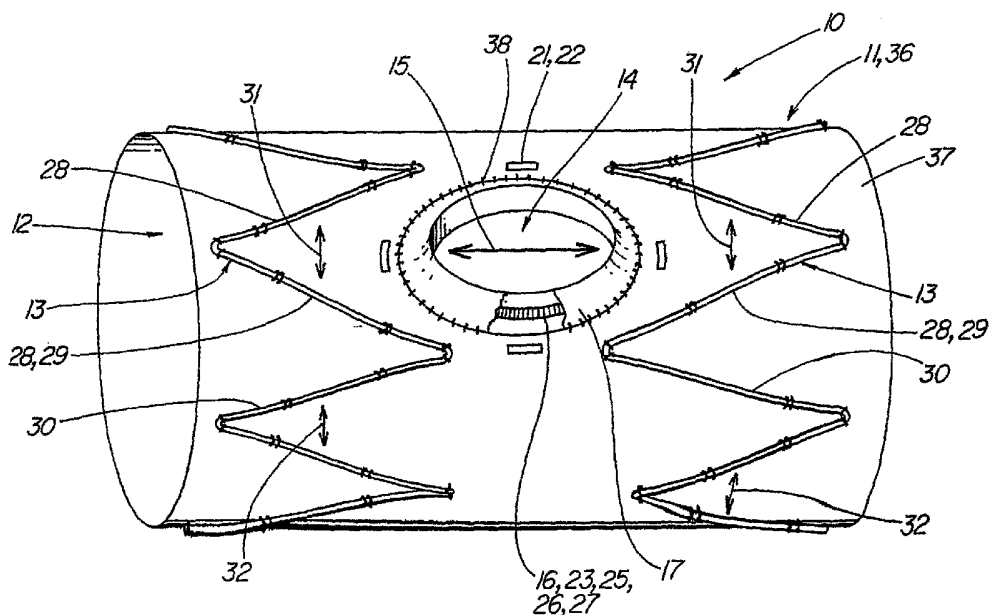
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STRETCHABLE PROSTHESIS FENESTRATION



(57) Abstract: A prosthesis (10) having a variable size or stretchable fenestration (14) in the graft material (37) of a biocompatible tubular graft (11). An expandable frame (16) is disposed about the fenestration, and a portion (17) of the graft material about the fenestration is folded back over the frame to cover the frame. Additional grafts or prosthesis of varying size can be inserted through the frame and fenestration with the stretched frame and folded portion compressing on the inserted graft forming a seal therewith.

STRETCHABLE PROSTHESIS FENESTRATION

DescriptionTechnical Field

This invention is related to medical devices and, in particular, to a prosthesis having a fenestration.

Background of the Invention

Prostheses such as stent grafts as used for stenting or repairing aneurysms as in the abdominal or thoracic aorta are usually fairly effective at excluding the aneurysm from exposure to blood pressure and therefore protect the patient from the dangers of aneurysm rupture. However, these stent grafts frequently block the flow of blood to the side branch vessels that carry blood to other organs and anatomy. The occlusion of the side branch vessels can result in damage to the tissue perfused by the blood flow from the side branch vessel.

Attempts to deal with these occlusions have been such things as by-pass vessels placed surgically to restore blood flow from a region of the aorta that is not stented and the placement of holes or fenestrations in the stent grafts that are aligned with the side branch vessel so as to allow blood to continue to flow into the side branch vessel. The fenestration approach is the preferred method since it does not involve major vascular surgery. Patients receiving stent grafts usually do so because they are too weak or sick to endure surgery. Once the fenestrated stent graft is deployed, the stent graft is anchored to the ostium of the side branch with a balloon expanded stent. This stent is placed so that the bulk of the stent length is in the side branch with 1 or 2 mm extending into the lumen of the stent graft. The 1 or 2 mm segment is then over expanded, or flared slightly, to hold the stent graft to the aortic wall and effect a seal that prevents blood from flowing into the aneurysm.

While this balloon stenting through a fenestration process is fairly effective, it is deficient in that the connection between the balloon expanded stent and the stent graft at the fenestration is never completely snug or tight. As a result, leaks often occur between the stent graft and aortic wall. The reason this

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connection can never truly be a tight, zero clearance fit is because balloon expandable stents always have some amount of recoil after they are expanded by the delivery balloon. This recoil is usually 4% to 10% of the stent diameter attained prior to balloon deflation. As a result, the fit between the balloon expandable stent and the stent graft fenestration is never truly tight. The eventual endothelialization of the area around the fenestration and the ostium or origin of the side branch is the only hope of an eventual complete seal and exclusion of the aneurysm. Before endothelialization occurs, the patient is still at risk of a ruptured aneurysm. In some cases, where the gap between the stent graft and aortic wall is large, a seal at the fenestration may never occur, leaving the patient with minimal or no protection from a ruptured aneurysm.

Other exemplary prostheses including stents, grafts, and stent grafts with, for example, fenestrations are disclosed in US Patent Nos. 6,524,335; 5,984,955; 6,395,018; 6,325,826; 6,077,296; 6,030,414; 5,617,878; 5,425,765; and 4,580,569, all of which are incorporated herein by reference in their entirety.

Summary of the Invention

According to an illustrative embodiment, the present invention seeks to provide a stretchable prosthesis fenestration that provides a snug fit with another prosthesis inserted therethrough according to Claim 1.

The foregoing problems are solved and a technical advance is achieved in an illustrative embodiment of a stretchable prosthesis fenestration including a variable size fenestration in the stent graft of the present invention. This invention provides a variable size fenestration or hole in the stent, graft or stent graft that is stretchable or elastic. By being stretchable, a balloon expandable stent can be advantageously expanded beyond the diameter of the fenestration without damaging the stent, graft or stent graft and will recoil along with the balloon expanded stent and maintain a close, snug fit to it. An expandable frame is disposed at least partially about the fenestration and at least partially controls the variable size of the fenestration to advantageously accommodate a close or snug fit with another prosthesis such as a stent, graft or stent graft positioned therethrough.

Brief Description of the Drawing

FIG. 1 shows a segment of stent graft with a fenestration of the present invention.

FIG. 2 shows a stretchable fenestration frame of the present invention made from coil spring material.

FIG. 3 shows an expandable fenestration frame of the present invention made from solid wire.

FIG. 4 shows a cross section through the stretchable fenestration of the present invention using the coil spring frame.

FIG. 5 shows a cross section of another stretchable fenestration frame of the present invention where the coil frame is an oval or flat coil spring.

Detailed Description

FIG. 1 depicts a pictorial view of a segment of an illustrative prosthesis 10 such as a stent graft of the present invention in which a variable size fenestration 14 is disposed in tubular graft 11, 36.

The fenestration 14 can be made by first cutting a round hole in the graft material 37 that is considerably smaller than the desired finished hole. An expandable frame 16 such as a stretchable coil loop 23 as in FIG. 2 is laid on the graft material, around the hole, then the graft material is everted through the coil loop and out over the loop back onto the graft material. The edge can then be sutured or sewn to the graft material, capturing the coil loop at the resulting hole or fenestration. The result is prosthesis 10 or elongated tubular member 36 depicted in FIG. 1. A tubular graft sleeve can also be positioned and attached to the hole to facilitate the eversion or fold back.

The portion of the graft that is everted through the coil frame and back out onto the graft material needs to be stitched far enough away from the coil frame so as to allow a space for the coil frame to expand. FIGS. 4 and 5 illustrate how the opening or fenestration expands as the coil loop frame is stretched. D-1 is the relaxed, un-stretched diameter and D-2 is the maximum stretched or expanded diameter. From the D-2 or expanded diameter, the coil loop frame will

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cause the fenestration to be tight or snug around the stent that is positioned through the fenestration and into the side branch artery.

The coil loop shown in FIG. 5 is an alternative form of coil loop frame. The coil from which the loop is made is made in an oval shape. This will result in a fenestration that has a flange or protrusion that will seat in the ostium of the side branch vessel and improve the seal between the stent graft and aorta. The oval shaped coil will also increase the amount of surface area in contact with the balloon expandable stent, further improving the seal between the stent graft and aorta.

FIG. 3 shows an alternate form of fenestration frame that uses a solid wire. It is simply a loop wherein the ends overlap. The overlap portion allows the loop to expand and contract a small amount. The expansion and contraction allows the fenestration to expand as needed when the balloon expandable stent is expanded in it and contract with the balloon expanded stent as the balloon is deflated, thus maintaining a tight fit to the balloon expanded stent.

The materials used to make the fenestration frames could be any springy, biocompatible material, such as, stainless steel, Nitinol, Elgiloy, MP35N, Platinum and many other materials including polymers. Platinum would have the added advantage of providing improved radiopacity of the fenestration, making it easier for the physician to accurately place the fenestration in the side branch vessel.

In addition to the wire and spring fenestration loops described, it would also be possible to make stretchable fenestration frames using elastic bands, such as Silicone rubber "O" rings, or any other biocompatible elastomer.

In addition to using the radiopacity of the fenestration frame to aid in the placement and orientation of the stent graft, separate radiopaque markers could be added to the stent graft in the vicinity of or around the periphery of the fenestration. These markers could be gold, platinum, tungsten, etc., bands or wires and could be shaped and/or oriented in such a way so as to indicate rotational orientation fluoroscopically.

The size of a fenestration would typically vary over a range of about 2 to 10 mm diameter. The wire used to make the coil frames would be in the .002 to .006 in. diameter range. Flat, square, rectangular and oval wire could also be used

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to make the coil loop frames. The diameter of the coil in the coil loop frame would be in the .010 to .050 in. range. The long and short axis of the oval coil loop frame would be in the .005 x .010 in. to .020 x .050 in. range. The long axis dimension could be greater if a longer or taller flange protrusion around the fenestration is desired. The wire in the wire loop frame could be in the .010 to .060 in. diameter range.

The coil loop frame could be made by first coiling the wire to the desired coil diameter by any number of well known coil spring winding techniques and then joining the ends of a length of the coil to form a loop of the desired diameter. The ends of the coil could be welded, soldered or glued together to form the continuous coil loop. The ends of the coil could also be stretched slightly over a distance of about 1 mm so that the two ends could be threaded or screwed together to form a mechanical connection. The oval coil loop would be made in much the same manner except that the original coil would be pressed or flattened to form the short diameter of the oval.

The shape of the stents used to make the stent graft could be altered to accommodate the inclusion of the fenestrations and frames. For example, the most common stent in a stent graft is the Gianturco "Z" stent (US Patent No. 4,580,568). The straight struts of the Z stent that are adjacent to the fenestration could be curved so that a larger space is provided for the fenestration. The Z stents could also just be spaced far enough apart so as to allow the formation of a fenestration between them. The length of the straight struts could also be reduced in the area of the fenestration so as to allow the stents to remain close together while providing a space for the fenestration.

In addition to a separate stretchable fenestration frame, a side branch graft could be attached to the fenestrated area in the main stent graft that is made of a "stretch fabric," similar to the tops of stockings and the like that has an unstretched diameter smaller than the side branch vessel diameter that allows it to be easily maneuvered into the side branch, and then another stent is placed inside it that would stretch the side branch portion up to the diameter of the side branch

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vessel and create a long fluid tight seal between the side branch vessel and the main stent graft.

The graft material can be any biocompatible material such as any biocompatible polymer such as Dacron and the like and biological materials such as extracellular matrix (ECM) material, for example, small intestine submucosa (SIS) of porcine, bovine and the like. This ECM material is described and claimed in the patents of Purdue University and Cook Biotech, which are all incorporated by reference herein. This SIS and other ECM material is commercially available from Cook Biotech, West Lafayette, IN.

The following list of figure elements is provided only for informational purposes and is not intended to limit the claims in any manner.

ELEMENT LIST

10. prosthesis
11. biocompatible tubular graft
12. lumen of 11
13. expandable stent
14. fenestration of 11
15. variable size of 14
16. expandable frame
17. folded portion of 11
18. second tubular graft
19. second lumen of 18
20. covered portion of 17
21. radiopaque marker
22. radiopaque material of 21
23. coil loop frame (round cross-sectional shape)
24. oval-shaped coil loop frame (oval cs shape)
25. O-ring
26. silicone rubber and any other elastic polymer material of 25

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- 27. gold, platinum, and any other high density material of 22
- 28. struts
- 39. first strut length
- 30. second strut length
- 31. first strut spacing
- 32. second strut spacing
- 33. side branch graft
- 34. internal to lumen 12
- 35. external to lumen 12
- 36. elongated tubular member
- 37. graft material
- 38. sutures
- 39. diameter (relaxed)
- 40. diameter (stretched)
- 41. solid wire frame (16)
- 42. branch stent

Claims

1. A prosthesis comprising a biocompatible tubular graft having a lumen extending at least longitudinally therein and an expandable stent engageable with said graft, wherein said stent is capable of maintaining at least a portion of said lumen of said graft patent;

characterized in that said graft further includes a fenestration therein, said fenestration having a variable size and communicating with said lumen, and in that said prosthesis further comprises an expandable frame disposed at least partially about said fenestration and at least partially controlling the size of said fenestration.

2. The prosthesis of claim 1, characterized in that said graft includes a folded portion at least partially adjacent said fenestration and greater in size than said fenestration.

3. The prosthesis of claim 1, characterized in that said prosthesis further comprises a second tubular graft having a second lumen and disposed on said first graft, said second graft including said fenestration.

4. The prosthesis of claim 2, characterized in that said folded portion at least partially covers said expandable frame and in that said folded portion is disposed over said expandable frame and includes a covered portion to allow said expandable frame to vary the size of said fenestration.

5. The prosthesis of claim 1, characterized in that said variable size preferably ranges from 1 to 15 millimeters, more preferably from 2 to 10 millimeters, and even more preferably from 2 to 5 millimeters, and in that said expandable frame ranges in size less than the size of said fenestration.

6. The prosthesis of claim 1, characterized in that said prosthesis further comprises at least one radiopaque marker disposed about said fenestration and including a radiopaque material including, but not limited to, at least one of gold, platinum and any other high density material.

7. The prosthesis of claim 1, characterized in that said expandable frame comprises at least one of a coil loop frame and an oval-shaped coil loop frame.

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8. The prosthesis of claim 1, characterized in that said expandable frame comprises an O ring, including at least one of silicone rubber and any other elastic polymer material.

9. The prosthesis of claim 1, characterized in that said expandable stent includes struts having at least two different lengths and wherein said struts have variable spacing therebetween.

10. The prosthesis of claim 1, characterized in that said fenestration includes a side branch graft extending therefrom either internal or external to said lumen.

11. A prosthesis comprising an elongated tubular member including at least one of a graft and a stent having a lumen extending at least longitudinally therein; characterized in that said tubular member includes a fenestration therein, said fenestration having a variable size and communicating with said lumen; and in that said prosthesis further comprises an expandable frame disposed at least partially about said fenestration and at least partially controlling the size of said fenestration.

12. The prosthesis of claim 11, characterized in that said graft includes a folded portion at least partially adjacent said fenestration and greater in size than said fenestration.

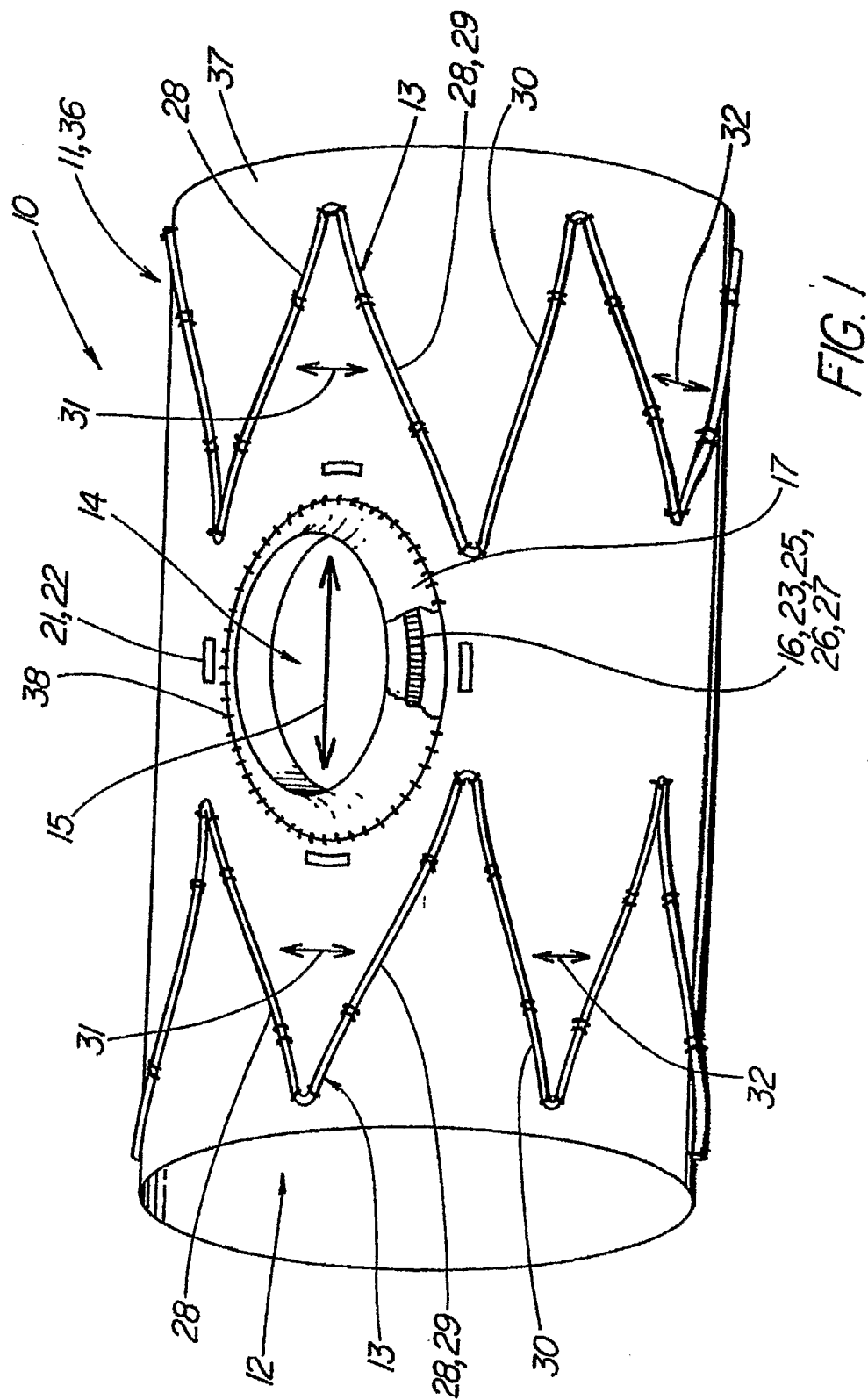
13. The prosthesis of claim 11, characterized in that said prosthesis further comprises a second tubular graft having a second lumen and disposed on said first graft, said second graft including said fenestration.

14. The prosthesis of claim 12, characterized in that said folded portion at least partially covers said expandable frame and in that said folded portion is disposed over said expandable frame and includes a covered portion to allow said expandable frame to vary said size of said fenestration.

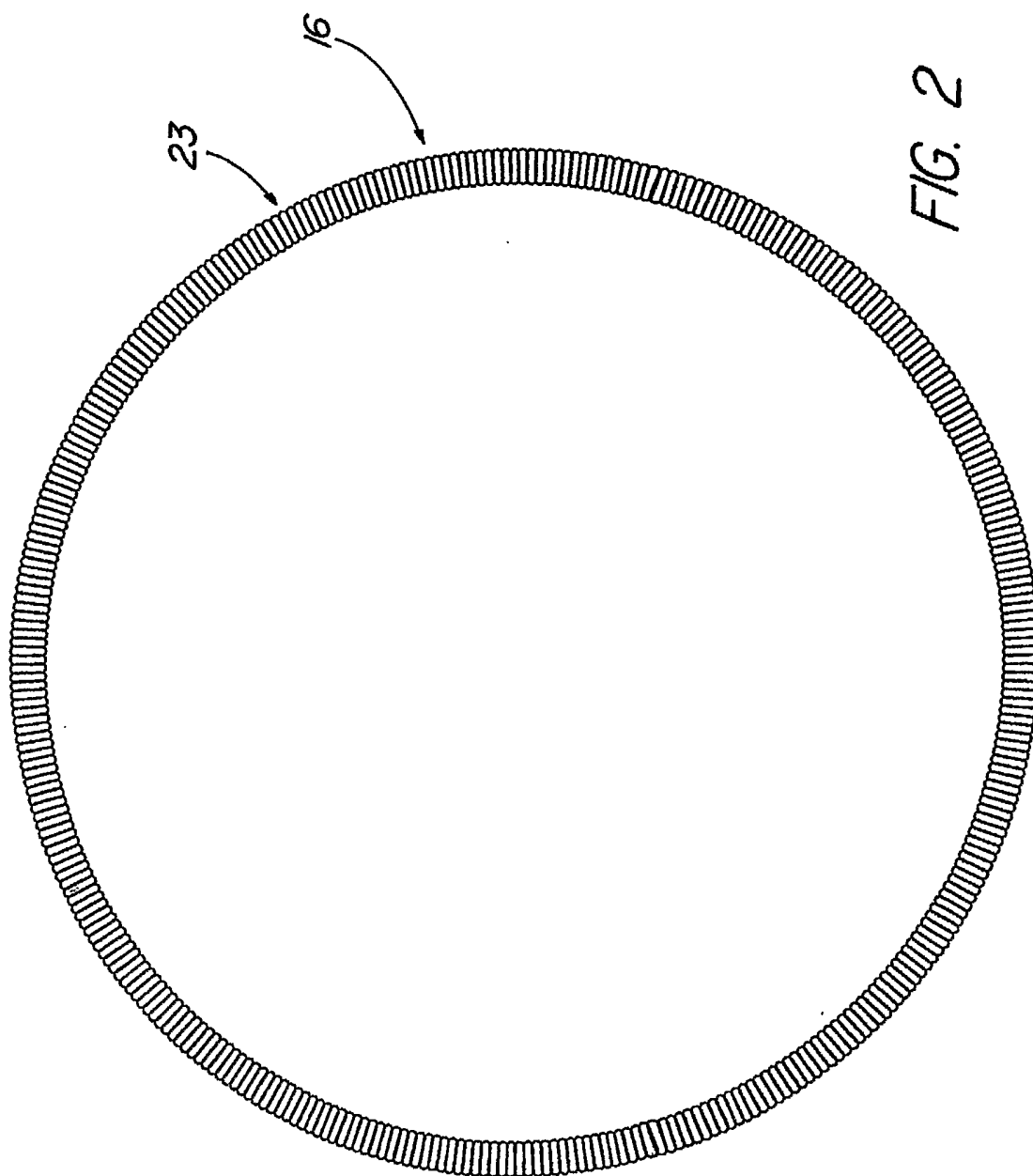
15. The prosthesis of claim 11, characterized in that said variable size preferably ranges from 1 to 15 millimeters, more preferably from 2 to 10 millimeters, and even more preferably from 2 to 5 millimeters and wherein said expandable frame ranges in size less than the size of said fenestration.

16. The prosthesis of claim 11, characterized in that said expandable frame comprises at least one of a coil loop frame and an oval-shaped coil loop frame.

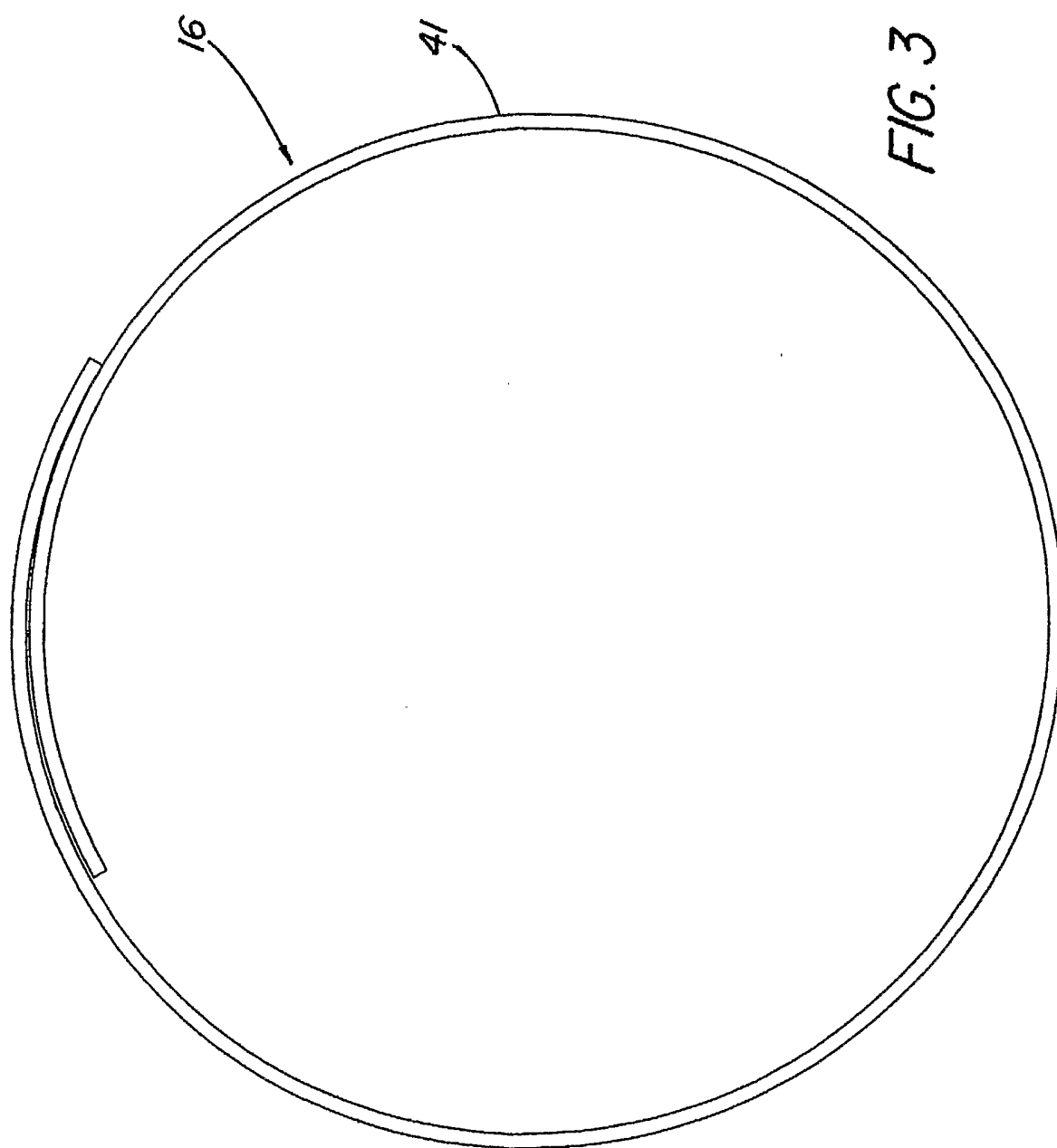
17. The prosthesis of claim 11, characterized in that said prosthesis further comprises at least one radiopaque marker disposed about said fenestration and including a radiopaque material including, but not limited to, at least one of gold, platinum, and any other high density material.
18. The prosthesis of claim 11, characterized in that said expandable frame comprises an O ring including at least one of silicone rubber and any other elastic polymer material.
19. The prosthesis of claim 11, characterized in that said expandable stent includes struts having at least two different lengths and in that said struts has variable spacing therebetween.
20. The prosthesis of claim 16, characterized in that said fenestration includes a side branch graft extending therefrom either internal or external to said lumen.



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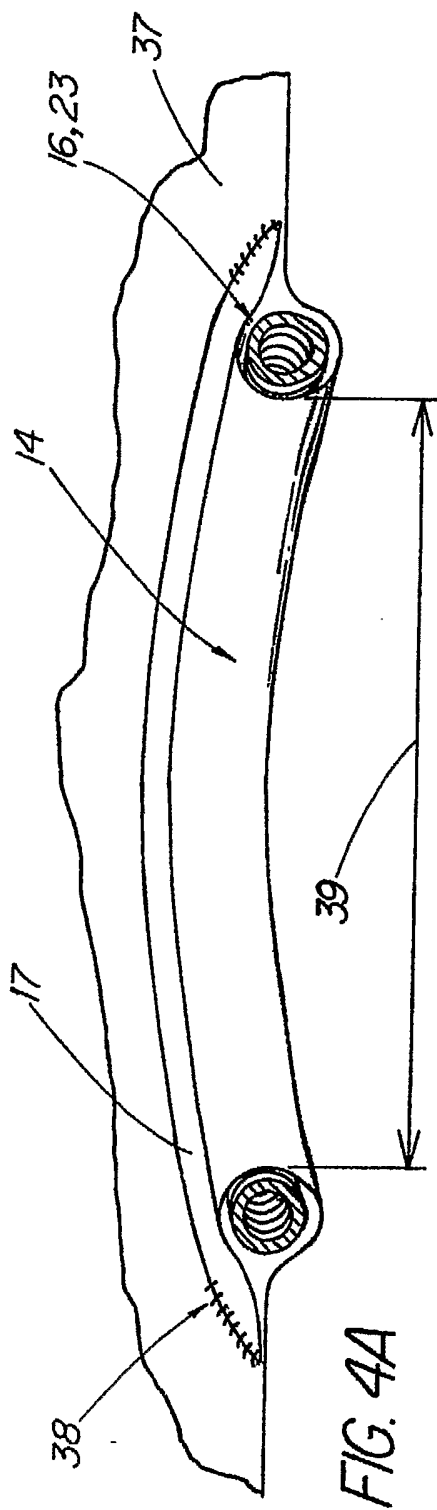


FIG. 4A

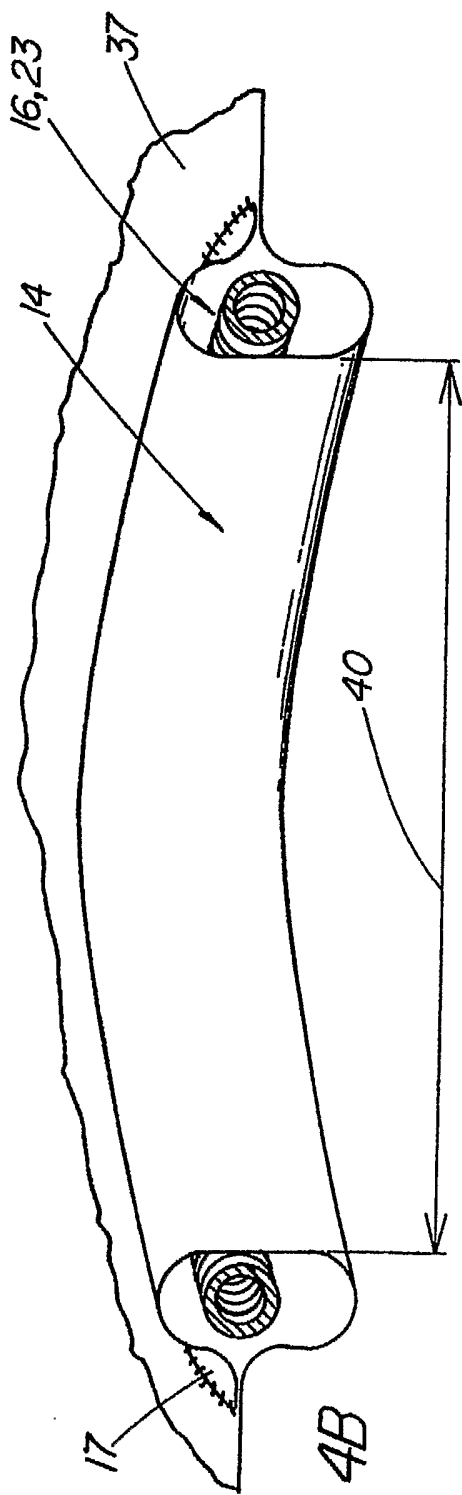
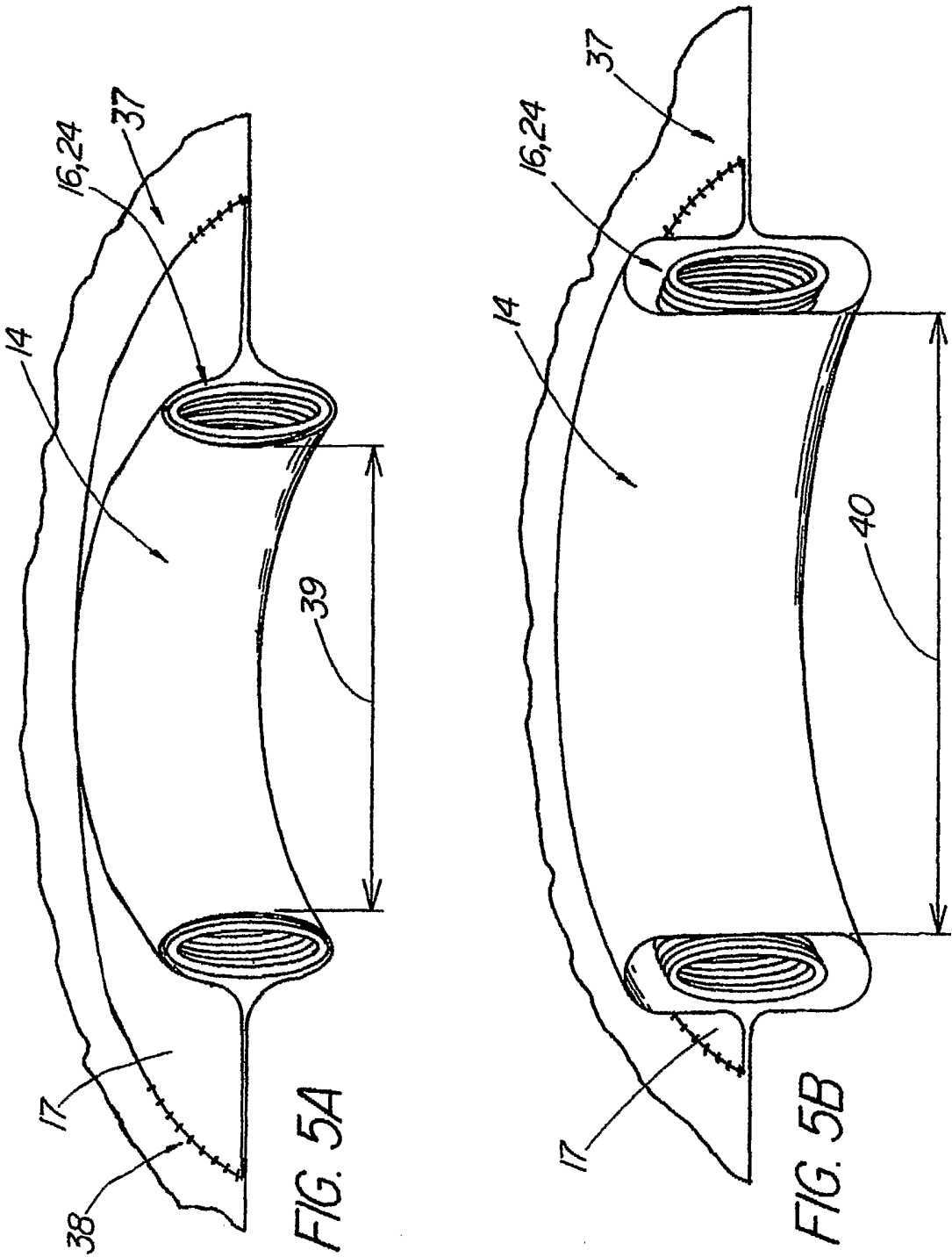


FIG. 4B



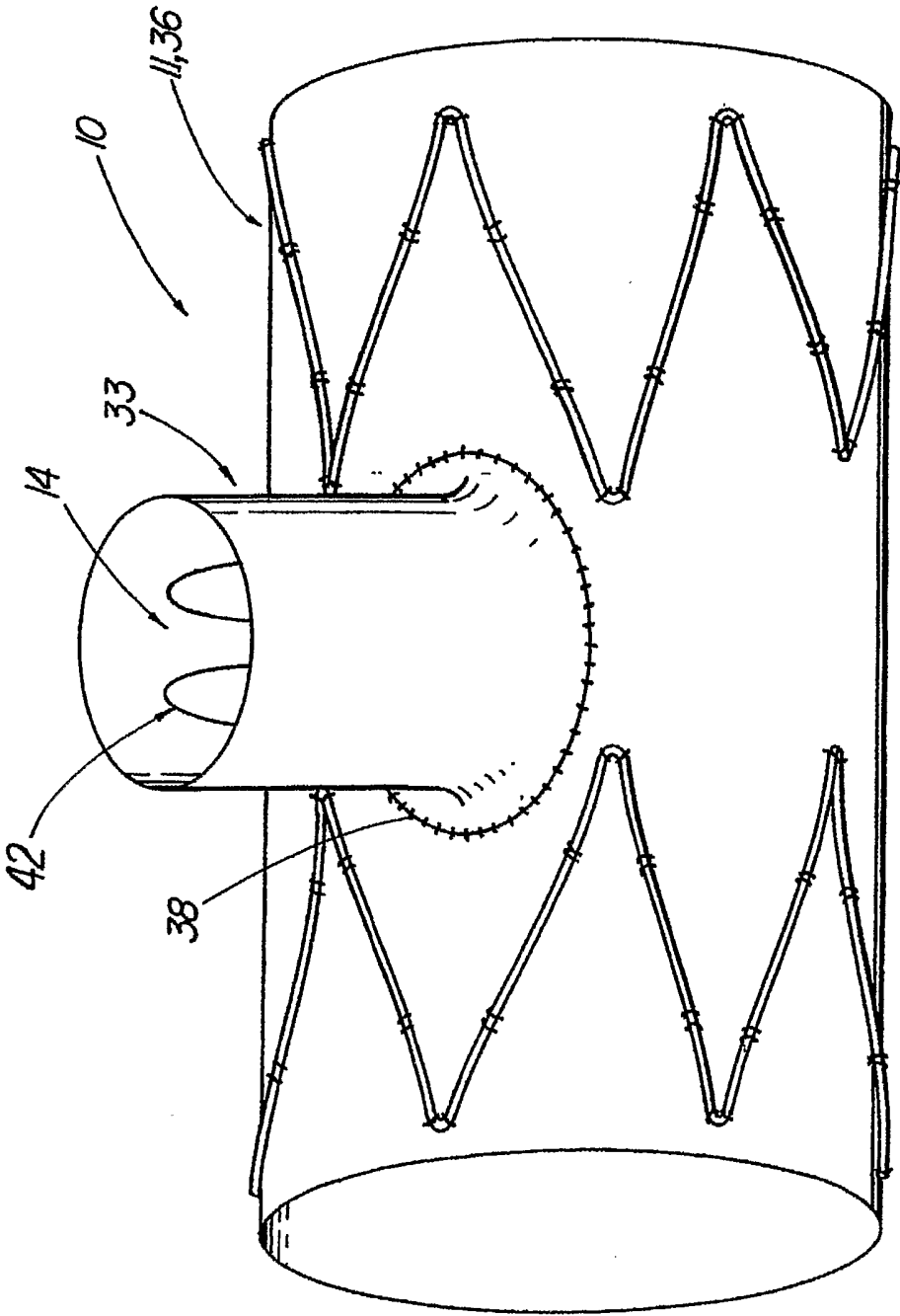


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/033570

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/06

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 395 018 B1 (CASTANEDA WILFRIDO R) 28 May 2002 (2002-05-28) the whole document	1,2,4-7, 11,12, 14-17
X	US 6 030 414 A (TAHERI SYDE A) 29 February 2000 (2000-02-29)	1,3,8, 10,11, 13,18,20
Y	abstract column 3, line 51 - line 54	9,19
Y	US 6 325 826 B1 (VARDI GIL M ET AL) 4 December 2001 (2001-12-04)	9,19
A	the whole document	1-8, 10-18,20

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *P* document published prior to the international filing date but later than the priority date claimed

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- *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

24 January 2005

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01/02/2005

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/033570

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 5 984 955 A (WISSELINK WILLEM) 16 November 1999 (1999-11-16) the whole document -----	1,11
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