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(54) Title: PARAPLEGIA PREVENTION STENT GRAFT

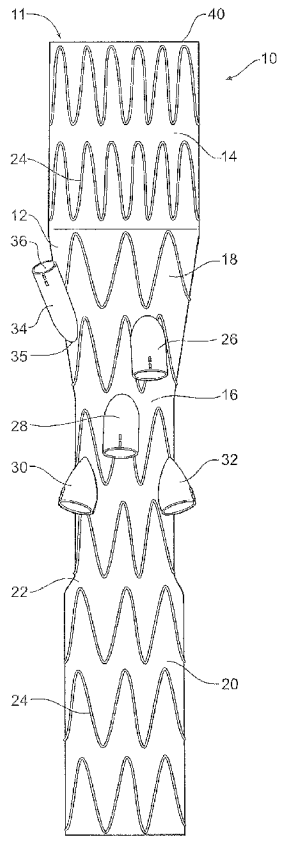

Fig 1

(57) Abstract: A stent graft (10) for deployment into the aorta of a patient has a tubular body (20) with a proximal portion (14) of a selected diameter and a portion (16) of a reduced diameter less than the selected diameter distal of the proximal portion and a tapered portion (18) extending between the proximal portion and the portion of reduced diameter. Low profile side arms (26, 28, 30, 32) are provided in the portion of reduced diameter and/or the tapered portion. The side arms are for connection of an arm extension to an aortic branch vessel. A paraplegia prevention vent tube (34) is provided in fluid communication with the main lumen and open to external of the tubular body in the region defined by the portion of reduced diameter and the tapered portion. The paraplegia prevention vent tube is not intended to be connected to a side branch of the aorta but to provide temporary perfusion to external of the stent graft after deployment of the stent graft into the aorta and intended to be subsequently blocked.

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

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

PARAPLEGIA PREVENTION STENT GRAFT

Description

Technical Field

This invention relates to a medical device and more particularly to an implantable endovascular device.

Background Art

This invention will be discussed in general with respect to aortic aneurysms and the use of an implantable device such as a stent graft to bridge an aneurysm and in particular in the descending aorta but the invention is not so limited and may be used for any region of the human or animal body and any type of implantable device.

A stent graft can be used to bridge an aortic aneurysm but where there are side branch arteries from the aorta it is necessary to have side branches extending from the stent graft to give a blood supply to as many side branch arteries as possible.

There are four main side branch arteries in the descending aorta. These are the celiac artery, the superior mesenteric artery, the right renal artery and the left renal artery. There are also a number of other minor side branch arteries but these are smaller and generally cannot be catheterized to enable placement of a side branch graft. One of these sets of arteries are the intercostal arteries.

After an endovascular operation to place a stent graft into the descending aorta, the human or animal body can in time adapt to lack of blood supply from some arteries which are excluded by the stent graft. For instance blood supply via the intercostal arteries to the spinal cord can be alternatively achieved via other arteries such as for instance the celiac artery, the superior mesenteric artery, lumbar and internal iliac arteries.

There can be a problem, however, of blood supply immediately after an operation, at least in part relating to blood pressure and it is the object of this invention to provide a possible solution or at least provide the physician with a useful alternative.

Throughout this specification the term distal with respect to a portion of the aorta, a deployment device or a prosthesis means the end of the aorta, deployment device or prosthesis further away in the direction of blood flow away from the heart and the term proximal means the portion of the aorta, deployment device or end of the

prosthesis nearer to the heart. When applied to other vessels similar terms such as caudal and cranial should be understood.

Disclosure of The Invention

In one form therefore the invention is said to reside in an implantable device comprising a tubular body of a biocompatible graft material, the tubular body defining a main lumen therethrough, a plurality of low profile side arms in the tubular body, each low profile side arm comprising a respective side arm lumen therethrough and the main lumen being in fluid communication with the respective side arm lumens, the side arms being each for connection of an arm extension to a branch vessel, a paraplegia prevention vent tube in fluid communication with the main lumen and open to external of the tubular body, wherein the further paraplegia prevention vent tube is not intended to be connected to a side branch vessel but to provide perfusion to external of the implantable device after deployment of the implantable device into a vessel of the human or animal body and intended to be subsequently blocked.

In a preferred embodiment the implantable device is intended for deployment into the descending aorta and the plurality low profile side arms comprise four low profile side arms being for the celiac artery, superior mesenteric artery, the right renal artery and the left renal artery and the paraplegia prevention vent tube is intended for temporary perfusion of the intercostal arteries.

In an alternative form the invention comprises a stent graft for deployment into the aorta of a patient, the stent graft comprising a tubular body of a biocompatible graft material, the tubular body defining a main lumen therethrough, the tubular body comprising a proximal portion of a selected diameter and a portion of reduced diameter less than the selected diameter distal of the proximal portion and a tapered portion extending between the proximal portion and the portion of reduced diameter, a plurality of low profile side arms in the portion of reduced diameter or the tapered portion, each low profile side arm comprising a respective side arm lumen therethrough and the main lumen being in fluid communication with the respective side arm lumens, the side arms being each for connection of an arm extension to an aortic branch vessel, a paraplegia prevention vent tube in fluid communication with the main lumen and open to external of the tubular body in the region defined by the portion of reduced diameter or the tapered portion, wherein the further paraplegia

prevention vent tube is not intended to be connected to a side branch of the aorta but to provide temporary perfusion to external of the stent graft after deployment of the stent graft into the aorta and intended to be subsequently blocked.

Preferably the paraplegia prevention vent tube has an open external end in a proximal direction from where it is mounted to the stent graft which gives an open internal end opening distally to allow for subsequent endoluminal access for instance from an femoral access point for the subsequent blocking.

The paraplegia prevention vent tube can be positioned on the tubular body proximally or distally of the plurality of low profile side arms.

Preferably the paraplegia prevention vent tube comprises a diameter of approximately 6 mm and a length of from 10 to 32 mm.

Preferably the plurality low profile side arms in the portion of reduced diameter or the tapered portion comprise four low profile side arms being for the celiac artery, superior mesenteric artery, the right renal artery and the left renal artery.

The tubular body can comprise a distal portion with a diameter less than the selected diameter and greater than that of the portion of reduced diameter distal of the proximal portion and a distal tapered portion extending between the distal portion and the portion of reduced diameter.

In one embodiment the proximal portion a comprises a diameter of approximately 34 mm, the distal portion comprising a diameter of approximately 24 mm and the portion of reduced diameter can comprise a diameter of approximately 20 mm.

Preferably the paraplegia prevention vent tube comprises radiopaque markers at its proximal and distal ends to assist with later location by radiographic techniques. For instance there may be to markers in line at the proximal end and three markers in line at the distal end.

In an alternative form the invention comprises an implantable device comprising a tubular body of a biocompatible graft material, the tubular body defining a main lumen therethrough and a paraplegia prevention vent tube in fluid communication with the main lumen and open to external of the tubular body, wherein the paraplegia prevention vent tube is not intended to be connected to a side branch vessel but to provide temporary perfusion to external of the implantable device after deployment of

the implantable device into a vessel of the human or animal body and intended to be subsequently blocked.

Hence it will be seen that by the various forms of the invention there is provided an arrangement by which, at the time of placement of the implantable device such as a stent graft and side branches, an annular space is defined outside the stent graft by there being the portion of reduced diameter of the stent graft and in the region of the intercostal arteries and these are not closed off to blood supply because blood can still exit the stent graft through the paraplegia prevention vent tube into that annular space. In particular the paraplegia prevention vent tube enables temporary perfusion to that portion of the descending aorta which is occluded by placement of the implantable device to enable temporary continued perfusion of any of the intercostal arteries which may extend from the descending aorta in that region.

This is counter intuitive to normal endovascular device placement because one of the aims of endovascular bridging of an aneurysm is to avoid endoleaks into the excluded portion of the aorta.

Immediately after an operation to deploy an endovascular stent graft, blood pressure in a patient can be low and there may be insufficient blood supplied through the side branch stent grafts to the branch arteries. The continued perfusion of the excluded annular space outside the stent graft in the region of the intercostal arteries enables a continued supply of blood to the vertebral region which can prevent paraplegia. Subsequently, perhaps a week later when blood pressure has risen generally in the patient, the vent tube can be closed off by placement of a vascular plug by endovascular techniques. Continued supply of blood to the vertebral region can then be obtained by blood supply from the placed side branches.

Brief Description of the Drawings

This then generally describes the invention but to assist with understanding reference will now be made to the accompanying drawings.

In the drawings:

Figure 1 shows a schematic view of a stent graft according to one embodiment of the invention;

Figure 2A shows a cross sectional view of the paraplegia prevention vent tube of Figure 1;

Figure 2B shows a cross sectional view of the paraplegia prevention vent tube of Figure 1 closed off with a plug;

Figure 2C shows a cross sectional view of an alternative embodiment of a paraplegia prevention vent tube;

Figure 3 shows a schematic view of a stent graft according to an alternative embodiment of the invention;

Figure 4A shows a cross sectional view of the paraplegia prevention vent tube of Figure 3; and

Figure 4B shows a cross sectional view of the paraplegia prevention vent tube of Figure 3 closed off with a plug.

DESCRIPTION OF PREFERRED EMBODIMENTS

Now looking at the Figure 1, 2A and 2B of the drawings in detail, a stent graft 10 according to one embodiment of the invention comprises a tubular body 12 of a biocompatible graft material. The tubular body has a main lumen 11 therethrough. The tubular body comprises a proximal portion 14 of a selected diameter and a portion of reduced diameter 16 less than the selected diameter distal of the proximal portion and a proximal tapered portion 18 extending between the proximal portion 14 and the portion of reduced diameter 16. The tubular body 12 also comprises a distal portion 20 which has a diameter less than the selected diameter and greater than that of the portion of reduced diameter 16 distal of the proximal portion and a distal tapered portion 22 extending between the distal portion 20 and the portion of reduced diameter 16. In this embodiment the proximal portion has a diameter of approximately 34 mm, the distal portion has a diameter of approximately 24 mm and the portion of reduced diameter has a diameter of approximately 20 mm.

Each of the proximal portion, the distal portion and the portion of reduced diameter are supported by stents 24 affixed to the graft material by stitching, adhesive or other method of affixation. The stents may be inside or outside of the tubular body. Each of the stents is preferably a self expanding Gianturco Z-stent formed from Nitinol or stainless steel wire.

There are four low profile side arms 26, 28, 30 and 32 extending from fenestrations in the portion of reduced diameter 16 or the proximal tapered portion 18. Each low profile side arm comprises a respective side arm lumen therethrough and

the main lumen is in fluid communication with the respective side arm lumens. Each of the four low profile side arms 26, 28, 30 and 32 are supported by stent structures and can have reinforcing rings at their internal and external ends.

The four low profile side arms 26, 28, 30 and 32 are intended in use to receive extension side arms for entry into the celiac artery, the superior mesenteric artery, the right renal artery and the left renal artery respectively.

US Patent Application Publication Number 20070219621 entitled "Side Branch Stent Graft Construction" discloses various forms of low profile side arms and the teachings there are incorporated herein in their entirety.

The tubular body 12 also includes a paraplegia prevention vent tube 34 extending from a fenestration 35 in the proximal tapered portion 18 and in fluid communication with the main lumen 11. The paraplegia prevention vent tube 34 is open to external of the tubular body at 36 in the region defined by the portion of reduced diameter and the tapered portion. The paraplegia prevention vent tube 34 is not intended to be connected to a side branch artery of the aorta but is used to provide temporary perfusion to external of the stent graft after deployment of the stent graft into the aorta and intended to be subsequently blocked.

The paraplegia prevention vent tube 34 can be formed from a biocompatible graft material and have a diameter of 6 mm and a length of from 16 to 32 mm.

Figure 2A shows a cross sectional view of a paraplegia prevention vent tube 34. The vent tube 34 is connected to the wall 38 of the tubular body 12 at a fenestration 35. The tube 34 is un-stented along its length and has an open proximal end 36.

The paraplegia prevention vent tube 34 has radiopaque markers 37 at its proximal end to assist with later location by radiographic techniques.

Figure 2B shows a cross sectional view of a paraplegia prevention vent tube closed off with a plug. The plug 38 is deployed endovascularly and released into the vent tube 34. The plug may for instance be an Amplatzer Vascular Plug (AGA Medical Corporation, MN, USA). The plug may have suitable over sizing to ensure it seals in the vent tube.

Figure 2C shows a cross sectional view of an alternative embodiment of a paraplegia prevention vent tube. In this embodiment the vent tube 40 includes a low

profile side arm 42 which has a portion 42a external of the wall 38 of the tubular body 12 at a fenestration 35 and a portion 42b internal of the wall 38. Connected to the low profile side arm 42 is a tubular portion 44 with an open proximal end 46. The tubular portion 44 can be stented or unstented along its length.

Now looking at the Figure 3, 4A and 4B drawings corresponding reference numerals are used for items corresponding to those in Figure 1. The stent graft 50 according to an alternative embodiment of the invention comprises a tubular body 12 of a biocompatible graft material. The tubular body has a main lumen 11 therethrough. The tubular body comprises a proximal portion 14 of a selected diameter and a portion of reduced diameter 16 less than the selected diameter distal of the proximal portion and a proximal tapered portion 18 extending between the proximal portion 14 and the portion of reduced diameter 16. The tubular body 12 also comprises a distal portion 20 which has a diameter less than the selected diameter and greater than that of the portion of reduced diameter 16 distal of the proximal portion and a distal tapered portion 22 extending between the distal portion 20 and the portion of reduced diameter 16. In this embodiment the proximal portion has a diameter of approximately 34 mm, the distal portion has a diameter of approximately 24 mm and the portion of reduced diameter has a diameter of approximately 20 mm.

Each of the proximal portion, the distal portion and the portion of reduced diameter are supported by stents 24 affixed to the graft material by stitching, adhesive or other method of affixation. The stents may be inside or outside of the tubular body. Each of the stents is preferably a self expanding Gianturco Z-stent formed from Nitinol or stainless steel wire.

There are four low profile side arms 26, 28, 30 and 32 extending from fenestrations in the portion of reduced diameter 16 or the proximal tapered portion 18. Each low profile side arm comprises a respective side arm lumen therethrough and the main lumen is in fluid communication with the respective side arm lumens. Each of the four low profile side arms 26, 28, 30 and 32 are supported by stent structures and can have reinforcing rings at their internal and external ends.

The four low profile side arms 26, 28, 30 and 32 are intended in use to receive extension side arms for entry into the celiac artery, the superior mesenteric artery, the right renal artery and the left renal artery respectively.

The tubular body 12 also includes a paraplegia prevention vent tube 52 extending from a fenestration 54 in the portion of reduced diameter 16 and in fluid communication with the main lumen 11. The paraplegia prevention vent tube 52 is open to external of the tubular body at 56 in the region defined by the portion of reduced diameter and the tapered portion. The paraplegia prevention vent tube 52 is not intended to be connected to a side branch artery of the aorta but is used to provide temporary perfusion to external of the stent graft after deployment of the stent graft into the aorta and intended to be subsequently blocked.

The paraplegia prevention vent tube 52 can be formed from a biocompatible graft material and have a diameter of 6 mm and a length of from 16 to 32 mm. The paraplegia prevention vent tube 52 can comprise supporting stents 58 and reinforcing rings 60a and 60b at the internal and external ends respectively.

The paraplegia prevention vent tube comprises radiopaque markers at its proximal and distal ends to assist with later location by radiographic techniques. In this embodiment there are two markers 64 in line at the proximal end and three markers 66 in line on the outside of the tubular body 12 at the distal end of the paraplegia prevention vent.

In a preferred embodiment of the invention the stent graft may have dimensions as follows:

Overall length	236 mm
Length of proximal portion	48 mm
Length of tapered portion	43 mm
Length of reduced diameter portion	71 mm
Length of distal portion	68 mm
Diameter of proximal portion	34 mm
Diameter of distal portion	24 mm
Diameter of portion of reduced diameter	20 mm

In a preferred embodiment of the invention taking the circumference of the stent graft as a clock face with the anterior point a 12 o'clock the side arms and paraplegia prevention vent tube may be placed as follows:

celiac artery	Distance from proximal end 89 mm, 8 mm diameter, length 18 mm, position 1 o'clock

superior mesenteric artery	Distance from proximal end 110 mm, 8 mm diameter, length 21 mm, position 12 o'clock
right renal artery	Distance from proximal end 128 mm, 6 mm diameter, length 18 mm, position 10:45 o'clock
left renal artery	Distance from proximal end 128 mm, 6 mm diameter, length 18 mm, position 2:45 o'clock
paraplegia prevention vent tube	Distance from proximal end 130 mm, 6 mm diameter, length 32 mm, position 1:30 o'clock

Figure 4A shows a cross sectional view of a paraplegia prevention vent tube 52. The vent tube 52 is connected by stitching 62 to the wall 38 of the tubular body 12.

Figure 4B shows a cross sectional view of a paraplegia prevention vent tube closed off with a plug 38. The plug 38 is deployed endovascularly and released into the vent tube 52. The plug may for instance be an Amplatzer Vascular Plug (AGA Medical Corporation, MN, USA). The plug may have suitable over sizing to ensure it seals in the vent tube.

Throughout this specification various indications have been given as to the scope of this invention but the invention is not limited to any one of these but may reside in two or more of these combined together. The examples are given for illustration only and not for limitation.

Throughout this specification and the claims that follow unless the context requires otherwise, the words 'comprise' and 'include' and variations such as 'comprising' and 'including' will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

Claims

1. A stent graft for deployment into the aorta of a patient, the stent graft comprising a tubular body of a biocompatible graft material, the tubular body defining a main lumen therethrough, the tubular body comprising a proximal portion of a selected diameter and a portion of reduced diameter less than the selected diameter distal of the proximal portion and a tapered portion extending between the proximal portion and the portion of reduced diameter, a plurality of low profile side arms in the portion of reduced diameter or the tapered portion, each low profile side arm comprising a respective side arm lumen therethrough and the main lumen being in fluid communication with the respective side arm lumens, the side arms being each for connection of an arm extension to an aortic branch vessel, a paraplegia prevention vent tube in fluid communication with the main lumen and open to external of the tubular body in the region defined by the portion of reduced diameter and the tapered portion, wherein the further paraplegia prevention vent tube is not intended to be connected to a side branch of the aorta but to provide temporary perfusion to external of the stent graft after deployment of the stent graft into the aorta and intended to be subsequently blocked.

2. A stent graft as in Claim 1 wherein the paraplegia prevention vent tube is open externally in a proximal direction.

3. A stent graft as in Claim 1 wherein the paraplegia prevention vent tube is positioned on the tubular body proximally of the plurality of low profile side arms.

4. A stent graft as in Claim 1 wherein the paraplegia prevention vent tube is positioned on the tubular body distally of the plurality of low profile side arms.

5. A stent graft as in Claim 1 wherein the paraplegia prevention vent tube comprises a diameter of approximately 6 mm and a length of from 10 to 32 mm.

6. A stent graft as in Claim 1 wherein the plurality low profile side arms in the portion of reduced diameter or the tapered portions comprise four low profile side arms being for the celiac artery, superior mesenteric artery, the right renal artery and the left renal artery.

7. A stent graft as in Claim 1 wherein the paraplegia prevention vent tube is unstented.

8. A stent graft as in Claim 1 wherein the tubular body comprises a distal portion

comprising a diameter less than the selected diameter and greater than that of the portion of reduced diameter distal of the proximal portion and a distal tapered portion extending between the distal portion and the portion of reduced diameter.

9. A stent graft as in Claim 1 wherein the proximal portion a comprises a diameter of approximately 34 mm, the distal portion comprising a diameter of 24 mm and the portion of reduced diameter comprises a diameter of 20 mm.

10. An implantable device comprising a tubular body of a biocompatible graft material, the tubular body defining a main lumen therethrough, a plurality of low profile side arms in the tubular body, each low profile side arm comprising a respective side arm lumen therethrough and the main lumen being in fluid communication with the respective side arm lumens, the side arms being each for connection of an arm extension to a branch vessel, a paraplegia prevention vent tube in fluid communication with the main lumen and open to external of the tubular body, wherein the paraplegia prevention vent tube is not intended to be connected to a side branch vessel but to provide temporary perfusion to external of the implantable device after deployment of the implantable device into a vessel of the human or animal body and intended to be subsequently blocked.

11. An implantable device as in Claim 10 wherein the paraplegia prevention vent tube is open externally in a proximal direction and internally in a distal direction.

12. An implantable device as in Claim 10 wherein the paraplegia prevention vent tube is positioned on the tubular body proximally of the plurality of low profile side arms.

13. An implantable device as in Claim 10 wherein the paraplegia prevention vent tube is positioned on the tubular body distally of the plurality of low profile side arms.

14. An implantable device as in Claim 10 wherein the paraplegia prevention vent tube comprises a diameter of approximately 6 mm and a length of from 10 to 32 mm.

15. An implantable device as in Claim 10 wherein the plurality low profile side arms comprise four low profile side arms being for the celiac artery, superior mesenteric artery, the right renal artery and the left renal artery and the paraplegia prevention vent tube is intended for the temporary perfusion of the intercostal arteries.

16. An implantable device comprising a tubular body of a biocompatible graft material, the tubular body defining a main lumen therethrough and a paraplegia

prevention vent tube in fluid communication with the main lumen and open to external of the tubular body, the paraplegia prevention vent tube being unstented, wherein the paraplegia prevention vent tube is not intended to be connected to a side branch vessel but to provide temporary perfusion to external of the implantable device after deployment of the implantable device into a vessel of the human or animal body and intended to be subsequently blocked.

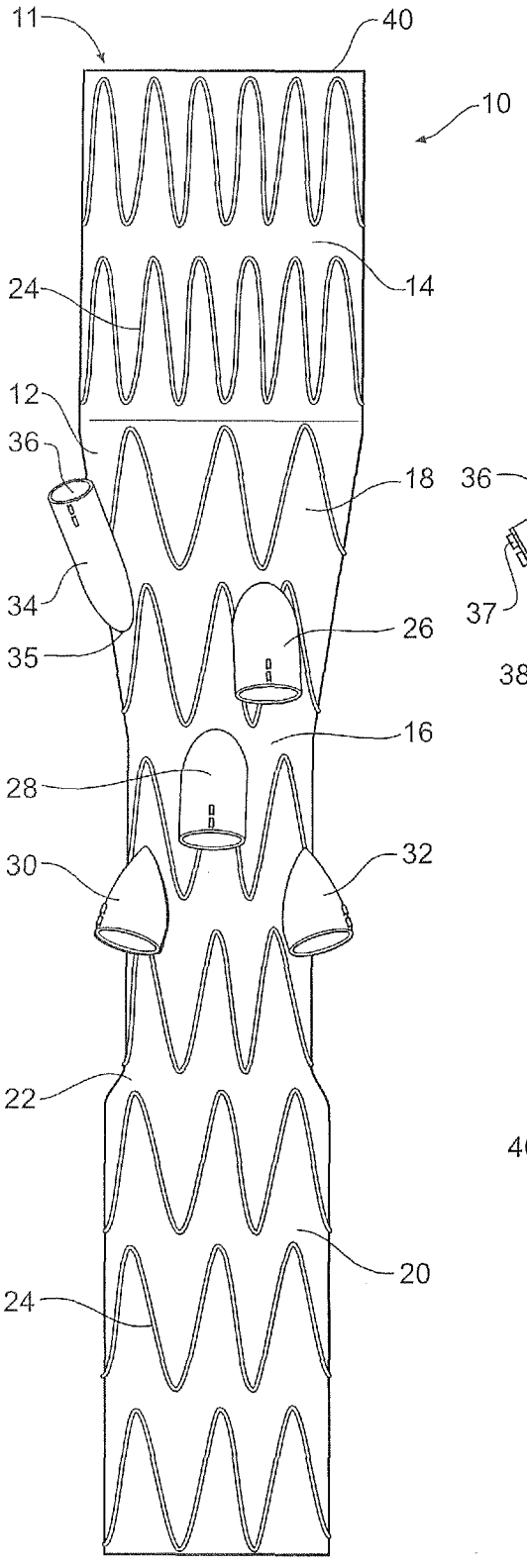

Fig 1

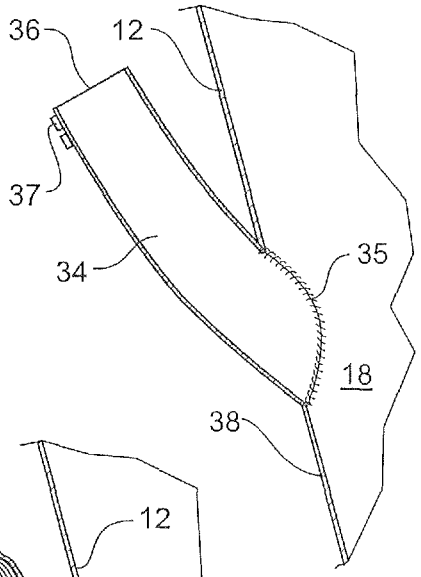

Fig 2A

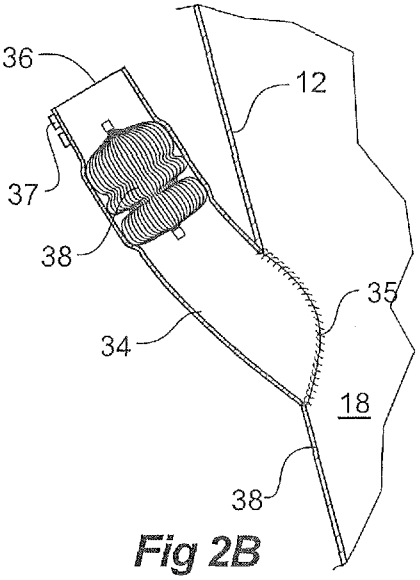

Fig 2B

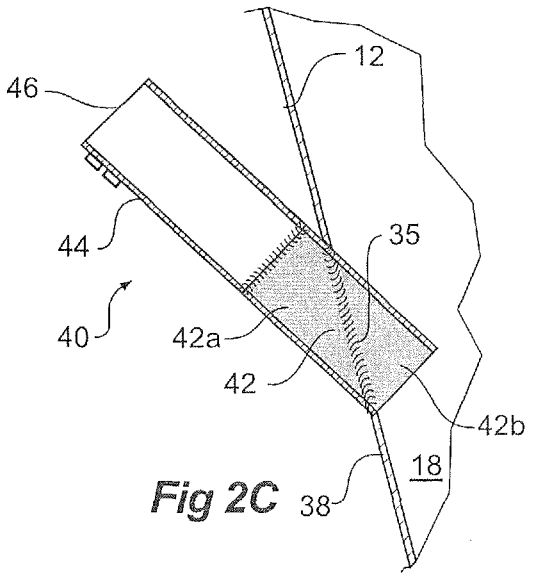

Fig 2C

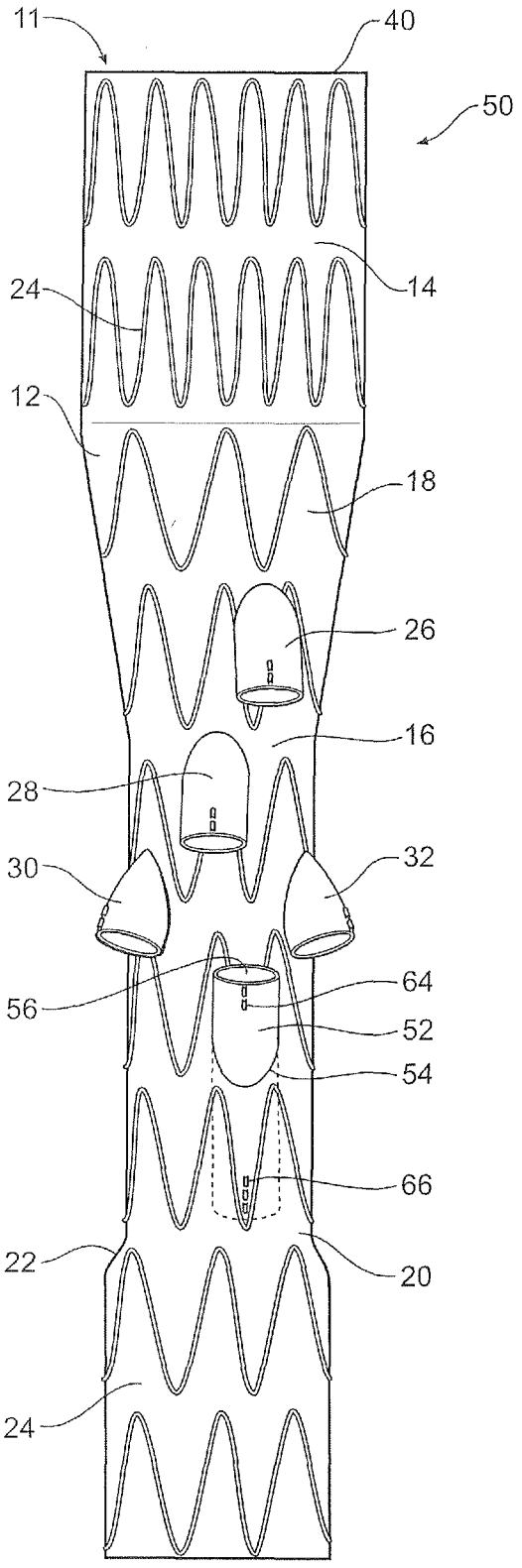

Fig 3

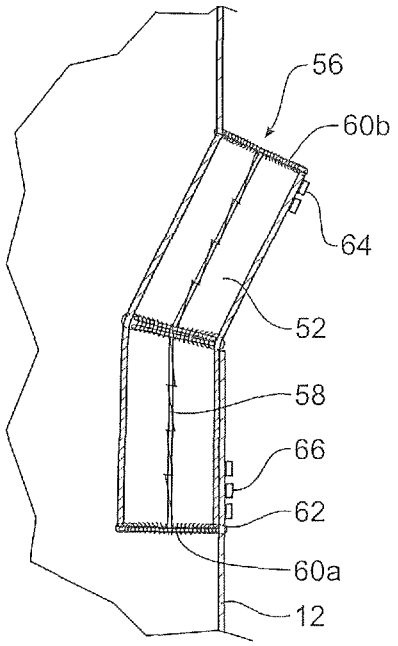

Fig 4A

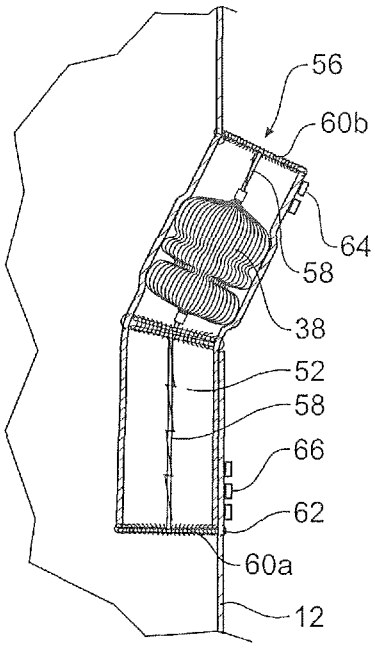

Fig 4B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/052446

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/06
ADD. A61B17/12

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)
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 Y	WO 2008/007397 A1 (IANNELLI GABRIELE [IT]) 17 January 2008 (2008-01-17) page 3, line 16 - page 5, line 17 page 7, lines 3-6 figures 1-5	10,11, 14-16 1-9,12, 13
X	US 2001/012962 A1 (SCHMITT PETER J [US] ET AL) 9 August 2001 (2001-08-09) paragraphs [0034] - [0044]; figures 3,4,7	10,14,16
Y	US 2005/102018 A1 (CARPENTER JUDITH T [US] ET AL) 12 May 2005 (2005-05-12) paragraphs [0030] - [0057]; figures 1-8	1-9,12, 13
Y	US 2006/184228 A1 (KHOURY MICHAEL D [US]) 17 August 2006 (2006-08-17) paragraphs [0015] - [0022]; figures 1-4	1-9,12, 13

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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"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	Date of mailing of the international search report
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Name and mailing address of the ISA/	Authorized officer
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