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(54) Title: THORACIC INTRODUCER

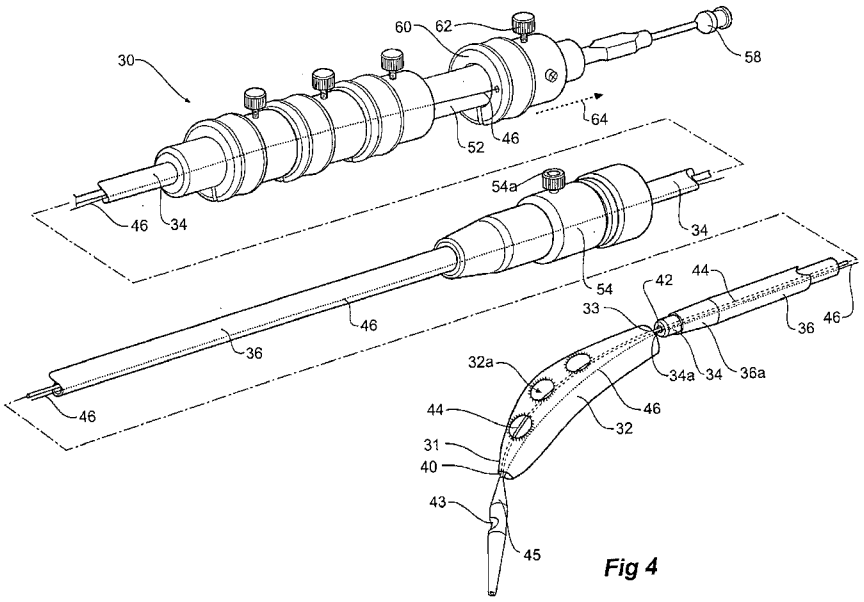

Fig 4

(57) Abstract: A stent graft delivery device (30) has a pull wire arrangement with a pull wire (46) fastened to the distal end of a nose cone dilator (45) and extending to a wire pull mechanism (60) for the pull wire associated with a handle (52) of the stent graft delivery device. The pull wire can be pulled by the wire pull mechanism to induce a curve in a guide wire catheter (44) distally of the nose cone dilator such that the proximal end of the delivery device more closely fits the shape of a portion of the vasculature of a patient into which the device is deployed.

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THORACIC INTRODUCER

Description

Technical Field

This invention relates to a medical device and more particularly to a medical device for the introduction of vascular devices into the body of a human or animal.

Background Art

In recent years endovascular implantable devices have been developed for treatment of aortic aneurysms. These devices are delivered to the treatment site through the vascular system of the patient rather than by open surgery. The devices include a tubular shape of graft material such as woven Dacron, polyester polytetrafluoroethylene or the like to which is secured a tubular or cylindrical framework or scaffolding of one or more stents. The devices are initially reduced to a small diameter, placed into the leading or proximal end of a catheter delivery system whereafter the delivery system is inserted into the vascular system of the patient such as through a femoral incision. The leading end of the delivery system is manoeuvred to the treatment site over a previously positioned guide wire.

Through manipulation of a control system that extends to the proximal end of the catheter from the distal end of the system outside the patient, the implantable device is deployed by holding the device at its location and withdrawing a surrounding sheath. The stent graft or implantable device can then be released and self expand or be expanded through the use of a balloon which is introduced with the stent graft introducible device. The stent graft becomes anchored into position to healthy wall tissue in the aorta (such as by barbs) whereafter the delivery system is removed leaving the device in position for reversing an aneurysm in the aorta. All blood flow is channelled through the stent graft so that no blood flow enters the aneurysm thereafter. As a result not only does the aneurysm no longer continue to grow and possibly rupture but the aneurysm actually begins to shrink and commonly disappears entirely.

For treatment of thoracic aortic aneurysms in particular it is necessary to introduce the implantable device high up in the aorta and in a region of the aorta which

is curved and where there can be strong blood flow.

There has also been proposed the use of side arms in the thoracic arch region of the aorta to span between the implantable device and the great branch vessels of the thoracic arch to ensure flow to these vessels. If an implantable device which is essentially a tube is deployed in the thoracic arch without side branches then loss of blood flow to these great branch vessels could cause serious consequences to a patient.

The great vessels are essentially on the outer side of the curve of the thoracic arch. The delivery device for the implantable device, being formed from a resilient material, when extended up into the thoracic arch will essentially form the largest diameter curve it can and hence it will lie in the aorta on the side of the greatest arch. The delivery device will therefore lie close to the great vessels and there will be little or no working space to catheterise the branch vessels from the implantable device or to catheterise fenestrations in the implantable device from the branch vessels. Slight misalignment between the fenestrations in the implantable device and the branch vessels could cause significant problems in catheterization.

It is desirable therefore that a deployment device or deployment system is provided in which the proximal end of the device, the end in the thoracic arch, takes up a lesser diameter of curvature so that some working space is provided on the outer side of the curve of the thoracic arch during the introduction process.

It is the object of this invention to provide a device which will overcome at least some of these problems 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.

Throughout this discussion the term “stent graft” is intended to mean a device which has a tubular body of biocompatible graft material and at least one stent fastened to the tubular body to define a lumen through the stent graft. The stent graft

may be bifurcated and have fenestrations, side arms or the like. Other arrangements of stent grafts are also within the scope of the invention.

Disclosure of the Invention

According to a first aspect of the present invention, there is provided a stent graft delivery device comprising:

a nose cone dilator at a proximal end of the device,

a resilient guide wire catheter extending from a distal end of the device to and through the nose cone dilator,

a pusher catheter extending from the distal end of the device towards the proximal end,

a stent graft retained on the delivery device between the distal end of the nose cone dilator and the pusher catheter, the stent graft having a graft lumen therethrough and wherein the guide wire catheter extends through the graft lumen, and the pusher catheter,

a pull wire fastened at or adjacent the distal end of the nose cone dilator such that when the guide wire catheter is curved during deployment the pull wire is fastened on the inside of the curve, said pull wire extending distally and through the stent graft lumen and the pusher catheter towards distal end of the device, and

a wire pull mechanism at or adjacent the distal end of the device operable to pull the pull wire to induce a curve in the guide wire catheter distally of the nose cone dilator.

As a result, the proximal end of the delivery device more closely fits the shape of a portion of the vasculature of a patient into which the device is deployed.

According to a further embodiment, there is provided a stent graft delivery device comprising a handle at a distal end, a nose cone dilator at a proximal end, the nose cone dilator including a distal end, a guide wire catheter extending from the handle to and through the nose cone dilator at the proximal end, the guide wire catheter being constructed from a resilient and flexible material, a pusher catheter extending from the handle towards the proximal end, a stent graft retained on the delivery device between the distal end of the nose cone dilator and the pusher catheter, the stent graft having a graft lumen therethrough and the guide wire catheter extending through the graft lumen, a pusher lumen through the pusher catheter, the

guide wire catheter extending through the pusher lumen and able to move longitudinally and rotationally with respect to the pusher, a pull wire fastened to the distal end of the nose cone dilator and the pull wire extending distally and adjacent to and outside the guide wire catheter and through the stent graft lumen and the pusher lumen to the handle and a wire pull mechanism for the pull wire associated with the handle, whereby the pull wire can be pulled by the wire pull mechanism to induce a curve in the guide wire catheter distally of the nose cone dilator such that the proximal end of the delivery device more closely fits the shape of a portion of the vasculature of a patient into which the device is deployed.

Preferably the nose cone dilator is formed from a radiopaque material. The radiographic marking may comprise the nose cone dilator being of a selected transverse profile whereby in a selected rotational orientation the nose cone dilator can be observed by radiographic means during an endovascular procedure to be in a selected rotational orientation. For instance the nose cone dilator can be formed from a radiopaque material and the radiographic marking can comprise a transverse notch in the nose cone dilator.

US Patent Application Serial No. 12/074755 (Publication No. 2008/0221656) entitled "Endovascular Deployment Device" teaches radiographic marking on a nose cone dilator and the teachings therein are incorporated in their entirety herein.

Preferably the stent graft delivery device further comprises a radiopaque marking on one side of the nose cone dilator whereby the rotational position of the nose cone dilator can be observed by radiographic techniques, the pull wire being fastened to the distal end of the nose cone dilator on an opposite side of the nose cone dilator to the radiopaque marking on the nose cone dilator.

In one embodiment the wire pull mechanism comprises a winch arrangement.

Preferably the wire pull mechanism comprises a lock mechanism whereby after the wire has been pulled it can be locked in a pulled position.

The guide wire catheter can comprise a tube formed from a nickel titanium alloy metal such as that sold under the Trade mark Nitinol.

The pull wire can comprise stainless steel wire or Nitinol™ wire.

Preferably the wire pull mechanism comprises a grip associated with the handle and the grip is able to be slid along the handle to pull the pull wire. A thumb screw arrangement may be associated with the grip to lock the grip to the handle at a selected curvature of the proximal end of the delivery device as observed by radiographic techniques.

Preferably the pusher catheter comprises a proximal pusher extension comprising a sleeve extending from the pusher catheter towards the nose cone dilator guide wire catheter and the pull wire extends through the pusher extension in order to restrict the length of guide wire catheter which is caused to bend by the pulling on the pull wire.

Preferably the stent graft delivery device further includes a constricting sheath around the pusher catheter and extending to the nose cone dilator, the sheath constraining the stent graft around the guide wire catheter during introduction of the stent graft into the vasculature.

According to a further aspect of the present invention, there is provided a method of treating an aortic aneurysm including deployment of a stent graft into the thoracic arch of a patient using a device as claimed in any of claims 1 to 14.

According to a further aspect of the present invention, there is provided a method of treating an aortic aneurysm including positioning a deployment device as claimed in any of claims 1 to 14 up through the descending aorta of a patient such that the proximal end of the device extends over the thoracic arch and into the ascending aorta, and pulling the pull wire in a distal direction to bend the proximal end of the guide wire catheter between the proximal end of the pusher catheter and the distal end of the nose cone dilator.

An advantage of this invention is that there is provided a delivery device which by pulling on a pull wire from external of the patient sufficient curvature may be provided in the proximal end of the delivery device for it to more closely fit the shape of the thoracic arch and to allow a working space in the outer side of the curve of the thoracic arch, for instance.

Brief Description of the Drawings

Preferred embodiments of the invention will now be described with reference to the accompanying drawings:

Figure 1 shows a schematic view of the thoracic arch of a patient with a stent graft partially deployed and curved therein according to one embodiment of the present invention;

Figure 2 shows detail of the nose cone dilator, guide wire catheter and pull wire of a delivery device according to one embodiment of the present invention;

Figure 3 shows a delivery device according to one embodiment of the present invention;

Figure 4 shows an induced curve of the delivery device of Fig 3; and

Figure 5 shows a delivery device according to another alternative embodiment of the present invention.

Description of the Preferred Embodiments

Now looking in detail at Figure 1 which shows a schematic cross sectional view of a thoracic aorta, it will be seen that the thoracic aorta 10 comprises an ascending aorta 12 which receives blood from the heart though an aortic valve 14. At the upper end of the ascending aorta there is a thoracic arch 15 with branches for the great vessels, the innominate artery 16, the left common carotid artery 18 and the left subclavian artery 20. The aorta after these great vessels is referred to as the descending aorta 22 and it is in this region that a thoracic aortic aneurysm can occur. In a thoracic aortic aneurysm part of the wall 24 of the descending aorta swells and can burst with serious consequences. The thoracic aortic aneurysm can extend to close to the great vessels or include the great vessels and hence it may be necessary to deploy a stent graft with side branches to extend into the great vessels. The thoracic arch has an inner side curve 26 and an outer side curve 28.

As shown in Figure 1, a deployment device 30 has been deployed up through the descending aorta over a pre-placed guide wire 31. The proximal end of the deployment device extends over the thoracic arch and into the ascending aorta 12. A sheath 36 of the deployment device has been withdrawn to partially release the stent graft 32 but the stent graft is still retained to the deployment device at region 40 at the proximal end 31 of the stent graft 32 and at region 42 at the distal end 33 of the stent graft 32.

US Patent Application Serial Number 10/447,406 entitled “Trigger Wire System “ teaches the use of trigger wire systems for retention of the ends of a stent

graft and the teachings therein are incorporated herein in their entirety.

The stent graft 32 includes three fenestrations 32a into which are intended to be deployed side branch stents or covered stents to maintain the patency of the great vessels when the stent graft is released into the thoracic arch.

The delivery device includes a guide wire catheter 44 made from stainless steel or Nitinol™. The guide wire catheter is resilient so that it can be bent to fit the shape of the thoracic arch. The bending of the guide wire catheter can caused by engagement with the wall of the aorta and hence the curve of the delivery device would be against the outer curve 28 of the thoracic arch. As this is where the great arteries branch off from the thoracic arch this does not allow working space adjacent to the major arteries and therefore the curving mechanism of the present invention is used. Part of the pusher catheter 34 of the deployment device can be seen at the distal end of the stent graft 32. The pusher catheter has a pusher lumen 34a (see also Figure 3) through which passes the guide wire catheter 44. The guide wire catheter 44 extending through the pusher lumen 34a is able to move longitudinally and rotationally with respect to the pusher catheter 34. The deployment device includes a nose cone dilator 45 at its proximal end and the lumen 47 of the guide wire catheter 44 extends to and through the nose cone dilator 45.

Detail of the proximal end of the deployment device can be seen in Figure 2. The nose cone dilator 45 is at the proximal end of the deployment device and the guide wire 44 catheter extends to and through the nose cone dilator 45. The guide wire catheter has a guide wire lumen 47 therethrough. The guide wire lumen 47 continues through the nose cone dilator 45. The nose cone dilator 45 has a notch 43 formed in it upper surface and the nose cone dilator 45 is formed from a radiopaque material such as a radiopaque polyurethane such that the orientation of the delivery device within the thoracic arch can be visualised by suitable radiographic techniques.

The curving mechanism includes a pull wire 46 which is fastened to the nose cone dilator 45 at the distal end 45a thereof where it joins to the guide wire catheter. For instance the pull wire 46 can be fastened at 49 to a sleeve 48 which is fastened such as by welding to the guide wire catheter and the nose cone dilator is fixed to the sleeve 48 by adhesive or the like. The pull wire is joined at 49 to the nose cone dilator 45 on the opposite side to the notch 43.

Referring back to Figure 1 it can be seen that the pull wire 46 extends through the lumen of the stent graft 32 and into the pusher lumen 34a of the pusher catheter 34 (but outside the guide wire catheter 36). The pull wire then extends back to a handle of the deployment device as is discussed below and shown in Figures 3 to 5. Pulling on the pull wire has caused the nose cone dilator to be pulled towards the pusher catheter which has caused the guide wire catheter to bend thereby forming a curve in the delivery device proximal end which more approximates the shape of the inner curve 26 of the thoracic arch and leaving some working space 50 between the stent graft and the outer curve 28 of the thoracic arch. It will be noted, too, that the notch 43 on the nose cone dilator is on the outside of the curve of the delivery device.

Figures 3 and 4 depicts a delivery device 30 according to one embodiment of the invention. The delivery device 30 has a guide wire catheter 44 which extends from a distal handle 52 to the proximal tapered nose cone dilator 45 longitudinally through a passageway or lumen 34a of a pusher catheter 34 which is connected to the handle 52 at its distal end. An introducer sheath 36 fits coaxially around the delivery catheter 34 and extends from a tapered proximal end 36a which optionally includes a radiopaque marker to a connector valve and hub 54 attached to the distal end of the sheath. The introducer sheath 36 extends proximally to the nose cone dilator 45 and covers the stent graft 32 during introduction of the deployment device into a patient and is withdrawn distally to expose the stent graft 32 during deployment when the deployment device is in a selected position within the vasculature of a patient. The stent graft or implantable device 32 is carried on the guide wire catheter 44 proximally of the pusher catheter 34 and distally of the nose cone dilator 45. The stent graft 32 comprises a tubular body of a biocompatible material and a plurality of self expanding stents (not shown for clarity). Connector valve and hub 54 includes a silicone disk assembly (not shown) for preventing the backflow of fluids therethrough. The disk assembly includes a slit for the insertion of the nose cone dilator 45 and delivery catheter 34. Connector and hub 54 also includes side arm 54a to which a tube may be connected for introducing and aspirating fluids therethrough. Nose cone dilator 45 includes a tapered proximal end 45a for accessing and dilating a vascular access site over a well-known and commercially available wire guide (not shown).

The wire guide is inserted in the vessel with an introducer needle using, for

example, the well-known percutaneous vascular access Seldinger technique. A well-known male Luer lock connector hub 58 is attached at the distal end of the guide wire catheter 44 for connection to syringes and other medical apparatus. The handle 52 at the distal end of the pusher catheter 34 remains outside a patient in use and carries the trigger wire release handle mechanisms used to release the various portions of the stent graft. The proximal end the stent graft 32 is retained on the delivery device by the use of trigger wires (not shown) connected to one of the release handles, the distal end of the stent graft is retained on the delivery device by the use of trigger wires (not shown) connected to another the release handles. The handle also includes a release mechanism for a release wire for diameter reducing ties (not shown) for the stent graft.

The pull wire 46 extends from where it is fastened to the distal end of the nose cone dilator 45 (see Figure 2) through the lumen 34a of the stent graft 32 and into the pusher lumen of the pusher catheter 34. The pull wire then extends back to a handle 52 of the deployment device where it is fastened to pull wire grip 60 which can be clamped to the handle by thumb screw 62. As can be seen on Figure 4 pulling on the grip 60 in the distal direction as shown by the arrow 64 causes the pull wire 46 to bend the proximal end of the guide wire catheter between the proximal end of the pusher catheter 34 and the distal end of the nose cone dilator 45 to form the curve as shown. This also bends the stent graft into a corresponding shape. Once the desired curvature has been obtained as can be seen by suitable radiographic techniques the thumb screw 62 can be used to clamp the grip 60 to the handle to hold the curvature during subsequent stages of the introduction procedure. At this stage the stent graft 32 is still retained on the deployment device at region 40 at the proximal end 31 of the stent graft and at region 42 at the distal end of the stent graft.

Subsequent stages of the introduction procedure can include catheterization of the fenestrations and introduction of a suitable side arm delivery device but before actual deployment of the side arms the pull wire can be released and the stent graft released from the delivery device. This would ensure that a side arm is not dislodged when the main stent graft settles into its final position in the thoracic arch.

Figure 5 shows an alternative embodiment of delivery or deployment device according to the present invention. In this embodiment the same reference numerals

are used for items corresponding to those in Figure 3 and 4.

The delivery device 70 of this embodiment has two variations from the earlier embodiment. First there is a winch arrangement for pulling the pull wire and second there is a pusher extension to reduce the amount of the guide wire catheter which is caused to bend by pulling on the pull wire. These two variations need not be used together and could be applied separately.

In this embodiment the handle 72 of the deployment device 70 has a winch assembly 74 which includes a winding handle 76 connected to a winch drum 78 within the winch assembly 74 and the pull wire is wound around the winch drum 78. The winch arrangement includes a releasable locking mechanism (not shown) to hold the winch drum in a selected rotational position.

At the proximal end of the pusher catheter 34 is a catheter extension 80 through which passes the guide wire catheter 44 and the pull 46 wire parallel to but outside the guide wire catheter. The catheter extension 80 extends part way into the lumen of the stent graft 32. This restricts the length of guide wire catheter which is bent by the pulling on the pull wire.

Rotating the winding handle 76 causes the pull wire 46 to bend the proximal end of the guide wire catheter between the proximal end 80a of the pusher catheter extension 80 and the distal end 45a of the nose cone dilator 45 to form the curve as shown in Figure 5. Once the desired curvature has been obtained as can be seen by suitable radiographic techniques the releasable locking mechanism holds the curvature.

The winch assembly can be placed on other parts of the handle 72.

Throughout this specification various indications have been given as to the scope of the 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.

Claims

1. A stent graft delivery device comprising:

a nose cone dilator at a proximal end of the device,

a resilient guide wire catheter extending from a distal end of the device to and through the nose cone dilator,

a pusher catheter extending from the distal end of the device towards the proximal end,

a stent graft retained on the delivery device between the distal end of the nose cone dilator and the pusher catheter, the stent graft having a graft lumen therethrough and wherein the guide wire catheter extends through the graft lumen and through the pusher catheter,

a pull wire fastened at or adjacent the distal end of the nose cone dilator such that when the guide wire catheter is curved during deployment, the pull wire is fastened on the inside of the curve, said pull wire extending distally and through the stent graft lumen and the pusher catheter towards the distal end of the device, and

a wire pull mechanism at or adjacent the distal end of the device operable to pull the pull wire to induce a curve in the guide wire catheter distally of the nose cone dilator.

2. A stent graft delivery device as in claim 1 further comprising a radiopaque marking on one side of the nose cone dilator whereby the rotational position of the nose cone dilator can be observed by radiographic techniques.

3. A stent graft delivery device as claimed in claim 2 wherein the pull wire is fastened at or adjacent the distal end of the nose cone dilator on an opposite side of the nose cone dilator to the radiopaque marking.

4. A stent graft delivery device as in any preceding claim wherein the wire pull mechanism comprises a lock mechanism to lock the wire in a pulled position.

5. A stent graft delivery device as in any preceding claim wherein the wire pull mechanism comprises a winch arrangement.

6. A stent graft delivery device as in claim 5 wherein the winch arrangement includes a winding handle connected to a winch drum and a releasable locking mechanism to hold the winch drum in a selected rotational position.

7. A stent graft delivery device as in any preceding claim wherein the guide wire

catheter comprises a tube formed from a nickel titanium alloy (Nitinol™) metal.

8. A stent graft delivery device as in claim 1 wherein the nose cone dilator is formed from a radiopaque material and the radiographic marking comprises the nose cone dilator being of a selected transverse profile whereby the nose cone dilator can be observed by radiographic means during an endovascular procedure to be in a selected rotational orientation.

9. A stent graft delivery device as in claim 8 wherein the nose cone dilator is formed from a radiopaque material and the radiographic marking comprises a notch in the nose cone dilator.

10. A stent graft delivery device as in any preceding claim wherein the pull wire comprises stainless steel wire or a nickel titanium alloy (Nitinol™) metal wire.

11. A stent graft delivery device as in any preceding claim further comprising a handle at the distal end of the device and wherein the wire pull mechanism comprises a grip associated with the handle and a thumb screw arrangement associated with the grip such that the grip is slideable along the handle to pull the pull wire and the thumb screw is operable to lock the grip to the handle once the proximal end of the delivery device is at a selected curvature.

12. A stent graft delivery device as in any preceding claim wherein the pusher catheter comprises a proximal pusher extension comprising a sleeve extending from the pusher catheter towards the nose cone dilator and part way into the stent graft, the pull wire extending through the pusher extension.

13. A stent graft delivery device as in any preceding claim further including a constricting sheath around the pusher catheter and extending to the nose cone dilator, the sheath constraining the stent graft around the guide wire catheter during introduction of the stent graft into the vasculature.

14. A stent graft delivery device comprising a handle at a distal end, a nose cone dilator at a proximal end, the nose cone dilator including a distal end, a guide wire catheter extending from the handle to and through the nose cone dilator at the proximal end, the guide wire catheter being constructed from a resilient and flexible material, a pusher catheter extending from the handle towards the proximal end, a stent graft retained on the delivery device between the distal end of the nose cone dilator and the pusher catheter, the stent graft having a graft lumen therethrough and

the guide wire catheter extending through the graft lumen, a pusher lumen through the pusher catheter, the guide wire catheter extending through the pusher lumen and able to move longitudinally and rotationally with respect to the pusher, a pull wire fastened to the distal end of the nose cone dilator and the pull wire extending distally and adjacent to and outside the guide wire catheter and through the stent graft lumen and the pusher lumen to the handle and a wire pull mechanism for the pull wire associated with the handle, whereby the pull wire can be pulled by the wire pull mechanism to induce a curve in the guide wire catheter distally of the nose cone dilator such that the proximal end of the delivery device more closely fits the shape of a portion of the vasculature of a patient into which the device is deployed.

15. A method of treating an aortic aneurysm including deployment of a stent graft into the thoracic arch of a patient using a device as claimed in any preceding claim.

16. A method of treating an aortic aneurysm including positioning a deployment device as claimed in any of claims 1 to 14 up through the descending aorta of a patient such that the proximal end of the device extends over the thoracic arch and into the ascending aorta, and pulling the pull wire in a distal direction to bend the proximal end of the guide wire catheter between the proximal end of the pusher catheter and the distal end of the nose cone dilator.

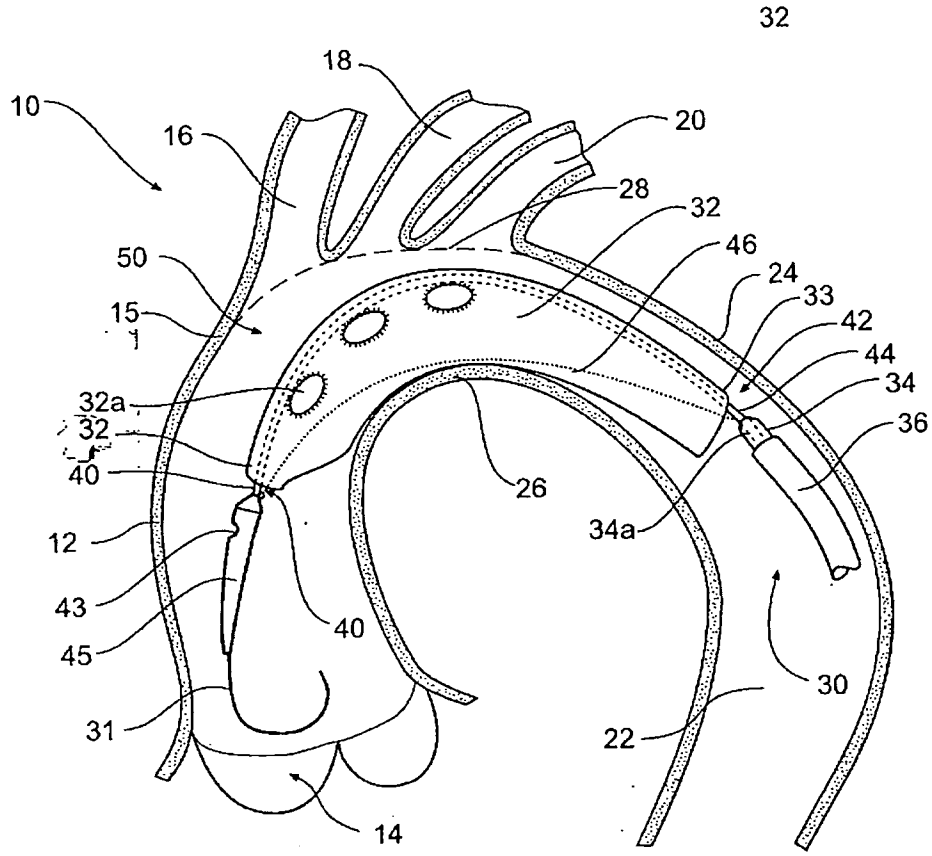
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Fig 1

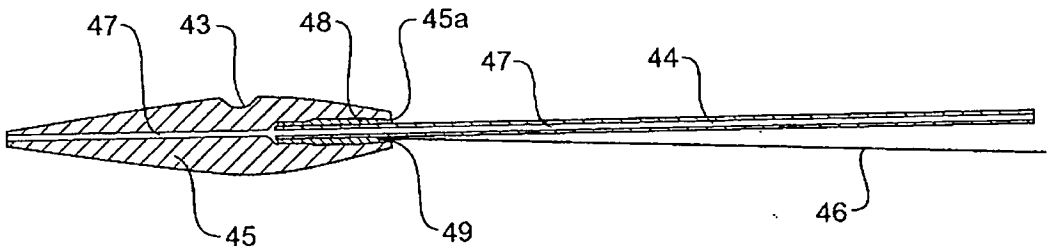
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Fig 2

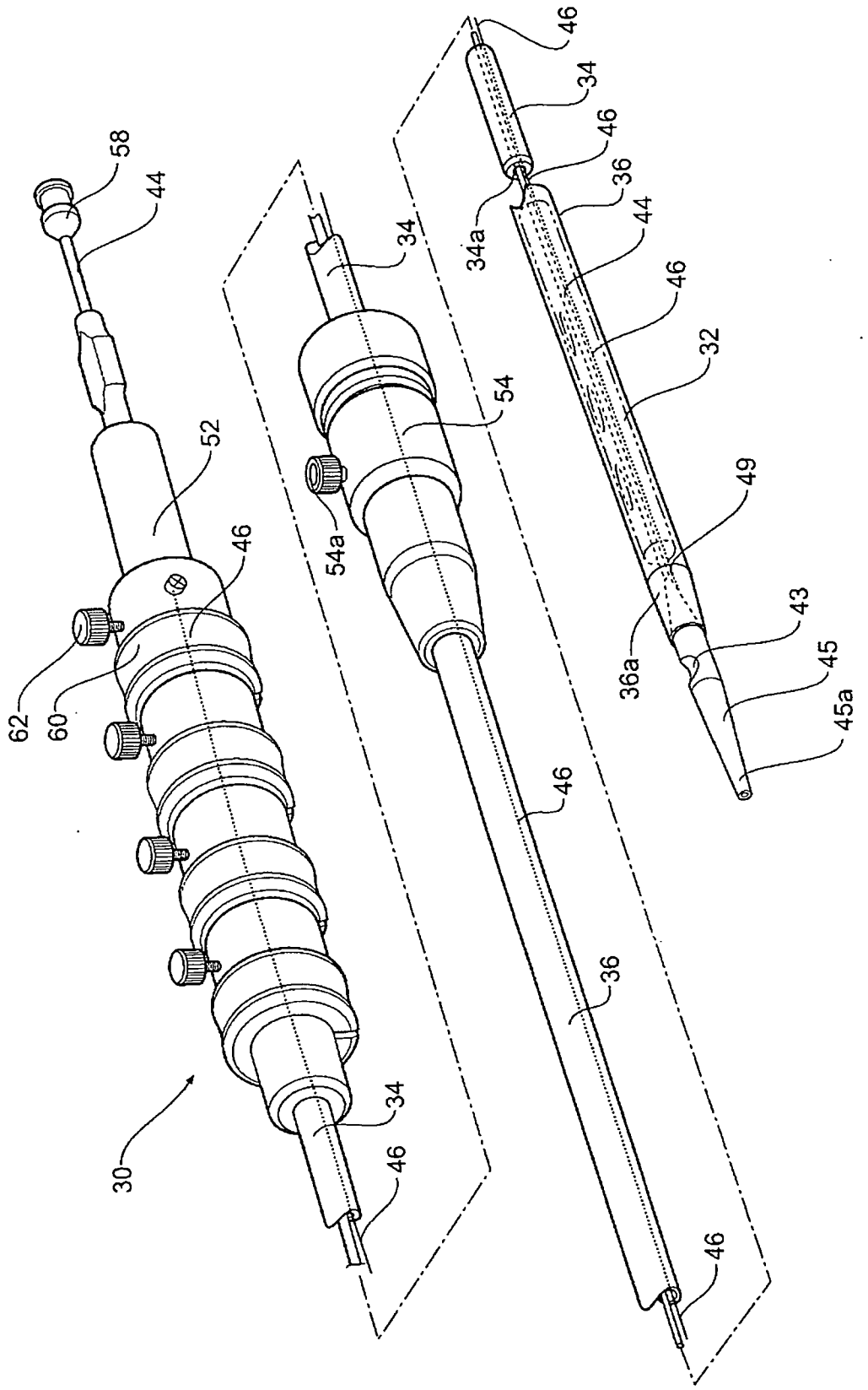
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Fig 3

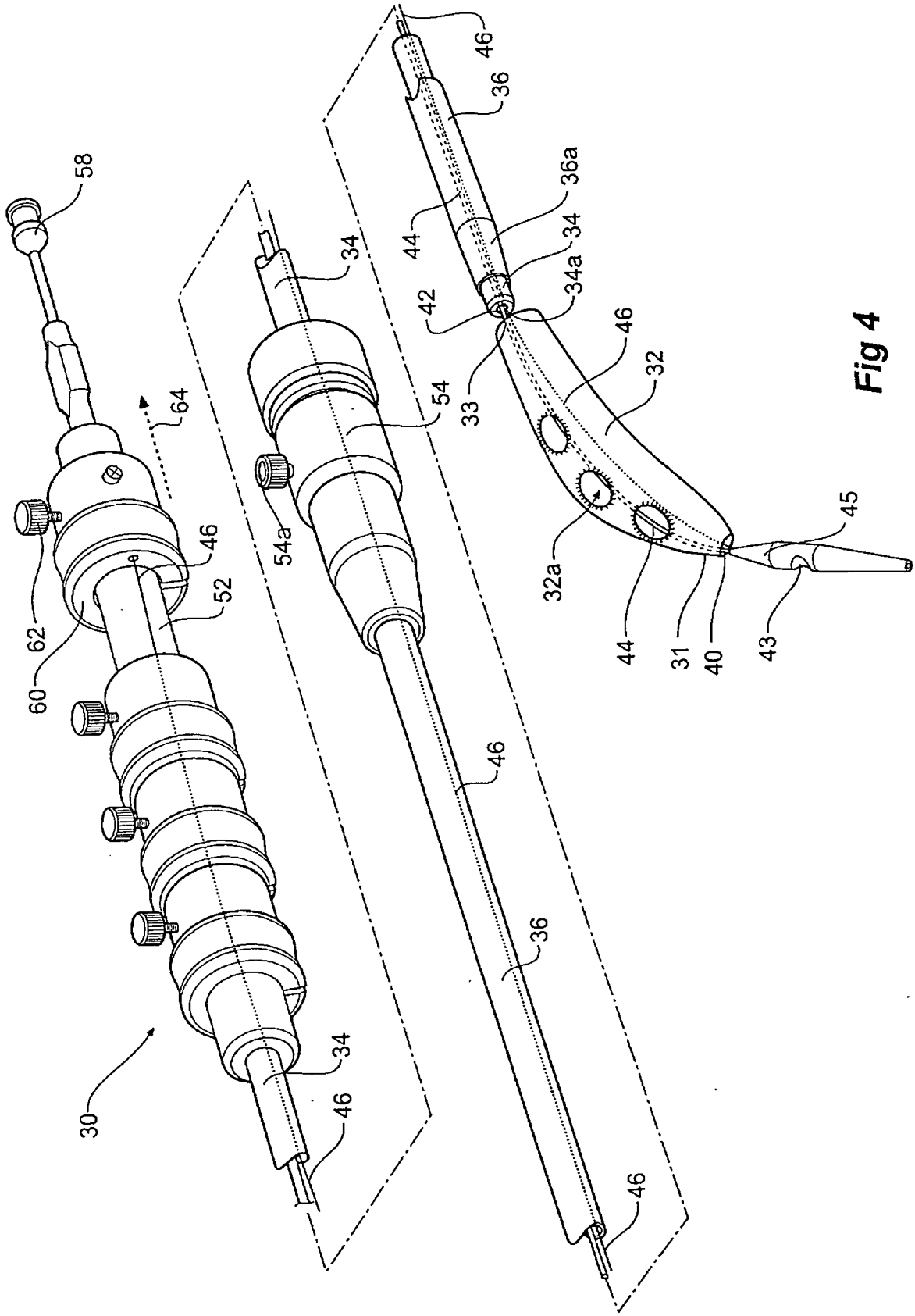
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Fig 4

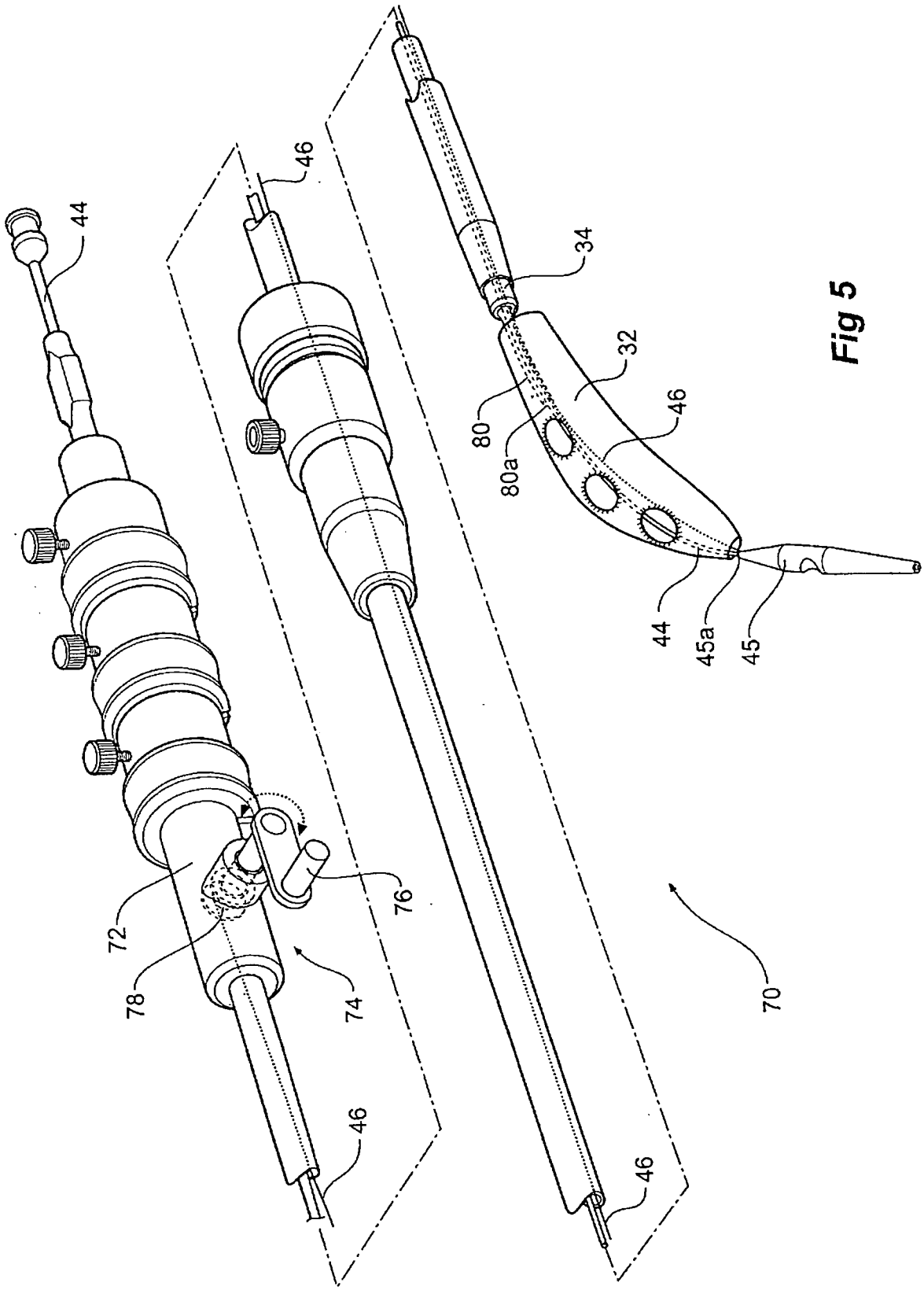

Fig 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/004807

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/84

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 A61M

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	WO 2007/092276 A (BOLTON MEDICAL INC [US]; MOORE MICHAEL [US]; ARBEFEUILLE SAMUEL [US];) 16 August 2007 (2007-08-16) page 51, line 20 - page 54, line 13 figures 19-24,63-67	1-14
X	WO 2007/082189 A (CORDIS CORP [US]; BURGERMEISTER ROBERT [US]; KREVER MATHEW [US]; FERRA) 19 July 2007 (2007-07-19) page 25, line 16 - page 28, line 18 figures 7A-7C,8A-8C	1,4-8, 10,11,14
X	US 2008/114440 A1 (HLAVKA EDWIN J [US] ET AL) 15 May 2008 (2008-05-15) paragraphs [0024] - [0030] figures 2,3A,3B,6	1,4-8, 10-14

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[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

"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	Date of mailing of the international search report
4 November 2009	11/11/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Chevalot, Nicolas

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/004807

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 126 633 A (KAJI KUNIHIDE [JP] ET AL) 3 October 2000 (2000-10-03) column 8, line 47 - column 9, line 14 column 11, line 18 - column 12, line 39 figures 10A,10B,16A-16C	1,4-6, 10,11,14
A	US 2004/106974 A1 (GREENBERG ROY K [US] ET AL) 3 June 2004 (2004-06-03) paragraphs [0039] - [0050] figures 1,2	1,7,8, 12-14
A	WO 2008/013777 A (COOK WILLIAM A AUSTRALIA [AU]; COOK INC [US]; COOK WILLIAM EUROP [DK];) 31 January 2008 (2008-01-31) page 4, line 26 - page 5, line 27 figures 1A-1E	1-14
P,X	WO 2008/112399 A (MEDTRONIC VASCULAR INC [US]; RUST MATTHEW [US]; MEIER STEPHEN [US]) 18 September 2008 (2008-09-18) paragraphs [0029] - [0065] figures 1-5	1-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/004807

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15,16
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/004807

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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