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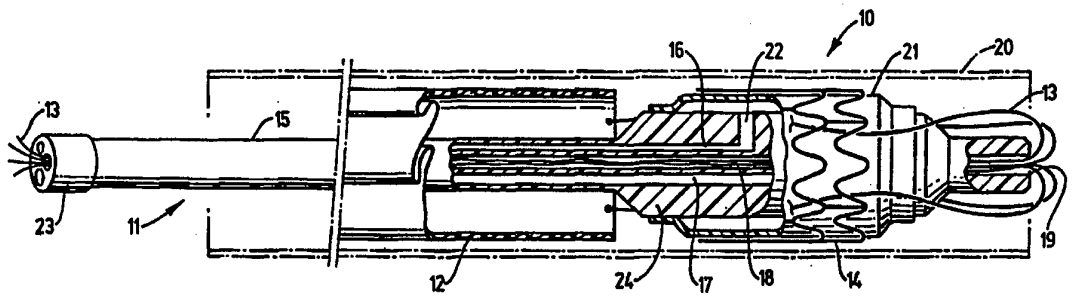

(57) Abstract

This invention provides a method and graft system for aneurysm repair comprising a prosthetic graft with means to draw a distal extremity of the graft over a portion of an expandable anchoring member. Prior to deployment, the graft and the anchoring member do not overlap to reduce the outer diameter of the delivery system. Preferably, the drawing means comprises pull strands connected to the distal extremity of the graft so that the distal extremity of the graft may be pulled over a proximal portion of the anchoring member. Subsequent expansion of the anchoring member seals the overlapped graft against the vessel wall to minimize blood flow-by and secures the graft in the vessel. Securing means may be advanced up each pull strand to abut the anchoring member and further secure the graft to the anchoring member. The graft may also comprise means to guide a second expandable anchoring member to the proximal end of the graft. Preferably, the guiding means comprise guide strands connected to a proximal extremity of the graft. The anchoring member can then be advanced up the guide strands until the graft overlaps the second anchoring member. Expansion of the second anchoring member secures the proximal end of the graft.

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PROSTHETIC GRAFT AND METHOD FOR ANEURYSM REPAIR

BACKGROUND

This invention relates to the delivery and placement of vascular grafts, and in particular, to a method and system for the repair of abdominal aortic aneurysms.

An aneurysm is a sac resulting from abnormal dilation of the artery wall and is often associated with arteriosclerotic disease. Unless treated, an aneurysm can rupture, leading to severe and often fatal hemorrhaging. Treating an aortic aneurysm generally involves transplanting a prosthetic graft to bridge the affected section of the aorta. Surgical implantation of the graft is possible but this treatment causes considerable trauma, results in high mortality and morbidity and, even when completely successful, requires a lengthy recuperation period. Due to the difficulty of the operation, direct surgical replacement is even less attractive when it must be performed on an emergency basis after the aneurysm has ruptured.

A less invasive alternative involves the use of a catheter to effect intraluminal delivery of a graft. Prior art graft delivery systems, such as disclosed in EP 0 461 791 A1 (Barone et al.), employ a graft with expandable portions that anchor the graft in the aorta. Often, the systems use an inflatable balloon on the delivery catheter to expand the anchoring portion of the graft as disclosed in United States Pat. No. 5,275,622 (Lazarus et al.) which is hereby incorporated in its entirety by reference thereto. This latter example requires the use of a bulky capsule to store the graft and a complicated pushrod system to deploy the graft.

Although the referenced prior art systems and others employ many different stent and graft configurations, none are completely

satisfactory. The principle limitation of the prior art systems is their size. They typically require a delivery catheter having a diameter of approximately 24-28 French (8 to 9.3 mm). Although it is desirable to introduce grafts through the femoral artery, its inner diameter is only about 4 to 6 mm. Thus, the size of the prior art devices restricts them to introduction through upper femoral sites, where access may be difficult. Accordingly, there is a need for a graft system capable of introduction through a smaller opening while maintaining the ability to reliably and securely deploy the graft.

The success of a percutaneous vessel repair depends in large part on getting the graft to the location of the vasculature in need of repair and deploying the graft effectively. Another difficulty associated with prior art graft deployment systems is blood flow-by which occurs when blood can pass between the graft and the patient's vessel, bypassing the graft. There is a need for a graft system which minimizes or prevents flow-by.

SUMMARY OF THE INVENTION

This invention provides a method and graft system for aneurysm repair which generally comprises a prosthetic graft with means to draw a distal extremity of the graft over a portion of an expandable anchoring member. For deployment, the graft and the anchoring member are radially compressed and positioned adjacent one another coaxially on a delivery catheter with essentially no overlap between the distal end of the graft and the proximal end of the anchoring member. The drawing means is connected to the distal extremity of the graft so that when tension is applied to the graft by the drawing means, the distal extremity of the graft is caused to overlap a proximal portion of the anchoring member. Subsequent expansion of the anchoring member seals the overlapped graft against the vessel wall to minimize blood flow-by and

secures the graft in the vessel. Since the graft and anchoring member do not overlap when loaded on the catheter prior to deployment, the system maintains an overall low profile.

In a preferred embodiment, the drawing means comprises at least one and preferably four pull strands attached to the distal end of the graft. The pull strands extend outside the distal end of the catheter, are threaded through an opening at the distal end of the delivery catheter and extend through a lumen in the catheter to the proximal end. After the graft is properly positioned within a patient's vasculature, tension is applied to the pull strands to cause the graft to slide distally along the catheter until the distal end of the graft extends over the proximal end of the anchoring member. Subsequent expansion of the anchoring member expands the graft, anchors it against the vessel wall and seals the graft against the vessel wall to minimize blood flow-by. Securing means may be advanced up the pull strand to abut the anchoring member and further secure the graft to the anchoring member.

The graft may also comprise means to guide a second expandable anchoring member to the proximal end of the graft. The guiding means are connected to a proximal extremity of the graft. In one embodiment, the guiding means comprises at least one and preferably four guide strands. After the distal end of the graft is anchored within the patient's vasculature, the guide strands are laced through the second anchoring member. The anchoring member can then be advanced up the guide strands until it is adjacent the proximal end of the graft. The graft overlaps the second anchoring member and expansion of the anchoring member secures the proximal end of the graft. Preferably, securing means secure the proximal end of the graft to the second anchoring member as described above regarding the drawing means.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a sectional elevation of a delivery catheter and graft system embodying features of this invention.

FIG. 2 is an elevational view of a distal portion of a delivery catheter and graft system of the invention comprising a self-expanding stent.

FIG. 3 shows an embodiment of the invention comprising pull strand securing means.

FIG. 4 illustrates an embodiment of the invention comprising guiding means and downstream graft anchoring.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 is a elevational view, in section, illustrating a catheter system **10** embodying features of the invention which generally comprises a catheter **11** with an aortic graft **12** having drawing means, a plurality of pull strands **13**, attached to the distal end and an expandable anchoring member, stent **14**, loaded for delivery. The catheter **11** comprises a flexible catheter shaft **15** with proximal and distal ends, an inflation lumen **16**, a guidewire lumen **17** and a pull strands lumen **18**. Pull strands **13** extend from graft **12**, enter the pull strands lumen **18** through opening **19** at the distal end of catheter **11** and exit from the proximal end of catheter **11**. Preferably, pull strands **13** may be laced through stent **14** at a point corresponding to the amount of overlap desired. In a preferred embodiment, graft **12** overlaps about half the length of stent **14** prior to expansion. A thin-walled retractable sheath **20** is slidably disposed over the catheter **11** and configured so that it covers the stent **14** and graft **13** during introduction and placement of the catheter system **10** and may be withdrawn once they are in an appropriate position within the patient. In the embodiment of FIG. **1**, the

catheter **11** includes an inflatable balloon **21** in fluid communication with the inflation lumen **15** through inflation passage **22** which is configured to expand stent **14**. The proximal end of catheter shaft **15** can have a cap **23** bonded to the end to provide access to inflation lumen **16**, guidewire lumen **17** and pull strands lumen **18**. The configuration of cap **23** allows it to mate in a conventional manner with a multi-arm adaptor (not shown) that supplies inflation fluid and allows guidewire control and manipulation of the pull strands. Cap **23** is preferably formed from metal, although other materials such as plastics are suitable. The diameter of cap **23** allows the compressed graft **12** and stent **14** to be threaded over the proximal end of catheter shaft **14**. In a preferred embodiment, catheter shaft **15** has an increased diameter delivery base **24** under balloon **21**. The delivery base **24** provides support for the expansion of stent **14** while allowing the remainder of the catheter shaft **15** to have a relatively small diameter. Further details regarding the design of suitable catheters as well as graft and stent materials may be found in the application Serial No. 08/336,875, filed November 9, 1994, which is hereby incorporated in its entirety by reference.

Preferably, the stent **14** is a Bronco® stent, available from Advanced Cardiovascular Systems, Inc. of Santa Clara, CA. Alternatively, stent **14** may be self-expanding as shown in FIG. **2**. For example, stent **14** may be constructed from shape-memory materials causing it to revert to its expanded shape at body temperatures. In such embodiments, thin-walled sheath **20** would restrain stent **14** until properly positioned. Other suitable means for expanding the stent may be used.

The effective wall thickness of stent **14** does not change between the pre-expanded and expanded states. On the other hand, the graft **12** bunches when compressed to conform to the catheter shaft **15** and forms overlaps and pleats, effectively increasing its wall thickness.

Stent **14** and graft **12** are coaxially threaded over the catheter **11**; the relatively thick compressed graft **12** is positioned solely over the relatively small diameter catheter shaft **15** while the stent **14** receives the increased support for expansion provided by larger diameter delivery base **24**. The lack of overlap between the graft **12** and the stent **14** when loaded for deployment on catheter shaft **15** saves approximately 1-3 mm from the diameter of system **10** over conventional systems. Accordingly, the delivery catheters of this invention have an insertion diameter of less than 7 mm and preferably about 6 mm. This allows system **10** to present a small outer diameter to facilitate introduction into the body, preferably through the femoral artery.

In embodiments where pull strands **13** are laced through stent **14**, securing means **25** may be employed to further anchor the graft **12** as shown in FIG. **3**. The securing means **25** thread over pull strands **13** and are configured so that they will not pass through the framework of stent **14**. In one embodiment, securing means **25** comprise one-way frictional sliding washers. Once graft **12** and stent **14** are deployed and catheter **11** removed, a simple catheter **26** is used to push securing means **25** up pull strands **13** until they are tightly seated against stent **14**. This secures pull strands **13** to stent **14** and further anchors the graft **12**.

FIG. **4** illustrates an embodiment of the invention which comprises guiding means, guide strands **27**, attached to the proximal end of graft **12**. Guide strands **27** are similar in configuration to pull strands **13**. In use, the graft's distal end (or ends in the case of a bifurcated graft) **12** may be anchored by lacing guide strands **27** through a second anchoring member, stent **28**, and advancing the stent **28** up the guide strands until it is at least immediately adjacent to the proximal end of graft **12**. Once positioned, the anchoring member **28** is expanded to secure the proximal end of graft **12** and maintain the graft's patency. Securing means **25** may be used to further anchor the graft as described above. In some

embodiments, the guide strands **27** are attached to the interior of graft **12** at a point inset from the proximal end to allow that proximal portion of graft **12** to overlap a distal portion of stent **28** such that expansion of stent **28** will sandwich the proximal end of the graft against the patient's vessel wall.

In general, anchoring members may be formed from any suitable material, including tantalum, stainless steel, other metals and polymers and when employing a self-expanding anchoring member, shape-memory metals such as NiTi alloys. The anchoring member may also be coated with a polymer or seeded with endothelial cells to further inhibit thrombosis. Generally, the anchoring member is formed in its pre-expanded state. Once it is positioned with the graft over the catheter shaft **15**, the anchoring member may be crimped down to a slightly smaller inner diameter onto the means for expanding the anchoring member to secure the assembly during introduction and to further reduce the delivery diameter. Anchoring member configurations are suitable so long as they are self supporting within the aortic passageway and provide suitable means for anchoring the graft.

The grafts of this invention are intact tubes, preferably constructed of a synthetic yarn, monofilament or multifilament, formed from materials such as polyesters (including Dacron®), polytetrafluoroethylene (PTFE), polyurethane or nylon. Dacron® in particular, a multifilament composed of polyethylene terephthalate (PET), has been shown to be suitable and may promote formation of intima. The synthetic material may be woven or knit. The woven grafts are generally stronger and less porous while knit grafts are softer and more porous. Additionally, the surface of the synthetic material may be texturized and woven or knit to form a velour surface which generally facilitates growth of tissue from the surrounding lumen through the velour loops to help secure the graft. If desirable, the graft may be

bifurcated.

The catheter **11** may be formed from any suitably flexible material, such as pseudoelastic metals (*e.g.* NiTi alloys) and a wide range of conventional polymers. Preferably, the catheter **11** is formed from an extrudable polymer such as polyethylene (PE).

The inflatable balloon **21** may be a relatively inelastic inflatable balloon to provide the degree of expansion control and durability necessary to effectively expand and anchor the anchoring member. The balloon may be formed from any suitable material such as PE, polyethylene terephthalate (PET) or nylon or other polyamide.

Pull strands **13** and guide strands **27** may comprise any suitable material having sufficient flexibility to easily thread through the anchoring means and the catheter while having sufficient strength to pull the graft over the stent. Suitable materials include plastics and metals. In some embodiments, pull strands **13** and guide strands **27** may comprise integral parts of the graft **12**. It may be desirable to form all or a portion of pull strands **13** and guide strands **27** from a bioabsorbable material. It is preferable to provide the graft **12** with four pull strands **13** and four guiding strands **27**, each radially spaced around the respective end of the graft.

The use of the catheter system **10** generally follows conventional procedures. In particular, a guidewire (not shown) is backloaded into guidewire receiving lumen **17** of the catheter **11** with sheath **20** extending over the compressed and loaded graft **12** and stent **14**, as shown in phantom. The catheter system **11** and guidewire are percutaneously introduced by means of conventional cut down techniques in the patient's arterial system, generally through the femoral artery. The guidewire is advanced out delivery catheter **11** and up the aorta via fluoroscopic imaging until it crosses the aneurysm. Then the catheter **11** is advanced over the guidewire until the stent **14** is

positioned within a healthy region of the aorta upstream from the aneurysm. The sheath **20** is retracted to expose the stent **14** and the graft **12**. Pull strands **13** are pulled to draw the distal end of the graft a desired amount over the proximal end of the stent **14**, preferably half the length of the stent. Then, balloon **21** is inflated to expand stent **14** to sandwich the distal end of graft **12** between the stent **14** and the aortic wall, thus anchoring it. The balloon **21** is deflated and the catheter **11** is removed, leaving the expanded anchoring member and graft in place. To further secure the graft, securing means **25** may be advanced up pull strands **13** until they abut the stent **14**. Once securing means **25**, if any, are positioned, all excess of the pull strands **13** may be cut.

Once deployed, the proximal end or ends of graft **12** may be anchored by advancing another anchoring member **28** along guide strands **27**. Securing means **25** may also be employed to further anchor the proximal end of graft **12** to anchoring member **28**.

While the invention has been described primarily with respect to a system comprising the catheter loaded with an anchoring member and graft, it includes the graft with drawing means alone, kits which comprise unassembled catheters, anchoring members and grafts, and methods of use. It should be recognized that various modifications and improvements can be made to the invention without departing from the scope thereof.

What is claimed is:

1. A graft delivery system comprising:

a) an elongated catheter with proximal and distal ends and a means for expanding an expandable anchoring member on a distal portion of the catheter;

b) an expandable anchoring member with proximal and distal ends mounted on the expanding means;

c) an aortic graft in a radially compressed state with proximal and distal ends and mounted on the catheter proximally adjacent to the anchoring member; and

d) drawing means secured to the distal end of the graft and configured to pull the distal end of the graft over the proximal end of the anchoring member.

2. The graft delivery system of claim 1 wherein the catheter further comprises a lumen with a opening at the distal end and extending to the proximal end and the drawing means comprises at least one pull strand extending from the distal end of the graft through the opening at the distal end of the catheter to the proximal end of the catheter.

3. The graft delivery system of claim 2 wherein the pull strands are laced through the anchoring member.

4. The graft delivery system of claim 1 wherein the means for expanding an anchoring member comprises an inflatable member.

5. The graft delivery system of claim 4 including an inflation lumen extending through the catheter in fluid communication with the

interior of the inflatable member.

6. The graft delivery system of claim 1 wherein the system has an outer diameter of less than about 7 mm.

7. The graft delivery system of claim 1 wherein the anchoring member comprises a stent.

8. The graft delivery system of claim 1 wherein the graft further comprises guiding means extending from the proximal end of the graft.

9. The graft delivery system of claim 8 wherein the guiding means comprise at least one guiding strand.

10. A graft delivery system comprising:

a) an elongated catheter with proximal and distal ends;

b) a self-expanding anchoring member with proximal and distal ends mounted on a distal portion of the catheter;

c) an aortic graft in a radially compressed state with proximal and distal ends and mounted on the catheter proximally adjacent to the anchoring member; and

d) drawing means secured to the distal end of the graft and configured to pull the distal end of the graft over the proximal end of the anchoring member.

11. The graft delivery system of claim 10 wherein the catheter further comprises a lumen with a opening at the distal end and extending to the proximal end and the drawing means comprise pull strands extending from the distal end of the graft through the opening at the

distal end of the catheter to the proximal end of the catheter.

12. The graft delivery system of claim 11 wherein the pull strands are laced through the anchoring member.

13. The graft delivery system of claim 10 wherein the self-expanding anchoring member is formed from shape-memory material.

14. The graft delivery system of claim 13 wherein the anchoring member is formed from a NiTi alloy.

15. The graft delivery system of claim 10 wherein the graft further comprises guiding means extending from the proximal end of the graft.

16. The graft delivery system of claim 15 wherein the guiding means comprise at least one guiding strand.

17. An aortic graft comprising a graft having proximal and distal ends with drawing means attached to the distal end.

18. The graft of claim 17 wherein the drawing means comprises at least one pull strand.

19. The graft of claim 17 wherein the graft further comprises guiding means extending from the proximal end of the graft.

20. The graft of claim 19 wherein the guiding means comprises at least one guiding strand.

21. A method for repairing a portion of a patient's vasculature comprising the steps of:

a) providing a catheter assembly having:

1) an elongated catheter with proximal and distal ends and a means for expanding an expandable anchoring member on a distal portion of the catheter,

2) an expandable anchoring member with proximal and distal ends mounted on the expanding means,

3) an aortic graft in a radially compressed state with proximal and distal ends and mounted on the catheter proximally adjacent to the anchoring member, and

4) drawing means secured to the distal end of the graft and configured to pull the distal end of the graft over the proximal end of the anchoring member; and

b) advancing the catheter assembly with the graft to the desired location in the patient's vasculature;

c) operating the drawing means to pull the distal end of the graft over the proximal end of the anchoring member; and

c) expanding the anchoring member to expand and anchor the graft within the patient's vasculature.

22. The method for repairing a portion of a patient's vasculature of claim 21 further comprising the step of attaching securing means on drawing means abutting the anchoring means to anchor the graft.

23. The method for repairing a portion of a patient's vasculature of claim 21 wherein the graft further comprises guiding means and further comprising the steps of:

a) lacing the guiding means through a second anchoring member;

b) advancing the second anchoring member along the guiding means through the patient's vasculature until it is at least adjacent to the proximal end of the graft; and

c) expanding the second anchoring member to anchor the proximal end of the graft.

24. A method for repairing a portion of a patient's vasculature comprising the steps of:

a) providing a catheter assembly having:

1) an elongated catheter with proximal and distal ends,

2) a self-expanding anchoring member with proximal and distal ends mounted on a distal portion of the catheter,

3) an aortic graft in a radially compressed state with proximal and distal ends and mounted on the catheter proximally adjacent to the anchoring member, and

4) drawing means secured to the distal end of the graft and configured to pull the distal end of the graft over the proximal end of the anchoring member; and

b) advancing the catheter assembly with the graft to the desired location in the patient's vasculature;

c) operating the drawing means to pull the distal end of the graft over the proximal end of the anchoring member; and

c) allowing the self-expanding the anchoring member to expand and anchor the graft within the patient's vasculature.

25. The method for repairing a portion of a patient's vasculature of claim 24 further comprising the step of attaching securing means on drawing means abutting the anchoring means to anchor the graft.

26. The method for repairing a portion of a patient's vasculature of claim 24 wherein the graft further comprises guiding means and further comprising the steps of:

a) lacing the guiding means through a second anchoring member;

b) advancing the second anchoring member along the guiding means through the patient's vasculature until it is at least adjacent to the proximal end of the graft; and

c) expanding the second anchoring member to anchor the proximal end of the graft.

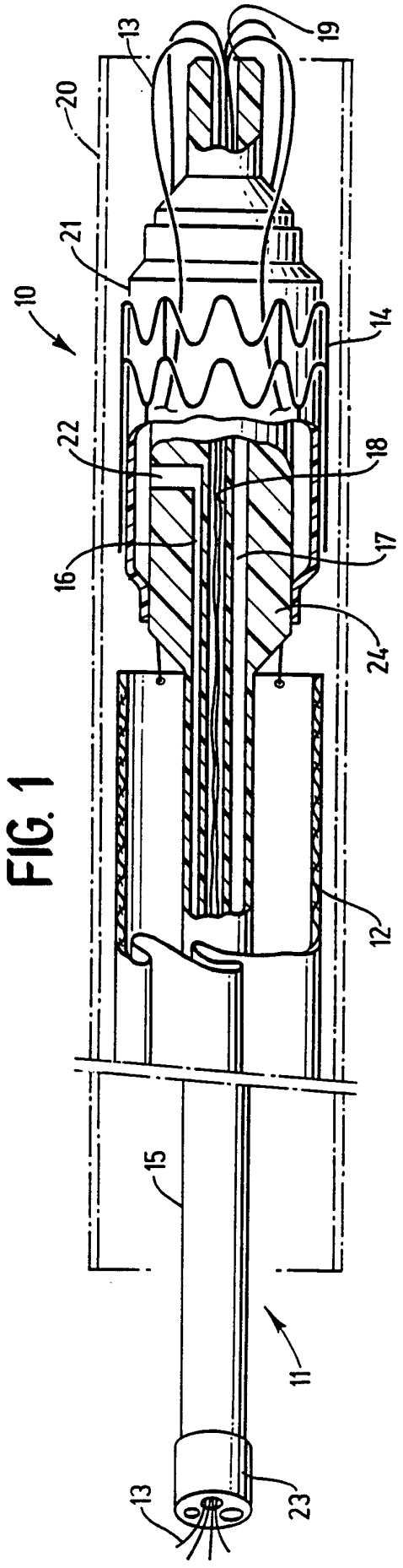


FIG. 1

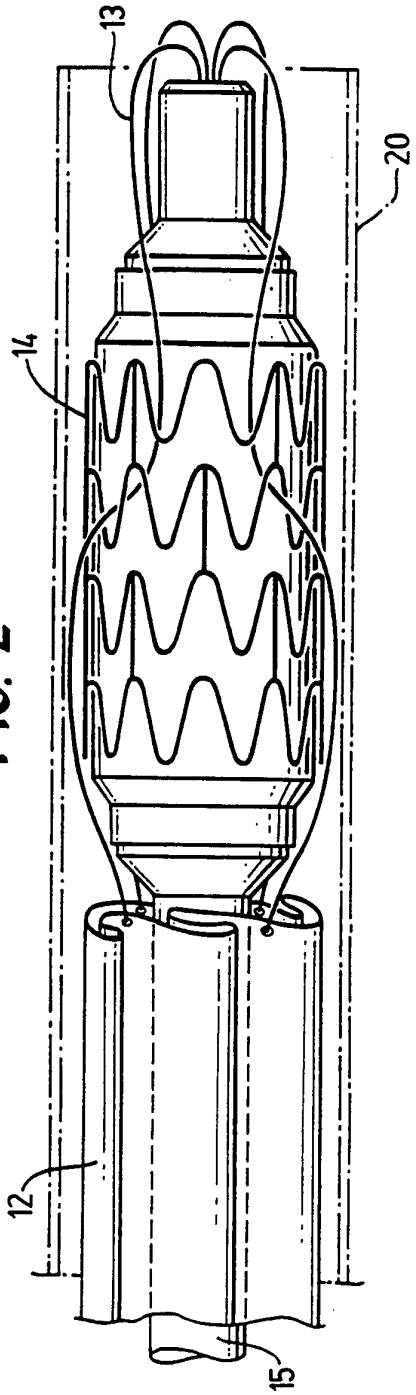


FIG. 2

FIG. 3

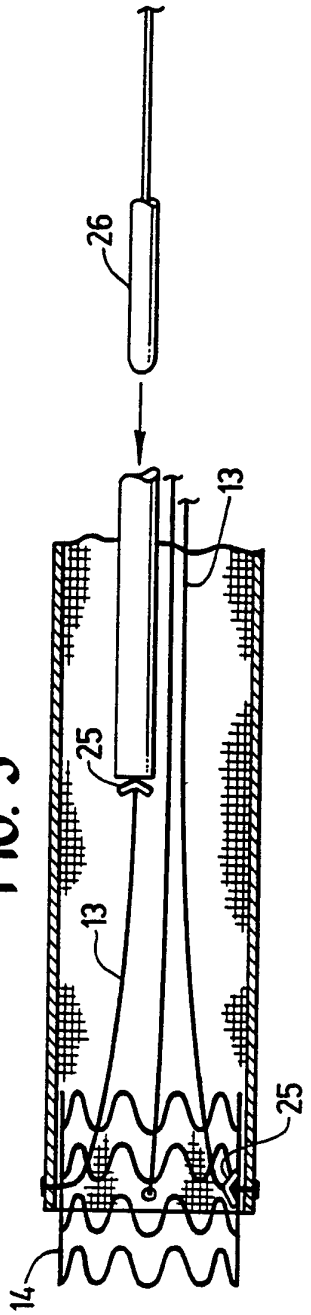
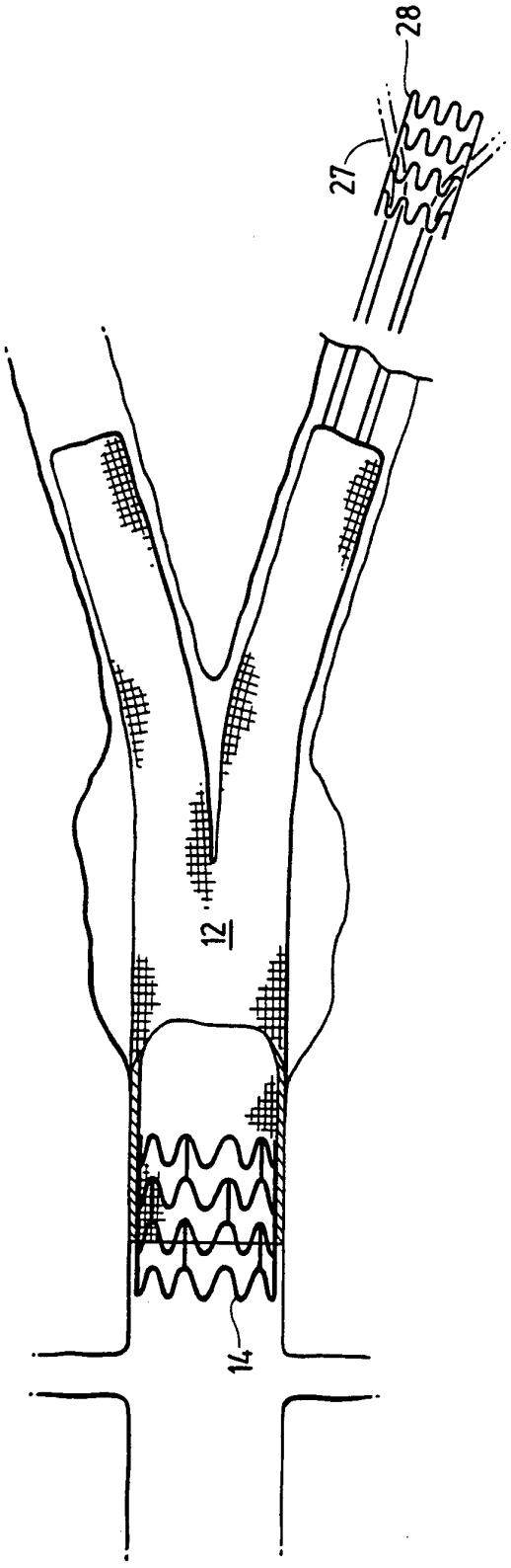


FIG. 4



INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/09149

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 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 6 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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 539 237 (COOK INC) 28 April 1993 see column 18, line 4 - line 18; figures	17-20
A		1,7-10, 15,16

Y	EP,A,0 637 454 (ENDOVASCULAR TECH INC) 8 February 1995 see the whole document	17,18
A		1,4-9

Y	EP,A,0 321 912 (DELSANTI GERARD L) 28 June 1989 see abstract; figures	17,18

A	EP,A,0 556 850 (ENDOTECH LTD) 25 August 1993 see column 4, line 42 - line 55; figures	1,7,10, 13,17

☐ 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

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

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"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
30 October 1996	06. 11. 96
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Authorized officer Neumann, E

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

rnational application No.
PCT/US 96/09149

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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.: 21-26
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1(iv)

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 II Observations where unity of invention is lacking (Continuation of item 2 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 all searchable claims.

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

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers 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.

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

INTERNATIONAL SEARCH REPORT

information on patent family members

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