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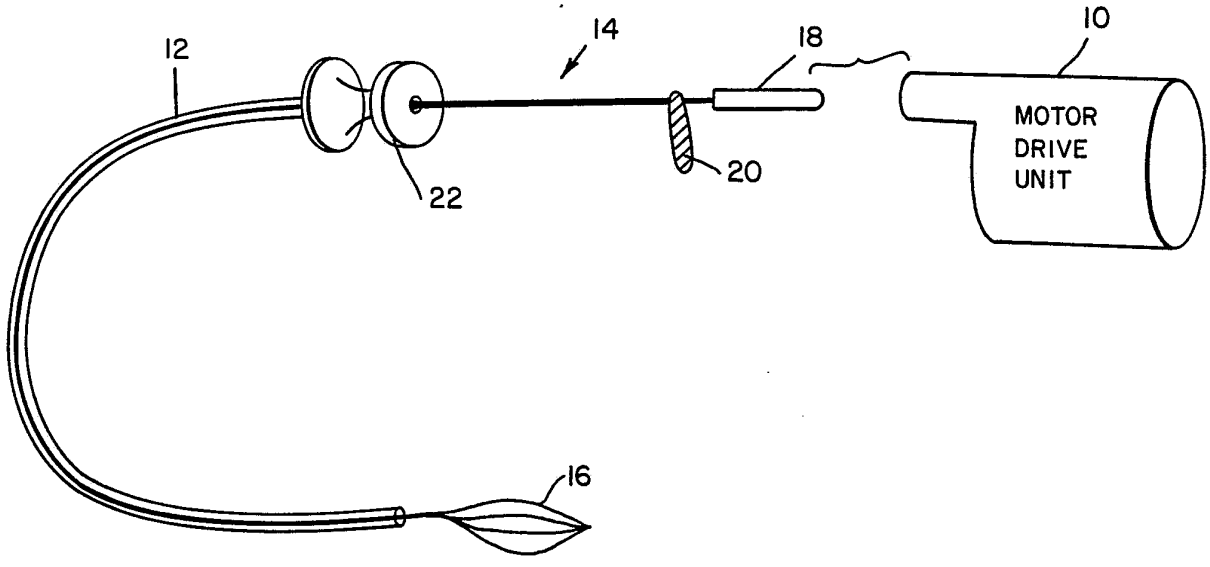

(57) Abstract

A percutaneous catheter system is disclosed for mechanically fragmenting thrombus in a vascular conduit. The system has a fragmentation catheter (14) inside an outer introducer sheath (12). A self-expandable fragmentation member (16) is attached to the distal end of the fragmentation catheter. A drive mechanism (10) is attached to the proximal end of the fragmentation catheter by a flexible drive shaft (18) which rotates the fragmentation member in order to break up the thrombolytic material into small particles.

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A Percutaneous Mechanical Fragmentation Catheter System

Technical Field

The present invention relates to a catheter for mechanically fragmenting clots within the vascular system and in particular, within occluded synthetic vascular grafts. The catheter is used percutaneously, thereby obviating surgery. Use of the catheter reduces or eliminates the need for pharmacological clot dissolution.

Background Art

Various prior art techniques have attempted to break up clots and/or other obstructing materials, such as neo-intimal hyperplasia in the vascular system and in synthetic grafts. Anti-thrombic drugs such as Urokinase or Streptokinase have been used to dissolve clots. However, these techniques prove to be very expensive and time consuming. For instance, chronic hemodialysis patients experience blockage of the synthetic access graft (the dialysis fistula) approximately 3 - 4 times a year. Use of anti-thrombic drugs requires the patient to spend a day in the hospital each time the dialysis fistula occludes. Pharmacological therapy requires long time commitments for infusion or medical personnel commitments for pulse-spray techniques.

Surgical thrombectomy has also been used to restore access to dialysis and has opened vascular ducts occluded by clots. Again, the expense is excessive because operating room time must be used. Such techniques use a Fogarty balloon catheter in the operating room, although a Fogarty balloon catheter may be used percutaneously.

Various mechanical devices have been developed that are designed to mechanically remove atheromatous plaque; most of these devices are said to remove thrombus material also. Most of these devices cut the material and then collect or remove the resulting debris from the vascular system. Various

atherectomy devices are described in the following patents: U.S. Patent 4,957,482 issued to Samuel Shiber; U.S. Patent 4,696,677 issued to Halmut Masch; U.S. Patent 5,034,001 issued to Michi E. Garrison, et al.; U.S. Patent 4,950,277 issued to Andrew Farr; U.S. Patent 4,926,858 issued to Hanson Grifford, III, et al.; U.S. Patent 4,886,061 issued to Robert E. Fischell, et al.; U.S. Patent 4,923,462 and 4,936,845 issued to Robert Stevers, et al.; and U.S. Patent 4,909,781 issued to Royce Hosted. The above devices share common problems--they require larger sheath size and create a limited channel size. The prior art devices do not automatically accommodate to changes in the inner lumen dimensions of the graft or vessel caused by the presence of a thrombus or automatically expand outward toward the vessel or conduct walls as the thrombus is being fragmented.

U.S. Patent 5,030,201, issued to Aubrey Palestrant, typifies the problems associated with prior art mechanical devices. Palestrant teaches a plurality of parallel cutting blades which are contained during transport within a protective sheath. In operation, the device cuts a portion of the obstructing material and then a second mean is used to manually expend the parallel cutting blade so that a larger core can be cut in the obstructing material. The Palestrant device relies on the relative movement of coaxial catheters to bow the blades outward. The amount of expansion is totally controlled by the operator and the Palestrant device cannot automatically compensate for changes in the inner lumen as obstructing material is removed. The coaxial structure also requires a large diameter protective sheath.

Various mechanical devices, rather than using rotating members to cut the obstructive material use ureteric stone catcher baskets mounted on a catheter tip to grab and remove thrombotic material. The following articles teach the use of such baskets to grab and remove thrombus: 1) "A Combined Technique for Peripheral Arterial Embolectomy" Arch Surg/Vol 105, December, 1972; 2) "Removal of an iatrogenic foreign body from the aorta by means of a ureteric stone catheter" Am. Heart J. March, 1967; 3)

"Nonsurgical Techniques for Removal of Catheter Fragments From the Pulmonary Artery" Catheterization and Cardiovascular Diagnosis 9:109-112 (1983); 4) "Atraumatic retrieval of catheter fragments from the central circulation in children" European Journal of Cardiology, 1974, 1/4, 421-422; 5) "Removal of Intravascular Foreign Body with Stone Retriever" Urology, Feb. 1981, Vol. XVII, No.2; 6) "Retrograde Embolectomy" The Lancet, April 6, 1963; 7) "Mechanical Clot Dissolution: New Concept" Radiology April, 1989, 17/:231-233; 8) "Mini basket for Percutaneous Embolectomy and Filter Protection Against Distal Embolization: Technical Note" Cardiovasc Intervent Radial (1991) 14:195-198; and, 9) "Percutaneous Aspiration Thromboembolectomy" Radiology July, 1985; 156:61-66.

An article appearing in Radiology entitled "New Device for Percutaneous Fragmentation of Pulmonary Emboli" (Radiology, 1991; 180:135-137) combines a spinning impeller contained within a stone basket. The stone basket does not rotate and is necessary to center the rotating impeller so that it does not inadvertently cut the vessel wall. The device cannot automatically expand the mechanical fragmentor to accommodate the inner lumen dimensions of the vascular conduit.

SUMMARY OF THE INVENTION

The present invention represents a new approach to fragmenting clots within the vascular system and in particular within synthetic vascular grafts. The present invention overcomes deficiencies in the prior art by: 1) automatically expanding to conform to the inner lumen dimensions and shape of the vessel; 2) applying a radial pressure so that the fragmentor automatically expand as the thrombus is fragmented and eventually presses against the walls of the conduit; 3) using a minimal number of components and components size so that the catheter can be deployed through a small introducer sheath.

The device consists of a stone retrieval basket modified to attach to a rotational drive motor. The catheter, ensheathed in a guiding catheter, is introduced into the clotted graft or vessel via an introducer sheath. When deployed, the basket will automatically conform to the inner dimensions of the vessel. The rotating basket is slowly withdrawn through the clotted graft, mechanically fragmenting the clot. The fragmented, homogenized debris (with pieces generally smaller than 2.0mm) would be flushed into the venous system. The wire cage that makes up the basket contains a designed "springiness" enabling it to self-expand. The cage conforms to the inner lumen dimensions and shape and applies radial pressure against the thrombus material, thereby expanding to homogenize the entire cross-section of the conduit. As the material homogenizes, the cage automatically expands until it is pressing against the wall of the vessel. The fragmentation catheter can be used percutaneously, thereby obviating surgery. The catheter reduces or eliminates the need for pharmacological clot dissolution. This new catheter offers the advantage of shortening procedure time, decreasing cost and risk, requiring the use of smaller sheath size and automatically accommodating differences in the vessel inside diameter.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1a and 1b are drawings of the percutaneous mechanical fragmentation catheter system, comprising: a drive motor, introducer sheath and self-expanding fragmentation catheter. Figure 1a shows the fragmentation cage in its deployed position, Figure 1b shows the catheter sheathed.

Figure 2 a and b are enlarged views of the fragmentation catheter. Figure 2a shows a spiraling fragmentation cage; Figure 2b shows a straight fragmentation cage.

Figure 3 is an enlarged view of a second embodiment the fragmentation catheter used in conjunction with a guide wire.

Figure 4a, 4b and 4c show the use of the percutaneous mechanical fragmentation catheter system in a dialysis fistula. Figure 4a shows introduction of the fragmentation catheter; Figure 4b and 4c shows deployment and use of the fragmentation catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1a is an enlarged drawing showing the percutaneous mechanical fragmentation catheter system as taught by the present invention. The catheter system consist of: a motor drive unit 10, an introducer sheath 12 and fragmentation catheter 14. The distal end of the fragmentation catheter 14 is attached to a stone retrieval basket 16. The stone retrieval basket may range in size from 4.0 - 30.0mm depending on the size of the conduit to be treated. The proximal end of the fragmentation catheter is attached via a shaft to a drive shaft 18. The drive shaft 18 is adapted to couple to the motor drive unit 10 so that the deployed fragmentation cage can be rotated. The introducer sheath 12 has a variable length but optimally around 50 cm. A handle 20 is attached to the proximal end of the fragmentation catheter just above the drive shaft 18. A second handle 22 is attached to the proximal end of introducer sheath 12. Movement of handle 20 toward handle 21 will move the fragmentation cage 16 from inside the sheath 12 and causes it to be deployed. Relative movement of handles 20 and 22 will correspondingly move the deployed fragmentation cage 16 along the vascular conduit (not shown in Figure 1). Figure 1a shows the deployed fragmentation cage 16; Figure 2b shows the fragmentation cage 16 positioned in the introducer sheath 12.

Figures 2a and b are enlarged views showing the deployed fragmentation cage 16. The fragmentation cage is made from three to six wires 24. The diameter of the wires and the number of wires defines the size of the introducer sheath 12. One can minimize trauma to vascular grafts by using the smallest possible introducer sheath 12. The introducer sheath could range in diameter from 3 to 9 French. The inventor has found that for

dialysis grafts a 4.5 - 5.0 French introduced sheath works very well. The wires 24 have a "spinginess" enabling them to expand. The normal relaxed position of the wires in the fragmentation cage 16 would bow out so that the fragmentation case would press against the inner lumen of the vascular conduit and automatically sense and conform to its size and shape. The wires 24 could be made of spring tempered wire such as thermal memory wire (nitinol wire). The fragmentation cage 16 could be made of spiraling wire like the traditional stone basket as shown in Figure 2a or could be made from straight wire as shown in Figure 2b. The wire could have a cutting edge or be impregnated with diamonds or other material, or could be shaped with a cutting edge (e.g. diamond shape) to help fragment the thrombotic material or to enable the device to remove etheroma or neo-intimal hyperplasia. The fragmentation cage 16 should be able to expand from the inner lumen of the introducer sheath 12 to fill the entire inner lumen of the vascular conduct--generally 6.0mm in the case of a dialysis fistula.

Figure 3 shows an alternative embodiment for the fragmentation catheter. The fragmentation cage 16 would connect to a hub 26 on its distal end and to a shaft 28 with an inner lumen on its proximal end. A guide wire 30 would be able to pass through the inner lumen of shaft 30 and hub 26. As a result, the guide wire 30 could be positioned in the vascular conduit (not shown) and the fragmentation cage 16 could be controlled by handles 20 and 22 (not shown) to be moved along the guide wire 30. An optional section means 31 could attach to the proximal end of the inner lumen of shaft 30 and draw debris homogenized by the catheter from the vessel.

Figure 4a is an anatomical view of the dialysis fistula showing how the catheter system would be deployed; Figures 4b and 4c show how the catheter system could be deployed to fragment and homogenize thrombic material. First, a guide wire would be inserted through a needle or through a slit into the graft and advanced to the far end of the thrombus. Then the introducer sheath 10 is advanced along the guide wire to the far end of the thrombus and

the guide wire is removed. Then the fragmentation catheter is advanced along the introducer sheath 10 to is distal end. This process is done under fluoroscopic control. Once in the proper position, the fragmentation catheter is advanced and the fragmentation cage 16 is deployed (see Figures 4b and 4c). The fragmentation cage 16 will automatically expand and match the dimensions of the inner lumen graft. The motor drive is attached and the rotating fragmentation cage is slowly withdrawn through the clotted graft, mechanically fragmenting the clot. The fragmentation catheter may be advanced and withdrawn a second time further homogenizing the thrombotic material. After the device is withdrawn, the graft is checked for residual clot using radiographic contrast dye under fluoroscopy. The fragmentation catheter is then reintroduced as needed. The inventor has found that rotatory of the fragmentation cage at 2000 rpm nicely fragments the thrombotic material generally smaller than 2.0mm, although other speeds can be used. The homogenized thrombic debris is carried safely away by the venous circulation. The device can homogenize blood clots and/or other obstructing material such as possibly neo-intimal hyperplasia or etheroma.

The inventor has described the use of the fragmentation catheter in a retrograde fashion, but the fragmentation catheter can also homogenize thrombus when advanced forward. When used with a dialysis fistula the flow of blood may be clamped or otherwise reduced, or eliminated. Several passes of the rotating fragmentation cage can then be made through the thrombotic material, until it is fully homogenized, before the debris is deposited into the venous system.

Although Figure 4 describes the use of the device in a dialysis fistula, it would work equally well in any vascular conduit such as a synthetic vascular graft, Hickman catheter, indwelling catheter, or peripheral graft. The device may also be used directly in natural blood vessels.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims the invention may be practiced otherwise than as specifically described.

What is claimed is:

1. A percutaneous mechanical fragmentation catheter system comprising:

an introducer sheath adapted to be percutaneously inserted into a vascular conduit in a living body;

a fragmentation catheter having a self-expandable fragmentation member operably connected at its proximal end to a flexible drive shaft, said fragmentation catheter adapted to be advanced through said introducer sheath, wherein said self-expandable fragmented member automatically expands to accommodate the inner lumen of the conduit and applies pressure radially against the inner lumen; and

an external drive mechanism coupled to the proximal end of said flexible drive shaft for rotating said expandable fragmentation member to fragment thrombotic material in said vascular conduit.

2. The catheter system of claim 1, wherein said self-expandable fragmentation member comprises a plurality of bowed wires, forming a cage, wherein the normal relaxed position of the wires would bias then to bow outward.

3. The catheter system of claim 1, wherein said self-expandable fragmentation member is a stone basket.

4. The catheter system of claim 2, wherein said wires are spring tempered wires.

5. The catheter system of claim 2, wherein said cage forms a spiral.

6. The catheter system of claim 2, wherein said bowed wires have a cutting edge.

7. The catheter system of claim 1, wherein said vascular conduit is a dialysis fistulae.

8. The catheter system of claim 1, wherein said vascular conduit is a synthetic vascular graft.

9. The catheter system of claim 1, wherein said vascular conduit is an indwelling catheter.

10. The catheter system of claim 1, wherein said vascular conduit is a Hickman catheter.

11. The catheter system of claim 1, wherein said vascular conduit is a peripheral graft.

12. The catheter system of claim 1, wherein said flexible drive shaft has an inner lumen, wherein said fragmentation member has a connection hub, and wherein a guide wire is inserted through the shaft lumen and through the connecting hub, whereby the fragmentation member rotates around the guide wire.

13. The catheter system of claim 12, wherein a suction means is attached to the proximal end of the drive shaft inner lumen for removing homogenized debris.

14. A method for fragmenting thrombotic material in a vascular conduit comprising the steps of:

advancing an introducer sheath to the far side of a thrombotic occlusion;

deploying a fragmentation catheter, whereby the fragmentation catheter has a distal fragmentation member that automatically expands to conform to the shape and size of the inner lumen of the vascular conduct; and

rotating the fragmentation catheter to homogenize the thrombotic material and allowing the debris to enter the venous system.

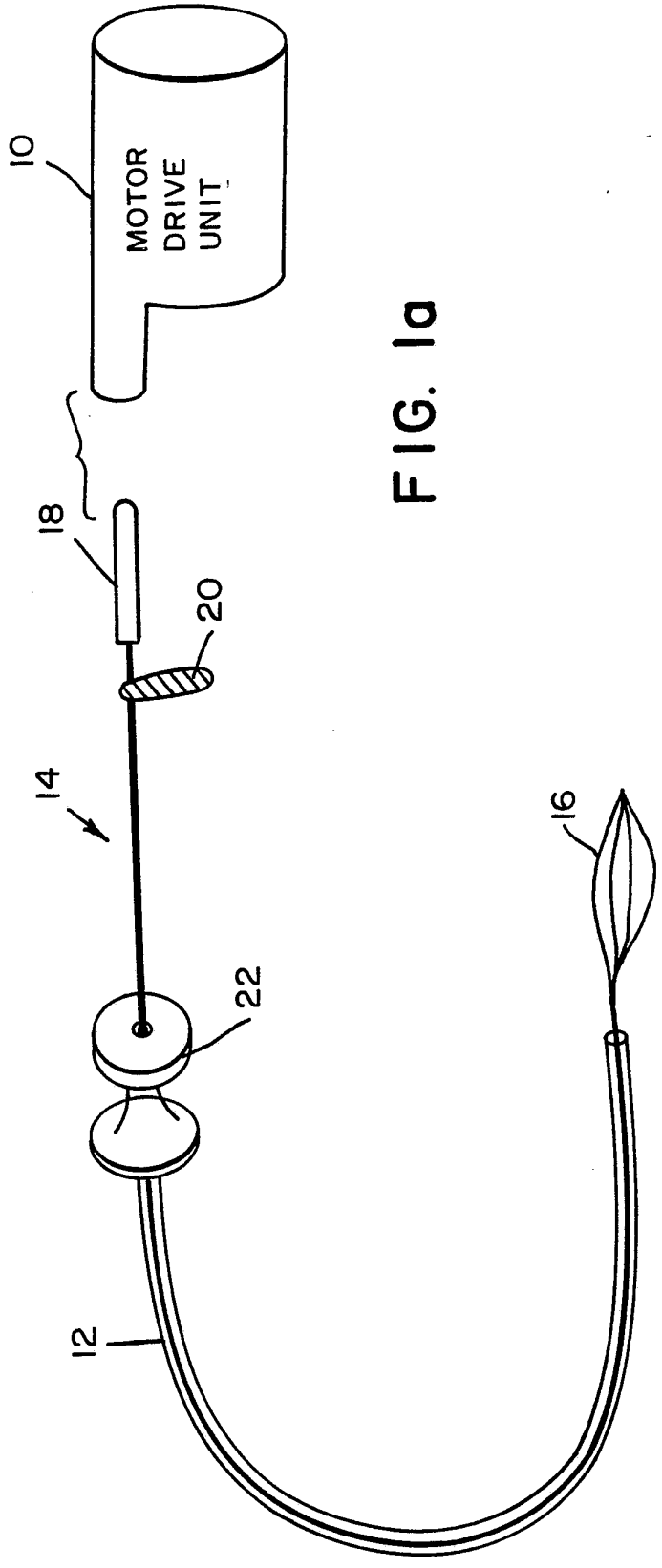

FIG. 1a

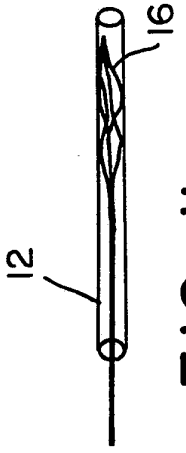

FIG. 1b

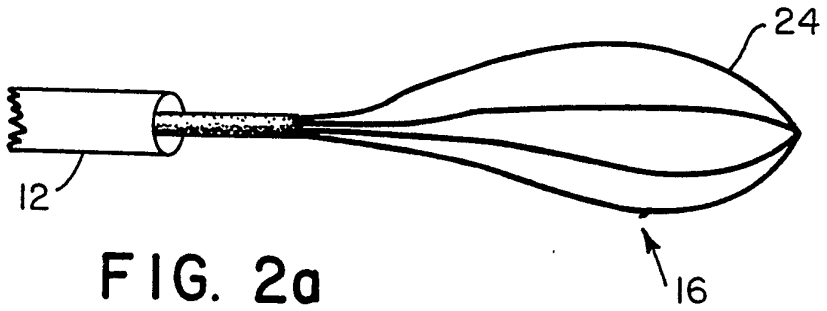

FIG. 2a

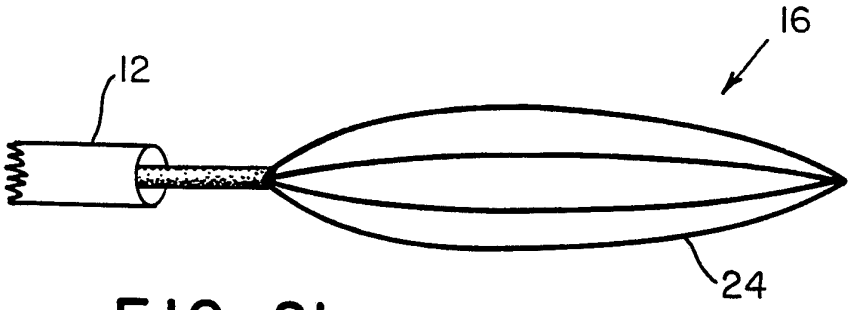

FIG. 2b

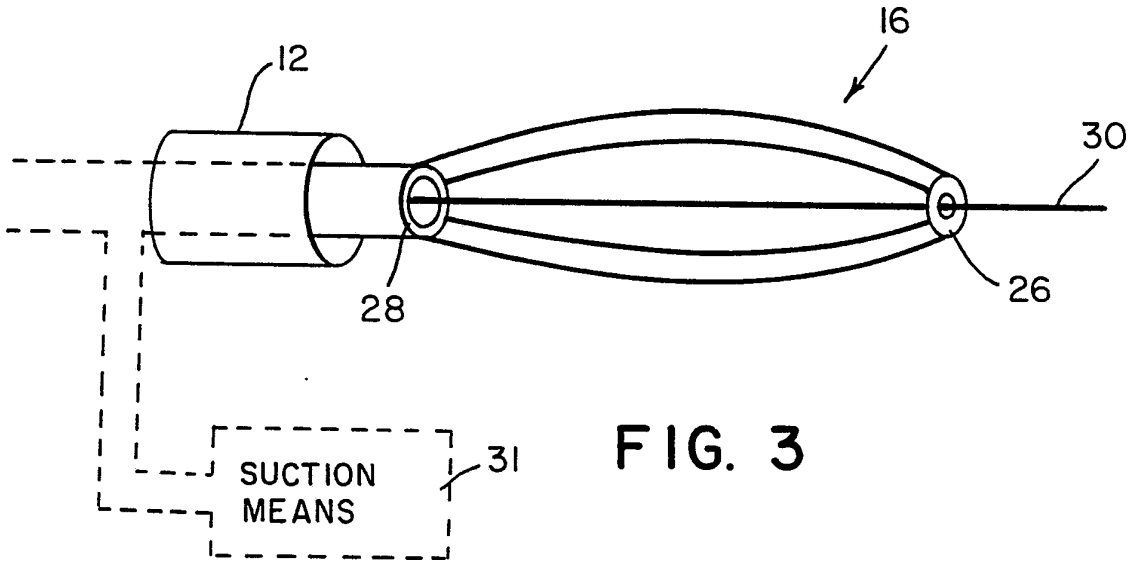

FIG. 3

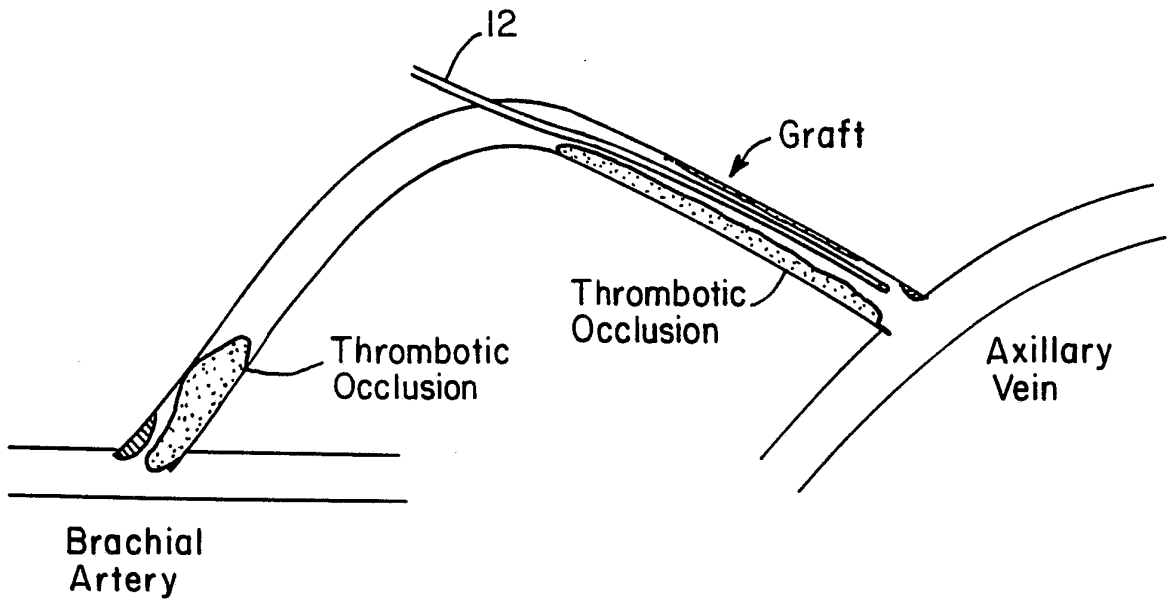
12
Graft
Thrombotic Occlusion
Thrombotic Occlusion
Axillary Vein
Brachial Artery

FIG. 4a

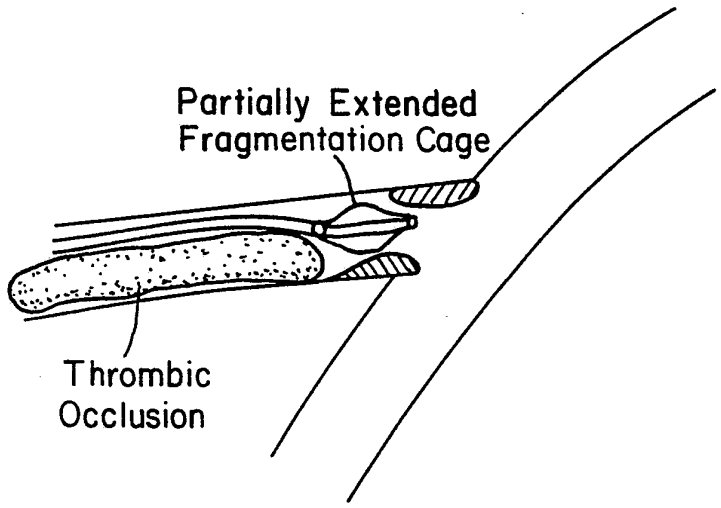
Partially Extended Fragmentation Cage
Thrombic Occlusion

FIG. 4b

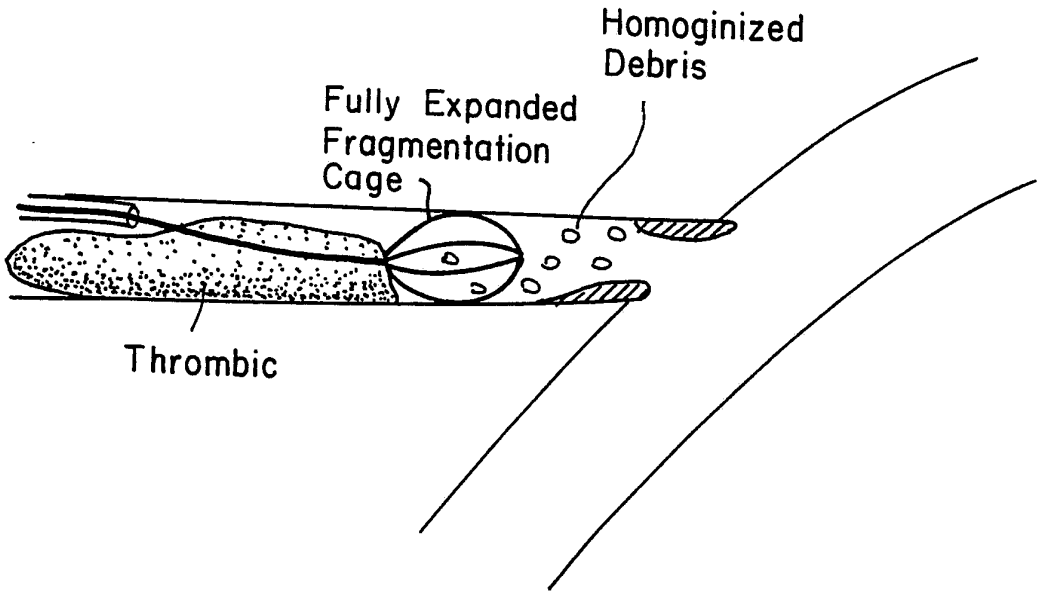
Homoginized
Debris
Fully Expanded
Fragmentation
Cage
Thrombic

FIG. 4c

INTERNATIONAL SEARCH REPORT

PCT/US93/03213

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 17/22, 17/32

US CL :606/159

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

B. FIELDS SEARCHED

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U.S. : 606/159 606/113,127,128,167,170,171,191,194; 604/164,264

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A, 5,030,201 (Patestrant) 09 July 1991 See the entire document.	1-4,6-14
Y	US,A, 4,926,858 (Gifford et al.) 22 May 1990 See the entire document.	1-5
Y,P	US,A, 5,192,291 (Pannek) 09 March 1993 See the entire document.	1-4,6-14
Y,P	US,A, 5,158,564 (Schnepp-Pesch et al.) 27 October 1992 See the entire document.	1-12
Y	US,A, 5,100,423 (Fearnot) 31 March 1992 See the entire document.	1-12

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Arch Sug. 12-72, Greep et al., A Combined Technique For Peripheral Arterial Embolectomy, Vol. 105 (December 1972) pp. 869-873	14
Y	Radiology, . July 1991, Schmitz-Rode et al., New Device For Percutaneous Fragmentation of Pulmonary Emboli, Vol, 180, No. 1, pp. 135-137.	14