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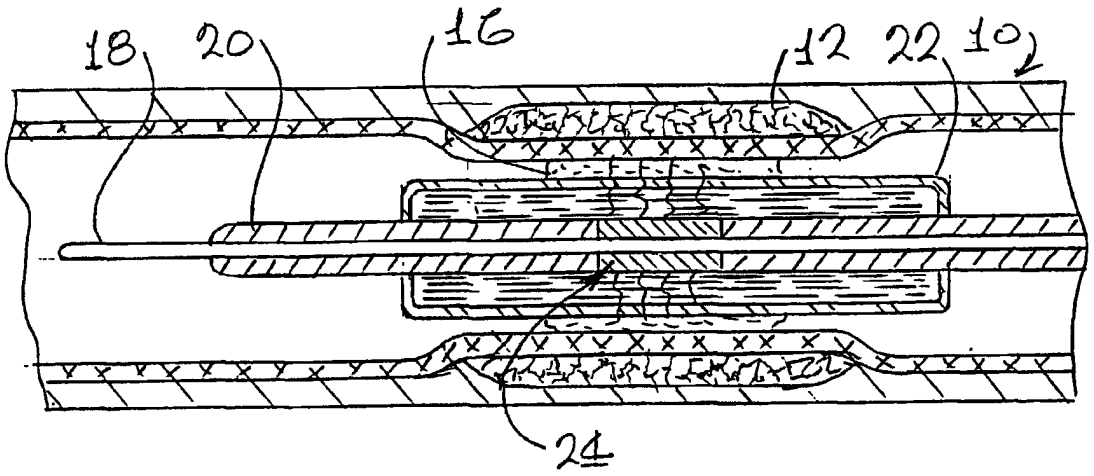
(54) Title: ANGIOPLASTY CATHETER WITH TRANSDUCER USING BALLOON FOR FOCUSING OF ULTRASONIC ENERGY



(57) Abstract: A catheter (20) for insertion into any artery having deposits of plaque, and/or thrombus includes, at its distal end an ultrasonic transducer (24), a dilatation balloon (22) surrounding the transducer such that when the balloon is in position in the artery, energizing of the ultrasonic transducer will focus the ultrasonic energy against the deposits to cause dissolution of the thrombus into microscopic particles. Other embodiments include the provision of a second ultrasonic transducer (32) as a means for viewing the treatment site, a second balloon (44) to cooperate with the first balloon to define a chamber between the balloons with a lumen, and a port (46) connected to the chamber to remove any debris larger than microscopic size. Also described is the use of an expandable filtering device (34) distal of the dilatation balloon for trapping such particles. Subsequently to the ultrasonic radiation of the deposits the dilatation balloon can be further inflated to force a stent (52) into the wall of the artery.

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ANGIOPLASTY CATHETER WITH TRANSDUCER USING BALLOON FOR FOCUSING OF ULTRASONIC ENERGY

BACKGROUND OF THE INVENTION

This invention relates to an ultrasonic angioplasty device for insertion into arteries for treating of obstructions caused by plaque and thrombi and more particularly to a vascular catheter which combines balloon dilatation capabilities with ablation through ultrasonic treatment of such obstructions.

One of the obstructions encountered in percutaneous transluminal angioplasty is thrombus or a blood clot which develops within the artery and the other is plaque which is present in the wall of the artery. Occasionally during balloon angioplasty the migration of large particles of thrombus material or plaque results either in damage to the blood vessel wall or movement of loose material into the blood vessel lumen causing reclosure or closure of other vessels. Similarly, it is sometimes difficult to dispel a large thrombus burden.

There have been a number of patents dealing either with the balloon angioplasty in combination with ultrasonic imaging means or with balloon angioplasty combined with removal of plaque and/or thrombi.

Patent No. 4,924,863 to Sterzer describes a method of removing plaque using two juxtaposed catheters in a vas. At the distal end of one catheter is a balloon which is inflated asymmetrically so that it presses against one side of the vas. The other catheter includes a heating element which, when the balloon is inflated presses the heating element against the region of plaque to be treated. Just enough heat is applied through microwave or radio frequency energy to cause some melting of the fatty plaque deposit. Suction is then applied to the second catheter to pull the liquefied plaque material out from the proximal end of the catheter. Where the plaque has become calcified, an ultrasonic transducer is substituted for the heating element

and is employed to ablate material from the surface of the plaque deposit and the ablated material is removed by suction applied to the proximal end of the second catheter.

Patent No. 5,195,955 to Don Michael shows a catheter in an artery obstructed by plaque and/or thrombus. The catheter includes a balloon designed to inflate asymmetrically, but to seal off the artery except for limited flow through one lumen of the catheter. Ports are supplied on opposite sides of the inflated balloon which permit limited flow of blood through the lumen, but the balloon seals off the artery so that debris from a separate procedure operating proximally of the balloon to remove the obstruction does not flow downstream. A separate lumen is described for applying suction to remove the debris.

Patent No. 5,118,831 to Yue-Teh Feng et al shows a vascular catheter with tandem imaging and dilatation components located in its distal end. Separate lumens within the catheter permit different fluids to be used for inflating the balloon and for ultrasonic imaging. A rotatable cable drives a rotatable scanning mirror which receives sonic signals from an adjacent transducer. This patent describes a straightforward angioplasty procedure enhanced by the use of an ultrasonic scanning device in the same catheter.

A recent article in The Journal of Invasive Cardiology, Vol. 10/Supplement A dated March 10, 1998 entitled "Mechanical Thrombectomy in Acute Ischemic Syndromes: Cutters, Suckers, and Busters" by Jeffrey W. Moses M.D. deals with many of the above problems and with methods and apparatus for dealing with such problems.

It seems clear that although many techniques have been devised for dealing with the problems discussed above, none are universally useful. While one method or technique may be helpful in one situation, it may not help in another. In particular there is a need for a device or apparatus which can remove or substantially ameliorate plaque and thrombi deposits while

minimizing the danger from migration of large particles of debris.

SUMMARY OF THE INVENTION

A unique feature of the present invention is the mounting of an ultrasonic device on the distal end of the catheter inside the span of the balloon on the catheter so that the balloon, when inflated, can focus and deliver ultrasound energy to two pathologic sites within the artery, i.e., the thrombus and the plaque sites. By focusing or concentrating ultrasound energy to the thrombus and the plaque deposits, the thrombus can be caused to disintegrate into microscopic sized particles which can pass into the circulatory system without damage to other vessels downstream. At the same time, or during the same procedure, the concentrated ultrasonic energy tends to fracture and thereby soften plaque deposits.

Depending upon the nature of the obstruction, the cardiologist may be concerned that larger sized thrombus particles or plaque particles may escape downstream and cause blockage of additional vessels. Applicant has devised a catheter arrangement utilizing a second balloon on the catheter distal of the first balloon thereby defining a chamber within the artery and between the balloons into which any such larger particles are contained. A port in the catheter wall communicates with this chamber and is connected to a source of negative pressure for drawing the debris from the chamber and out the proximal end of the catheter.

Another embodiment of this invention utilizes an expandable umbrella-like element carried on the catheter downstream of the balloon and the ultrasonic transducer. This device, which may constitute a filter capable of passing normal blood, is expanded at the time the ultrasonic transducer is energized to trap any larger particles, preventing them from moving

downstream. At the end of the procedure, the umbrella-like element is collapsed around the larger particles which are then removed along with the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

This invention may be more clearly understood with the following detailed description and by reference to the drawings in which:

Fig. 1 is a cross-sectional view of an artery substantially blocked by plaque and thrombus;

Fig. 2 is a cross-sectional view of the artery of Fig. 1 with a balloon catheter placed in the artery and an ultrasound transducer within the balloon;

Fig. 3 is a cross-sectional view of the artery of Figs. 1 and 2 with the balloon inflated at low pressure;

Fig. 4 is a cross-sectional view of the artery of Figs. 1-3 showing another embodiment of the invention;

Fig. 5 is a cross-sectional view similar to Fig. 4 showing an additional embodiment of the invention; and

Fig. 6 is a cross-sectional view similar to that of Fig. 1 in which the obstruction is only plaque.

DETAILED DESCRIPTION OF THE INVENTION

Referring to Fig. 1, there is shown a portion of the length of an artery 10 such as a coronary artery. The lumen of artery 10 is partially occluded by artherosclertic plaque 12 embedded in the wall of artery 10 between the inner layer or intima 11 and the central layer or media. Because of the presence of calcified plaque 12 a crack or ulceration 14 has occurred in the intima 11 resulting in a blood clot or thrombus 16 which has substantially blocked flow through artery 10. Inserted through thrombus 16 is a guide wire 18 and a catheter 20 carrying a balloon 22. This represents a typical prior art balloon angioplasty arrangement in which the balloon, when inflated as shown by the dashed lines, significantly opens the occluded part of the artery by pressing the thrombus against the internal wall of artery 10.

While the above procedure is often successful, at least for a time, problems frequently occur because the procedure may result in creation of large aggregates of thrombus material which float downstream, block capillaries, reduce flow and produce some degree of micro-infarction. As a result, patients may develop ventricular tachycardia, accelerated idioventricular rhythm or complete heart block. While these problems are currently dealt with through the use of 23B platelet inhibitors, this is associated with a risk of bleeding.

Applicant's device and method minimizes the above risks by using the balloon to trap the thrombus and to serve as a focusing device and coupling device to efficiently deliver ultrasonic energy into the thrombus. Referring now to Fig. 2, the catheter 20 carrying a balloon 22 at its distal end is inserted into artery 10 and through thrombus 16 along guide wire 18. Catheter 20 will typically carry a plurality (such as three) internal lumens to inflate the balloon, to slide over a guidewire and to carry wires for electrical energy or imaging. These have not been shown to

avoid unnecessarily confusing the drawings. Carried on catheter 20 is an ultrasonic transducer 24 (typically a piezoelectric member) connected to an ultrasonic signal source (not shown) adjacent the proximal end of catheter 20. With the catheter 20, balloon 22 and transducer 24 positioned within artery 10 as shown, the balloon 22 is inflated to a moderate pressure (1 to 3 atmospheres) through injection of an aqueous solution containing a contrast agent as an aid in viewing the process as shown in Fig. 3. The balloon 22 thus presses against or traps the thrombus 16 against the inner layer or intema 11 wall of artery 10. Following inflation of the balloon 20, the ultrasonic transducer 24 is energized causing ultrasonic energy to pass through the inflated balloon to the thrombus 16. The aqueous solution in the balloon 22 readily transmits and focuses energy to the thrombus which breaks up the thrombus into microparticulate matter with particles as small as 8 to 10 microns. This matter can then flow through the patient's system without producing any of the adverse effects referred to above including no flow or slow flow.

The ultrasonic energy from transducer 23 also creates microfractures within the calcified plaque 12 which is embedded in the wall of artery 10. This leaves the plaque 12 softer and in better condition to be dealt with by other interventional modalities such as mechanical ablation or intracoronary stent.

Depending upon the nature of the plaque 12 and the thrombus material 16 the cardiologist may have concerns that either plaque particles or thrombus particles of significantly larger size than the microscopic particles referred to above may tend to flow downstream of the obstruction following the ultrasonic radiation process referred to above. In such case, a catheter arrangement like that of Figs. 4 or 5 may be used. In Fig. 4, a catheter 30 is inserted over guide wire 18 into an artery 10 occluded by plaque deposits 12 and thrombus 16. In additional to balloon 22 and ultrasonic transducer 24, catheter 30 also carries a second ultrasonic transducer 32 used as an

imaging device for assisting the cardiologist in observing the obstruction and the results of the ultrasonic radiation process. A collapsible and expandable umbrella-like shield 34 is positioned a short distance distally of the transducer 32 and is shown in opened configuration where it blocks the passage further downstream of larger particles of plaque or thrombus material. Shield 34 may act as a filter passing normal blood components but blocking larger particles. Following completion of the above described ultrasonic radiation procedure, the balloon 22 is deflated and shield 34 is collapsed over the particles trapped within it and the catheter 30 is withdrawn.

In Fig. 5, a catheter 40 is fed into artery 10 over a guide wire 18. Catheter 40 carries a balloon 22, an ultrasonic transducer 24, a second ultrasonic transducer 42 and a second balloon 44. Balloon 22 is placed in artery 10 within plaque deposits 12 and a thrombus 16. Energizing of ultrasonic transducer 24 operates as described above to cause dissolution of the thrombus 16 and to crack and soften the plaque deposit 12. Transducer 42 is for imaging as described above. Full inflation of the second balloon 44 blocks any flow downstream of itself and traps any large particles which result from ultrasonic irradiation of the plaque 12 and thrombus 16. A port 46 connected to an additional lumen (not shown) within catheter 40 is connected to a vacuum source which is operated to withdraw all the contents of the chamber between balloons 22 and 44 to the proximal end of catheter 40 and out of the artery 10. Following this, the balloons are deflated and catheter 40 is withdrawn from artery 10.

In some cases, the artery is substantially blocked by plaque deposits only. The balloon angioplasty process described above may be used to fracture and soften the plaque deposits. Alternatively, the process may have resulted in dissipating a thrombus. In either case, what remains is an artery whose internal wall is cracked and damaged, but with softened and fractured plaque remaining in the wall. This situation presents a considerable danger of migrating plaque

particles or thrombus reforming at essentially the same location.

One way of treating the damaged artery 10 is as shown in Fig. 6. Assuming that one of the above processes has been completed, the catheter 20, 30 or 40 is removed and a new catheter 50 is inserted over guide wire 18 in which an intracoronary stent or sleeve 52 (typically of stainless steel) is placed over the balloon 54. Once located within the softened plaque deposit 12, the balloon 54 is inflated to a greater pressure than described above (up to 6-8 atmospheres) which causes stent 52 to become embedded in the artery wall, thereby closing off any cracks or fissures in the artery wall and eliminating the major source of thrombi.

Since time is often a concern with the above processes, another method is to place the stent over the balloon 22 at the outset. The process is then carried out as described in connection with Figs. 2 and 3. Balloon 22 is then deflated permitting the material from thrombus 16 to be carried away after which the balloon 22 is again inflated to the higher pressure (up to 6-8 atmospheres) again forcing the stent 52 into the internal wall of the artery to seal off or close any cracks or fissures. A similar process can be used with the catheters of Figs. 4 and 5 in which a similar stent can be placed over the balloon 22.

The above-described embodiments of the present invention are merely descriptive of its principles and are not to be considered limiting. The scope of the present invention instead shall be determined from the scope of the following claims including their equivalents.

CLAIMS

I Claim:

1. A catheter for insertion into an artery having an interior wall and deposits of plaque and/or thrombus, said catheter comprising an elongated body including at least one lumen and having a proximal end and a distal end;

a dilatation balloon located generally at the distal end of said catheter for positioning within an artery in the region of said deposits and means for inflating and deflating said balloon;

a transducer carried by said catheter and positioned within said balloon and means for supplying power to said transducer such that energy is projected through said balloon into said deposits.

2. A catheter as claimed in Claim 1 further comprising a guide wire to be inserted into said artery and wherein said catheter is inserted over said guide wire.

3. A catheter as claimed in Claim 1 further comprising a second balloon located on said catheter distal of said dilatation balloon, a port positioned on said catheter between said dilatation balloon and said second balloon, a lumen connected to said port and negative pressure means connected to said lumen.

4. A catheter as claimed in Claim 1 further comprising an expandable member secured to said catheter distal of said dilatation balloon, and means to expand said member to substantially block said artery and to collapse said member against said catheter.

5. A catheter as claimed in Claim 1 wherein said deposits include a thrombus, said dilatation balloon is positionable within said thrombus and inflatable to press said thrombus against said interior wall of said artery, and energizing of said transducer causes energy to be transmitted through said balloon to said thrombus to substantially reduce said thrombus.

6. A catheter as claimed in Claim 1 further comprising a second ultrasonic transducer secured to said catheter for providing images of said deposits.

7. An angioplasty device for insertion into an artery having an interior wall and having deposits of plaque comprising:

an elongate flexible catheter having a proximal end, a distal end, and at least one lumen extending longitudinally therethrough:

a transducer at the distal end of said catheter and means for energizing said transducer; and

an annular dilatation balloon at the distal end of said catheter surrounding said transducer and means for inflating said balloon such that when said transducer is energized, energy from said transducer is transmitted through said balloon to said deposits.

8. A catheter as claimed in Claim 7 wherein said deposits include a thrombus, said dilatation balloon is positionable within said thrombus and inflatable to press said thrombus against the interior wall of said artery, and energizing of said transducer causes energy to be transmitted through said balloon to said thrombus to substantially reduce said thrombus.

9. An ultrasonic angioplasty device as claimed in Claim 7 further comprising a stent to be placed over said dilatation balloon such that further inflation of said dilatation balloon forces said stent into the wall of said artery.

10. An ultrasonic angioplasty device for insertion into an artery having an internal wall and plaque deposits within said wall comprising:

an elongated flexible catheter having a proximal end, a distal end and at least one lumen extending longitudinally therethrough:

an ultrasonic transducer near the distal end of said catheter and means for energizing said transducer;

an annular dilatation balloon near the distal end of said catheter surrounding said transducer; and

means for inflating said balloon until its surface is adjacent the inner wall of said artery at the location of said plaque deposits such that when said transducer is energized, ultrasonic energy from said transducer is transmitted through said balloon to said deposits to fracture and soften said deposits.

11. An ultrasonic angioplasty device as claimed in Claim 10 wherein a thrombus is located in said artery adjacent said plaque deposits; and

energizing of said ultrasonic transducer causes dissolution of said thrombus.

12. An ultrasonic angioplasty device as claimed in Claim 10 wherein a second balloon is carried on said catheter distal of said dilatation balloon, said balloons when inflated defining a chamber in said artery between said balloons, a port is located in said catheter between said balloons; and

a lumen is connected to said port and to a source of negative pressure for withdrawing debris from said chamber.

13. An ultrasonic angioplasty device as claimed in Claim 11 wherein a second balloon is carried on said catheter distal of said dilatation balloon, said balloons when inflated defining a chamber in said artery between said balloons, a port is located in said catheter between said balloons; and

a lumen is connected to said port and to a source of negative pressure for withdrawing debris from said chamber.

14. An ultrasonic angioplasty device as claimed in Claim 11 further comprising an expandable artery blocking device carried on said catheter distal of said dilatation balloon, and means for expanding said device to temporarily block said artery and for collapsing said device following energizing of said transducer to trap debris between said device and the surface of said catheter.

15. An ultrasonic angioplasty device as claimed in Claim 14 wherein said expandible artery blocking device functions as a filter to permit normal blood flow through said device.

16. An ultrasonic angioplasty device as claimed in Claim 12 wherein following energizing of said transducer said balloons are collapsed and said catheter is withdrawn from said artery.

17. An ultrasonic angioplasty device as claimed in Claim 13 wherein following energizing of said transducer said balloons are collapsed and said catheter is withdrawn from said artery.

18. An ultrasonic angioplasty device as claimed in Claim 10 further comprising a stent to be placed in said artery over said balloon at the location of said deposits such that inflation of said dilatation balloon forces said stent into the wall of said artery.

19. An ultrasonic angioplasty device as claimed in Claim 11 further comprising a stent to be placed in said artery over said balloon at the location of said deposits such that inflation of said dilatation balloon forces said stent into the wall of said artery.

AMENDED CLAIMS

[received by the International Bureau on 15 November 2000 (15.11.00) ;
original claims 1-19 replaced by new claims 1-10 (3 pages)]

1. An angioplasty device for insertion into an artery having an interior wall and having undesired deposits comprising:

an elongate flexible catheter having a proximal end, a distal end, and at least one lumen extending longitudinally therethrough:

first and second transducers at the distal end of said catheter and means for energizing said transducers; and

an annular dilatation balloon at the distal end of said catheter surrounding said transducer and means for inflating said balloon such that when said transducers are energized, energy from said transducer is transmitted through said balloon to said deposits.

2. An ultrasonic angioplasty device as claimed in Claim 1 further comprising a stent to be placed over said dilatation balloon such that further inflation of said dilatation balloon forces said stent into the wall of said artery.

3. An ultrasonic angioplasty device as claimed in Claim 1 further comprising an expandable artery blocking device carried on said catheter distal of said dilatation balloon, and means for expanding said device to temporarily block said artery and for collapsing said device following energizing of said transducer to trap debris between said device and the surface of said catheter.

4. An ultrasonic angioplasty device as claimed in claim 1 wherein said second ultrasonic transducer is energized to provide images of said deposits.

5. An ultrasonic angioplasty device as claimed in Claim 1 wherein said expandible artery blocking device functions as a filter to permit normal blood flow through said device.

6. An ultrasonic angioplasty device for insertion into an artery having an internal wall and undesired deposits within said wall comprising:

an elongated flexible catheter having a proximal end, a distal end and at least one lumen extending longitudinally therethrough:

an ultrasonic transducer near the distal end of said catheter and means for energizing said transducer;

an annular dilatation balloon near the distal end of said catheter surrounding said transducer;

means for inflating said balloon until its surface is adjacent the inner wall of said artery at the location of said undesired deposits such that when said transducer is energized, ultrasonic energy from said transducer is transmitted through said balloon to said deposits; and

a second ultrasonic transducer secured to said catheter for providing images of said deposits.

7. An ultrasonic angioplasty device as claimed in Claim 5 wherein a second balloon is carried on said catheter distal of said dilatation balloon, said balloons when inflated defining a chamber in said artery between said balloons, a port is located in said catheter between said balloons; and

a lumen is connected to said port and to a source of negative pressure for withdrawing debris from said chamber.

8. An ultrasonic angioplasty device as claimed in Claim 5 further comprising an expandable artery blocking device carried on said catheter distal of said dilatation balloon, and means for expanding said device to temporarily block said artery and for collapsing said device following energizing of said transducer to trap debris between said device and the surface of said catheter.

9. An ultrasonic angioplasty device as claimed in Claim 7 wherein said expandible artery blocking device functions as a filter to permit normal blood flow through said device.

10. An ultrasonic angioplasty device as claimed in Claim 5 further comprising a stent to be placed in said artery over said balloon at the location of said deposits such that inflation of said dilatation balloon forces said stent into the wall of said artery.

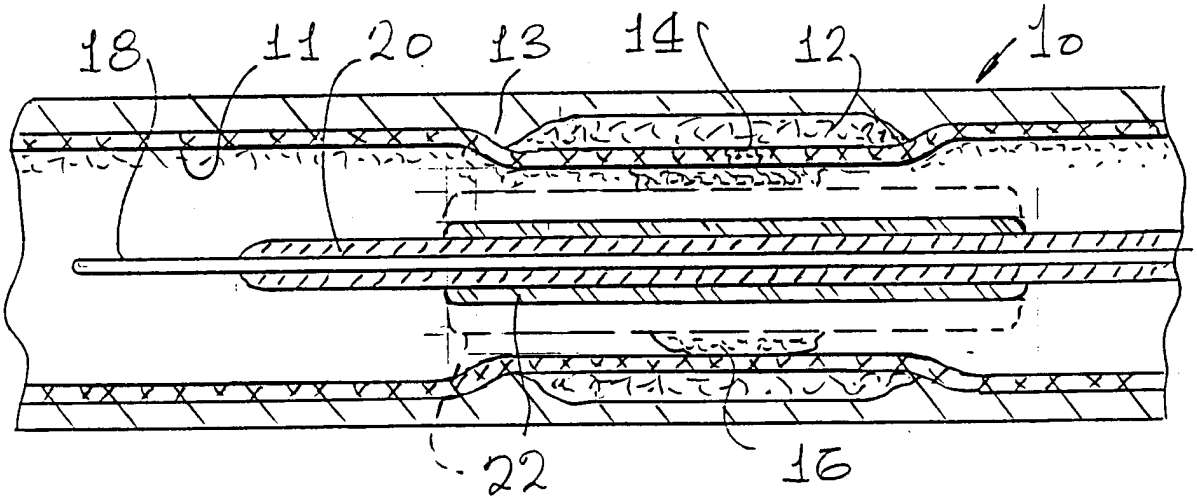


FIG 1
PRIOR ART

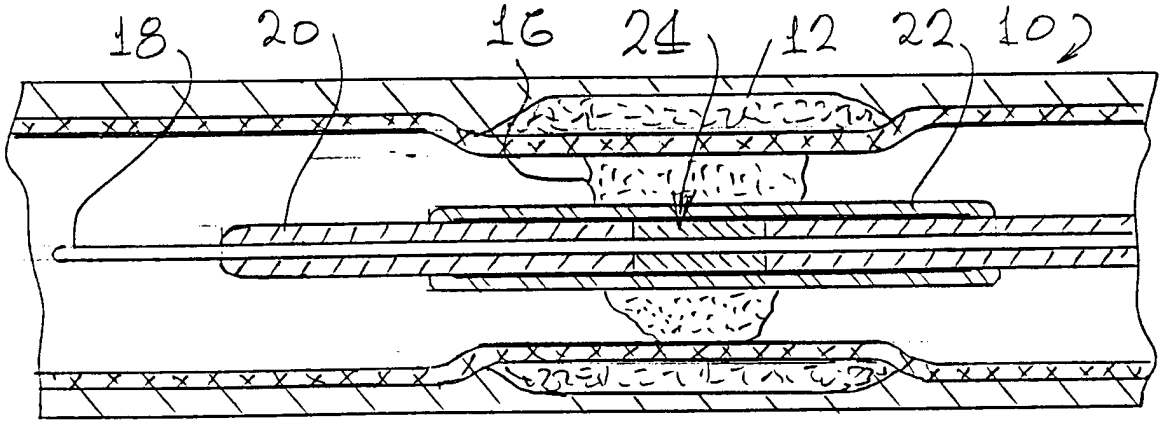


FIG 2

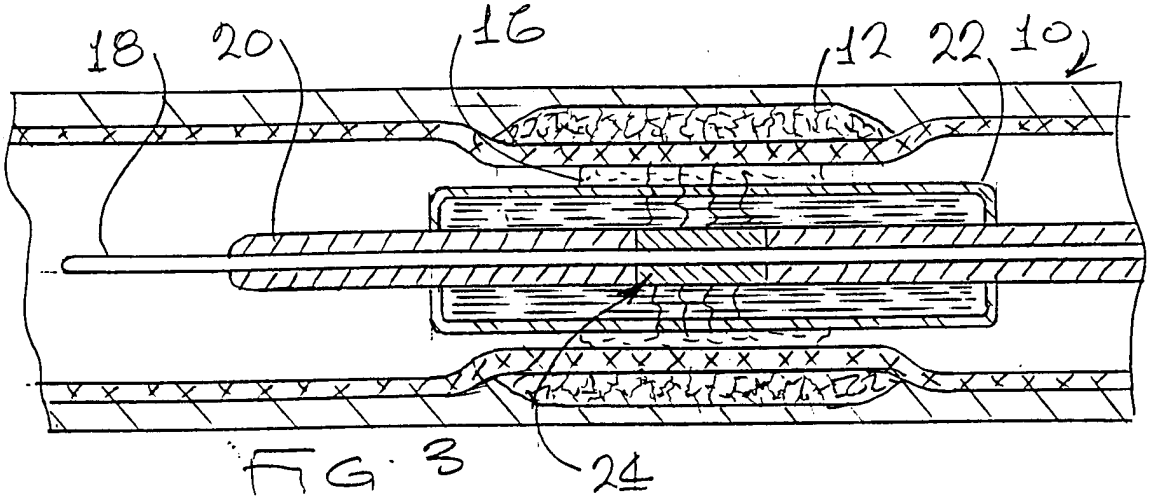


FIG 3

FIG 4

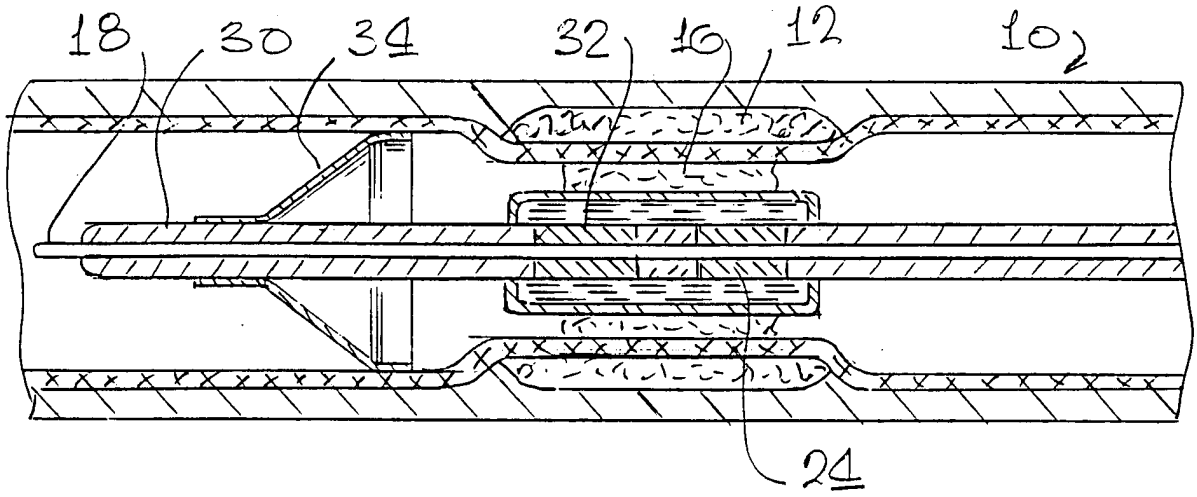


FIG 5

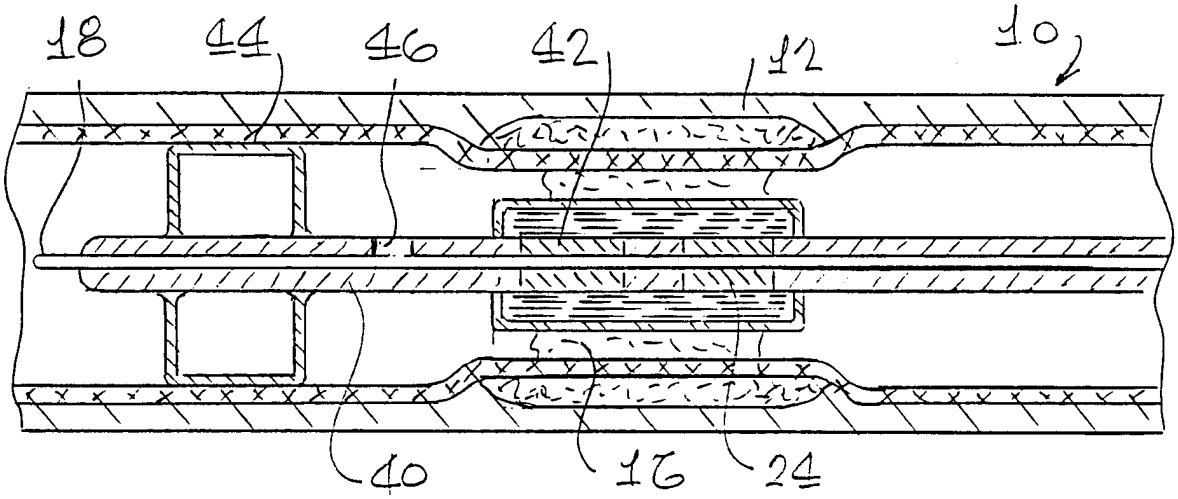
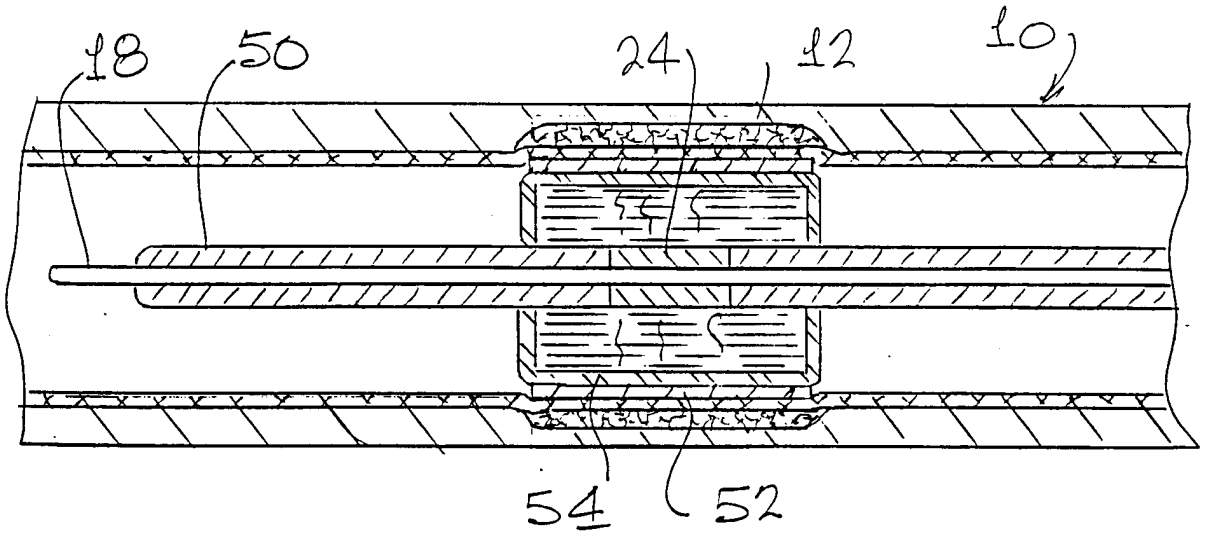


FIG 6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/17126

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/20
US CL :601/2; 604/22, 96; 606/169, 194
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)

U.S. : 601/2; 604/22, 96; 606/169, 194

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 practicable, 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 --- Y	US 5,846,218 A (BRISKEN et al) 08 December 1998, entire document.	1, 2, 5, 7-11, 18, 19 --- 3, 4, 6, 12-17
Y	US 5,222,941 A (DON MICHAEL) 29 June 1993, entire document.	3, 12, 13, 16, 17
Y	US 5,571,086 A (KAPLAN et al.) 05 November 1996, entire document.	6, 18, 19
Y	US 5,616,114 A (THORNTON et al.) 01 April 1997, entire document.	4, 14
Y	US 5,695,519 A (SUMMERS et al.) 09 December 1997, entire document.	15

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 10 AUGUST 2000	Date of mailing of the international search report 15 SEP 2000
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Form PCT/ISA/210 (second sheet) (July 1998)*

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当前申请(专利权)人(译)	奥康纳LAWRENCE		
[标]发明人	OCONNOR LAWRENCE		
发明人	O'CONNOR, LAWRENCE		
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外部链接	Espacenet		

摘要(译)

用于插入具有斑块和/或血栓沉积物的任何动脉的导管（20）在其远端包括超声换能器（24），围绕换能器的扩张球囊（22），使得当球囊处于适当位置时在动脉中，超声换能器的激励将使超声能量聚焦在沉积物上，从而使血栓溶解成微观颗粒。其他实施例包括提供第二超声换能器（32）作为观察治疗部位的装置，第二球囊（44）与第一球囊配合以在具有内腔的球囊之间限定腔室，以及端口（46））连接到腔室以去除任何大于微观尺寸的碎片。还描述了使用膨胀球囊远端的可膨胀过滤装置（34）来捕获这些颗粒。在沉积物的超声辐射之后，可以进一步使膨胀球囊膨胀以迫使支架（52）进入动脉壁。