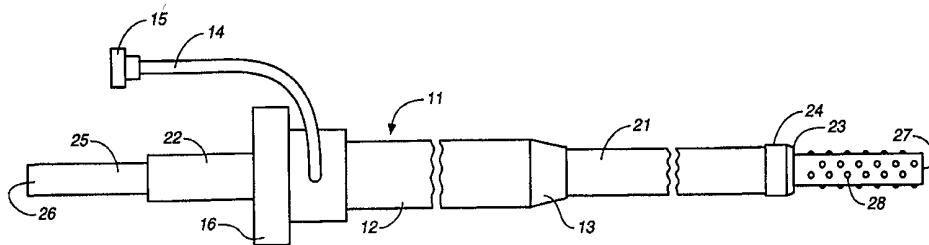




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(54) Title: A CATHETER DEVICE FOR ABRADING A PATENT FORAMEN OVALE AND METHOD OF USING THE DEVICE



## (57) Abstract

A device and method for closing a patent foramen ovale comprising a catheter sheath (21) with proximal and distal ends. An abrasive surface (28) on a member is deployably retained within the distal end of the catheter sheath (21). Once the catheter sheath (21) is placed by a treating health care professional across a patent foramen ovale, the abrasive member (28) is deployed outside of the distal end of the catheter sheath (21). When the abrasive member (28) has been deployed, the treating health care professional abrades the inner surfaces of the patent foramen ovale to thereby cause an area of thrombogenesis. The abrasive member (28) is then repositioned into the distal end of the catheter sheath (21), and is then removed from the patient. The thrombogenic area created along the inner surfaces of the patent foramen ovale then creates a thrombus which over time turns into a scar, and the foramen ovale is obliterated.

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## A CATHETER DEVICE FOR ABRADING A PATENT FORAMEN OVALE AND METHOD OF USING THE DEVICE

### FIELD OF THE INVENTION

The present invention is related generally to medical/surgical devices that can  
5 be placed within the body of a patient to perform a procedure. More specifically, the  
present invention is a minimally invasive device useful in closing a patent foramen  
ovale.

### BACKGROUND OF THE INVENTION

The fetal circulation is vastly different than the normal adult circulation.  
10 The blood circulating in a fetus is oxygenated by the placenta, not the developing  
lungs. Therefore, the fetal circulation directs only a small percentage of the  
circulating blood to the fetal lungs. Most of the circulating blood is shunted away  
from the lungs to the peripheral tissues through specialized vessels and  
foramens that are open ("patent") during fetal life. In most people these specialized  
15 structures quickly close after birth, unfortunately, sometimes they fail to close and  
create hemodynamic problems that can be fatal if left untreated.

The fetal circulation is illustrated in Fig. 1. The umbilical arteries branch off  
of the iliac arteries and deliver unoxygenated (blue) blood to the placenta. The fetal  
blood travels through the capillary bed in the placenta and transfers carbon dioxide  
20 to the maternal blood and takes oxygen and other nutrients from the maternal blood.  
The umbilical vein returns oxygenated (red) blood to the fetus. Most of the  
oxygenated blood from the umbilical vein bypasses the developing liver and travels  
through a specialized vessel called the ductus venosus to the inferior vena cava and  
then into the right atrium. A good portion of the oxygenated blood from the inferior  
25 vena cava is directed across the right atrium and into the left atrium through a  
specialized curtain like opening in the heart called the foramen ovale. The blood  
from the left atrium then enters the left ventricle and then into the aorta where it

travels to the head and other body tissues delivering the needed oxygen and nutrients.

The small amount of blood entering the right atrium that does not pass through the foramen ovale, most of which comes from the superior vena cava, flows into the right ventricle and then gets pumped into the pulmonary trunk and pulmonary arteries. Some of this blood is pumped into the developing lungs. However, the fetal lungs are collapsed which causes a high resistance to blood flow. Another specialized vessel, called the ductus arteriosus, is a vessel that connects the high pressure pulmonary artery to the lower pressure aorta. Therefore, most of the blood in the pulmonary artery flows into the lower pressure aorta through this specialized vessel.

Upon birth, the circulatory system goes through profound changes. The flow through the umbilical arteries and umbilical vein stops and consequently the flow through the musculature around the ductus venosus constricts and the blood flow through the ductus venosus stops. The lungs fill with air and the resistance to blood flow into the lungs drastically decreases. The corresponding pressure in the right atrium, right ventricle, and pulmonary arteries also decrease. The decrease in pressure in the right atrium causes the curtain like opening of the foramen ovale to close, driving more blood into the right ventricle and then to the lungs for oxygenation. Over time, the foramen ovale is replaced with a membrane called the fossa ovalis. Similarly, the decrease in pressure in the pulmonary arteries reduced the pulmonary arterial pressure to the same as or slightly less than the pressure in the aorta, which stops or reverses the flow through the ductus arteriosus. Once the muscular tissue of the ductus arteriosus is perfused with well oxygenated blood, the muscle begins to constrict and close the ductus arteriosus. The ductus arteriosus normally closes within about one week of life.

Usually over time, the unique openings of the fetal circulation become obliterated and a solid mass of tissue forms where these opening once were. However, in some people the openings remain. A patent ductus venosus after birth is very rare and almost always fatal. A patent ductus arteriosus occurs in about 1 out of every 5000 births. The patent ductus arteriosus once diagnosed is either

medically treated or surgically ligated to close the ductus. In about one of four people, the foramen ovale does not seal shut, instead it remains patent. Since the pressure in the left atrium is about two to four mm Hg greater than the pressure in the right atrium, the curtain like opening usually remains shut. However, if the  
5 pressure in the right atrium increases, such as upon heavy lifting or while performing a Val Salva type maneuver, the curtain like fold of tissue opens and the blood flows from the right atrium to the left ventricle.

Studies have shown that adults with strokes of unknown origin (cryptogenic strokes) have about twice the normal rate of patent foramen ovals than the normal  
10 population. Although there is a correlation between strokes and patent foramen ovals, it is currently unknown why this correlation exists. Many people theorize that blood clots and plaque that have formed in the peripheral venous circulation (in the legs for example) break off and travel to the heart. Normally, the clots and plaque get delivered to the lungs where it is trapped and usually cause no harm to the  
15 patient. Patients with a patent foramen ovale, however, have a potential opening that the clots or plaque can pass through the venous circulation and into the arterial circulation and then into the brain or other tissues to cause a thromboembolic event like a stroke. The clots may pass to the arterial side when there is an increase in the pressure in the right atrium. Then the clots travel through the left side of the heart,  
20 to the aorta, and then to the brain via the carotid arteries where they cause a stroke and the associated neurological deficits.

Currently, the method of choice to close a patent foramen ovale is open heart surgery and ligation of the foramen ovale to close it. This obviously is associated with the usually risks of general anesthesia, open heart procedures, infections, etc.  
25 Another method is a catheter based method which places two opposing umbrella shaped devices around the foramen ovale, one in the right atrium and one in the left atrium. Unfortunately, this procedure is technically difficult and leaves behind two foreign objects that could dislodge or cause a thromboembolus which could break off and cause thromboembolic events. What is needed therefore is a least invasive  
30 method for closing a patent foramen ovale which does not have the associated risk of an open heart procedure, is technically easy to perform, and which does not leave

any foreign material behind.

#### SUMMARY OF THE INVENTION

The present invention provides a device and method for closing a patent foramen ovale. The present invention comprises a catheter sheath with proximal and distal ends. An abrasive surface on a member is deployably retained within the distal end of the catheter sheath. Once the catheter sheath is placed by a treating health care professional across a patent foramen ovale, the abrasive member is deployed outside of the distal end of the catheter sheath. When the abrasive member has been deployed, the treating healthcare professional places the abrasive member in the patent foramen ovale and abrades the inner surfaces of the foramen ovale to thereby cause an area of abrasion. The abrasive member is then repositioned into the distal end of the catheter sheath and is then removed from the patient. The abraded area created along the inner surfaces of the patent foramen ovale will heal and over time turns into a scar obliterating the foramen ovale.

#### BRIEF DESCRIPTION OF THE DRAWINGS

As used herein, like reference numerals will designate similar elements in the various embodiments of the present invention wherein:

Fig. 1 is a schematic diagram of the fetal circulation of a mammal;

Fig. 2 is a schematic diagram of a catheter of the present invention traveling up the inferior vena cava of a mammal into the right atrium and through the foramen ovale;

Fig. 3 is a schematic plan view of a foramen ovale catheter of the present invention;

Fig. 4 is a cross-sectional view of an alternate embodiment of the distal end of the present invention;

Fig. 5 is a schematic plan view, partially is cross-section of a further embodiment of the distal end of the present invention;

Fig. 6 is a cross-sectional view of an additional embodiment of the distal end of the present invention;

Fig. 7 is a schematic plan view, partially is cross-section of yet a further embodiment of the distal end of the present invention;

5 Fig. 8 is a cross-sectional view of still a further embodiment of the distal end of the present invention;

Fig. 9 is a cross-sectional view of an additional embodiment of the present invention;

10 Fig. 10 is a schematic plan view of yet a further embodiment of the present invention;

Fig. 11 is a schematic plan view of still another embodiment of the present invention;

Fig. 12 is a schematic plan view of yet a further embodiment of the present invention; and

15 Fig. 13 is a schematic plan view of the embodiment of Fig. 12 in an actuated position;

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

20 The present invention provides a novel least invasive device and method for closing a patent foramen ovale in a mammal. The device is specifically designed to be used in catheterization laboratories in hospitals for treating humans as well as veterinary hospitals for treating animals. As used herein the term "patient" shall refer to human patients as well as animal patients. As illustrated in Fig. 2, the device is introduced into the blood stream using well known catheterization procedures.

25 The device is initially introduced within a catheter sheath 21 with a distal end 23. The device is then positioned to extend distally from the catheter sheath to span the patent foramen ovale. The device has a plurality of abrasive members on its outer surface such that the operator of the device can remove endothelial cells and create trauma to the area. The device is then removed from the patient. Once the  
30 endothelium has been removed and the area inside the patent foramen ovale has been

abraded, the body's healing mechanism begins. Because the pressure within the left atrium is greater than the pressure in the right atrium, the curtains of tissue that comprises the patent foramen ovale are directly opposed to each other. The body's healing mechanism then replaces the abraded tissue with scar tissue and the scar  
5 tissue forms across the curtain of tissue permanently sealing the foramen ovale. Over time, the foramen ovale becomes completely obliterated and turns into a normal fossa ovalis.

Turning now to Fig. 3, the foramen ovale catheter of the present invention is further illustrated. In order to obtain access to the blood stream, the foramen ovale  
10 catheter has to be advanced through the skin of the patient into a blood vessel, preferably a standard femoral vein catheterization is used that is well known in the art, however other vessel access to the atriums can be used. Typically, a standard introducer 11 is used to gain access from the skin of the patient to the lumen of the vessel. These introducers are commercially available from many different  
15 manufacturers, Cordis Corporation of Miami Florida being one, Cook of Bloomington Indiana being another. The introducer can be of many different sizes, in the preferred embodiment the introducer varies from a 6 French to a 15 French introducer. Presently it is preferred to use a 7 or 8 French introducer. The introducers usually have a hollow shaft 12, a tapered distal end 13, a catheter access  
20 port 16 with an internal seal (not illustrated) to ensure that fluids do not leak from the access port, and an irrigation port 15 connected via flexible tubing 14. The irrigation port is used to flush the introducer and to inject anticoagulant or other medications directly into the vessel.

A sheath catheter 21 is then advanced through the catheter port of the  
25 introducer. The outer diameter of the sheath catheter can vary from about 5 French to about 15 French. The inner diameter is such that a 4 French to about a 14 French foramen ovale catheter can be placed within its lumen. In the preferred embodiment, the sheath catheter is a single lumen catheter made by extruding standard catheter materials using standard extrusion techniques. Currently it is preferred to extrude  
30 polyether-block-amide, nylon, polyurethane, polyimide, or a polyolefin copolyester. However, any other extrudable catheter material well known in the art can be used to



manufacture the catheter. The smaller the catheter, the stronger the extruding material should be. With very small catheters, the catheter can be reinforced by using braided meshing, a technique already well known in the catheter arts. The sheath catheter's length is such that it can easily be used from a femoral site to reach  
5 an atrium of the heart, about 80 to 140 cm, with about 120 . cm being preferred. Optionally, the distal end of the sheath catheter can have a radio-opaque marker 24 such as a metallic ring placed around the distal end or incorporated into the distal end such that the distal end is visible under imaging techniques such as fluoroscopy.

10 Inserted inside the sheath catheter's lumen is a foramen ovale catheter 25 of the present invention. The foramen ovale catheter's outer diameter can vary from as small as it can be made, about 3 French to about 14 French, with 7 and 8 French being presently most preferred. The foramen ovale catheter can be made by extruding standard catheter materials using standard extrusion techniques, just like the sheath catheter. The catheter has a proximal end 26 and a distal end 27.  
15 Attached to the outer circumference of the distal end is a plurality of abrasive members 28. In the embodiment illustrated, the abrasive members are a plurality of glue drops attached to the outer circumference of the distal end of the catheter. The glue can be any appropriate material, currently cyanoacrylate is preferred.

Turning now to Fig. 4, an alternate distal end 32 of an alternate foramen  
20 ovale catheter 31 is illustrated in cross-section. In this embodiment, the abrasive members are stiff wires 33 adhered to the distal end 32 of the foramen ovale catheter. The wires can be made out of an appropriate metal such as surgical stainless steel, a nickel-titanium alloy, and the like, or could be made out of an appropriate plastic material such as nylon, polyimide, polyamide and the like. The  
25 wires are either inserted into the outer circumference of the foramen ovale catheter and then glued in place with an appropriate adhesive, or they can be interwoven between coils of a coiled or twisted foramen ovale catheter (not illustrated). Preferably the wires range in length from about 1 mm to about 20 mm, with about 5 mm being currently preferred. The wires are flexible enough to retract into the  
30 sheath catheter such that the wires will not abrade any surface until the foramen ovale catheter is deployed in the foramen ovale.

Fig. 5 illustrates a further embodiment of the present invention. The foramen ovale catheter 36 has a distal end 37 with a plurality of axial sharp edges 38 attached to its outer circumference. The sharp edges are preferably metallic pieces that are adhered to the outer circumference of the catheter with an appropriate adhesive such as cyanoacrylate and the like. Alternatively, the sharp edges could be made from a plastic material such as polycarbonate, polyurethane, and the like and adhered with a plastic adhesive such as a cyanoacrylate, a cured acrylic, and the like.

In the embodiment illustrated in Fig. 6, the foramen ovale catheter 41 comprises a single lumen catheter that has been sliced axially at the distal end to form a plurality of projections 43. Depending on the material used to make the catheter, the projections can be quite sharp and can abrade the surface of the foramen ovale.

Referring now to Fig. 7, a further embodiment is illustrated. In this embodiment, the foramen ovale catheter 46 has a distal end 47 with a plurality of partial cups 48 adhered to the outer circumference of the foramen ovale catheter. The partial cups are a hollow  $\frac{1}{2}$  dome shape where the bottom edge is adhered to the foramen ovale catheter with an appropriate adhesive. The cups can be made out of a suitable material such as a metal, e.g. surgical stainless steel, or a plastic, e.g. polycarbonate. The cups preferably protrude from the outer circumference of the foramen ovale catheter about 1 mm and have a radius of about 1 mm, although other dimensions could be used.

Figures 8 and 9 illustrate two similar embodiments. In Fig. 8, the foramen ovale catheter 51 is constructed out of a solid material, however it could be constructed out of a hollow extrusion. Provided at the distal end 52 of the foramen ovale catheter are a plurality of elevated rings 54 around the outer circumference. The rings are elevated from the outer surface of the catheter by a plurality of spacing rings 53 that are more narrow in width than the elevated rings such that each elevated ring has at least one circular edge that can abrade tissue within the foramen ovale. The width of the spacer can vary, but should be less than the elevated rings width. Currently the preferred elevated ring width is about 2 mm and the width of the spacer ring is about 1 mm. The outer rings should be made from an appropriate

stiff material such as a hard plastic or a metal. Currently stainless steel rings are used. The spacer rings can be made out of any appropriate material that elevates the elevated rings. In the preferred embodiment the spacer rings are constructed out of polyimide. The spacer rings should have a wall thickness of about 0.010 inches to  
5 about 0.100 inches with 0.050 inches being presently preferred to appropriately elevate the elevated rings. In the embodiment of Fig. 9, the foramen ovale catheter 56 has a distal end 57, a plurality of spacer rings 58, a plurality of elevated rings 59, and a bent up proximal edge 60 on each elevated ring. Currently the edge is bent up using appropriate mechanical force. The advantage of this embodiment is that the  
10 bent up edge will abrade tissue in the foramen ovale easier than the elevated edges in the embodiment of Fig. 8.

In the spirit of the present invention, the abrasive members do not need to be directly attached to the catheter to abrade the surface. In Figs. 10 and 11, the abrasive members are attached to wires that deploy once the wires are free from the  
15 constraining catheter they are in. Turning to Fig. 10, a single lumen flexible catheter 61 is used to constrain the deployable catheter 64 with its plurality of wire members 69 that form a twisted basket configuration. The flexible single lumen catheter has an access port at its proximal end 63 that allows the deployable catheter fit inside. Additionally, a standard lure lock type fitting 62 can be attached to the flexible  
20 catheter's proximal end. The flexible catheter can be any standard commercially available single lumen catheter, such catheters are commonly sold by numerous manufacturers, Cordis Corporation of Miami FL being one.

Attached to the distal end of the deployable catheter are a plurality of wires that are twisted. The wires can be made out of any suitable material such as stainless  
25 steel, a nickel-titanium-alloy, and the like. The wires themselves can be abrasive, especially if the wires were made rectangular in cross-section. Additionally, as illustrated in Fig. 1, optionally attached to the wires are abrasive members 70. The abrasive members are spaced apart on the different wires such that the members do not overlap when the wires are constrained within the constraining catheter. The  
30 abrasive members can be many different shapes and materials with beads of glue and small metallic cylinders being presently preferred. The deployable catheter

preferably has at least one lumen for the insertion of a guide wire 67 to help place the catheter in the foramen ovale. The guide wire can be any standard guide wire well known in the art and readily commercially available. Typically the guide wire will be flexible and will actually be comprised of a helical coil with a blunt distal end 68.

The distal ends of the wires are attached to a free floating ring 66 that fits over the guide wire. As can be appreciated, when the deployable catheter is constrained and completely contained within the constraining catheter, the wires are fairly straight. Deploying the deployable catheter by translating the catheter distally relative to the constraining catheter will deploy the catheter and the wires will resume the twisted configuration as illustrated in Fig. 10.

Fig. 11 illustrates an alternate deployable catheter that has straight wires 76 with abrasive members 77 instead of twisted wires. The embodiments of Figs. 10 and 11 are identical except for the wires. As can be appreciated, the embodiment of Fig. 10 will adopt the basket shape as illustrated easier once deployed than the embodiment of Fig. 11. Thus, a control means may optionally be placed within the deployable catheter of Fig. 11. An example of a suitable control means would be a puller wire attached to the ring 66 to be able to translate the ring proximally in order for the wires to adopt the basket configuration.

Figs. 12 and 13 illustrate a further embodiment of the present invention. In this embodiment, a single lumen flexible catheter 81 is used to create the plurality of abrasive members 84 near its distal end 82. The flexible catheter is provided with a plurality of axial slits 83 near its distal end. The length of the slits can vary from about 5 mm to about 30 mm, with 15 mm being presently preferred. At the midpoint of each slit, the flexible catheter is provided with a notch 85 on the interior of each abrasive member such that the member will want to bend at the location of the notch.

Located within the flexible catheter is a control catheter 87. The distal end of the control catheter is attached to the distal end of the flexible catheter. Thus, when the control catheter is translated proximally relative to the flexible catheter, the abrasive members will bend outward from the flexible catheter and form a basket

configuration. The edges of the abrasive members cant then be used to abrade the interior of the foramen ovale.

The control catheter preferably has at least one lumen for a guide wire 88 to help place the catheter through the foramen ovale. Another optional feature is a  
5 radiopaque marker ring 86 fixed to the distal end of the flexible catheter such that it is easier to see using imaging techniques such as fluoroscopy.

Those acquainted with medical procedures will appreciate that any medical procedure involving the heart should be practiced only by health care professionals with extensive training and experience in cardiology and/or cardiac surgery.

10 Therefore the present invention provides for a method of training a person to perform the procedure of abrading a patent foramen ovale using the disclosed embodiments. The method of training includes the steps of demonstrating the device, supervising the person being trained, and the labeling instructions included with the device on when and how to use the device.

15 The embodiments of the present invention are all used similarly. First, access is gained to a blood vessel. Typically the femoral vein is catheterized using any one of may commercially available introducing catheters that are well known in the art. Once the introducing catheter is in place, a single lumen catheter that is long enough to reach the foramen ovale and is large enough to allow the particular  
20 embodiment of the present invention to pass through the lumen is placed through the introducing catheter. An example of this type of catheter is the 8 French Mullins Introducer Set manufactured by Cook of Bloomington IN. Typically these catheters are provided with a fairly stiff guide wire to allow for probing the right atrium for the foramen ovale. The single lumen catheter is advanced to the right atrium and  
25 then through the foramen ovale to the left atrium.

Next the guide wire is removed and the interventional foramen ovale catheter is advanced in the single lumen catheter to the left atrium. The single lumen catheter is then removed from the left atrium and the foramen ovale.

30 Depending on the particular embodiment being used, the abrasive members of the foramen ovale catheter are either exposed or need to be deployed, this is typically done in the left atrium. The foramen ovale catheter is then slowly pulled

back through the foramen ovale to abrade the interior of the foramen ovale. Usually the foramen ovale catheter is rotated while passing through the foramen ovale to enhance the abrasions being made. After the interior is abraded, the foramen ovale catheter is then withdrawn into the single lumen catheter and then removed from the patient. All the catheters are then removed and the puncture site is sealed using standard techniques.

The abrasions created within the foramen ovale start a healing process which over time seals the foramen ovale shut with scar tissue. Once the foramen ovale is shut, the patient no longer has the risks associated with an patent foramen ovale.

While several particular embodiments of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited except as by the appended claims.

## What is Claimed is:

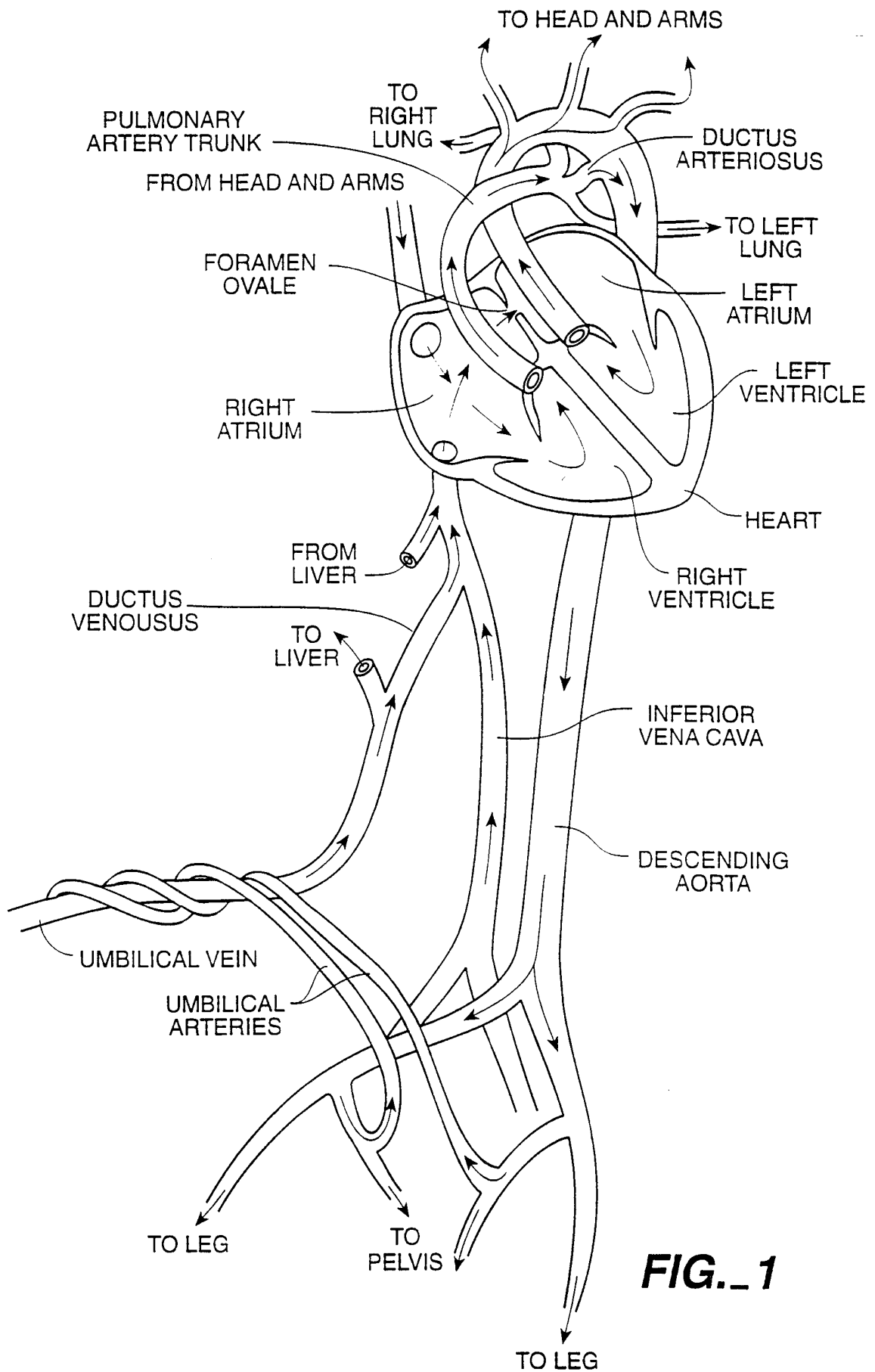
1. A catheter device for abrading a patent foramen ovale comprising:
  - A a sheath catheter with proximal and distal ends;
  - B a foramen ovale catheter deployably retained within the sheath
  - 5 C a plurality of abrasive members attached to the distal end of the foramen ovale catheter.
2. The catheter device of claim 1 wherein the abrasive members are a plurality of glue drops.
- 10 3. The catheter device of claim 1 wherein the abrasive members are a plurality of wires.
4. The catheter device of claim 1 wherein the abrasive members are a plurality of sharp edges.
- 15 5. The catheter device of claim 1 wherein the abrasive members are a plurality of projects created by axially cutting the distal end of the foramen ovale catheter.
6. The catheter device of claim 1 wherein the abrasive members are a plurality of elevated rings.
- 20 7. The catheter device of claim 6 wherein the elevated rings have a bent up edge.
8. The catheter device of claim 1 wherein the abrasive members are a plurality of wires to form a basket configuration.
9. The catheter device of claim 8 wherein the wires have a plurality of abrasive

cylinders attached to each wire.

10. The catheter device of claim 8 wherein the wire have a plurality of abrasive glue drops attached to each wire.
11. The catheter device of claim 1 wherein the abrasive members are a plurality  
5 of axial projections that extend near the distal end of the foramen ovale catheter but do not extend all the way to the distal end of the foramen ovale catheter and are created by providing a plurality of axial slits near the distal end of the foramen ovale catheter, and further comprising a control catheter attached to the distal end of the foramen ovale catheter wherein translating  
10 the control catheter proximally relative to the foramen ovale catheter causes the axial projects to bend outward from the foramen ovale catheter.
12. A method of abrading a patent foramen ovale comprising the steps of:
  - A inserting an introducer catheter into a vessel of a patient with a patent foramen ovale;
  - 15 B inserting a foramen ovale catheter with proximal and distal ends and with a plurality of abrasive members attached to or near the distal end through the introducer catheter;
  - C advancing the foramen ovale catheter through the patent foramen ovale;
  - 20 D abrading the patent foramen ovale by manipulating the foramen ovale catheter such that the abrasive members abrade the lining of the foramen ovale;
  - E removing the foramen ovale catheter and the introducer catheter from the patient.
- 25 13. The method of abrading a patent foramen ovale of claim 12 further comprising the step of inserting a sheath catheter through the introducer catheter.

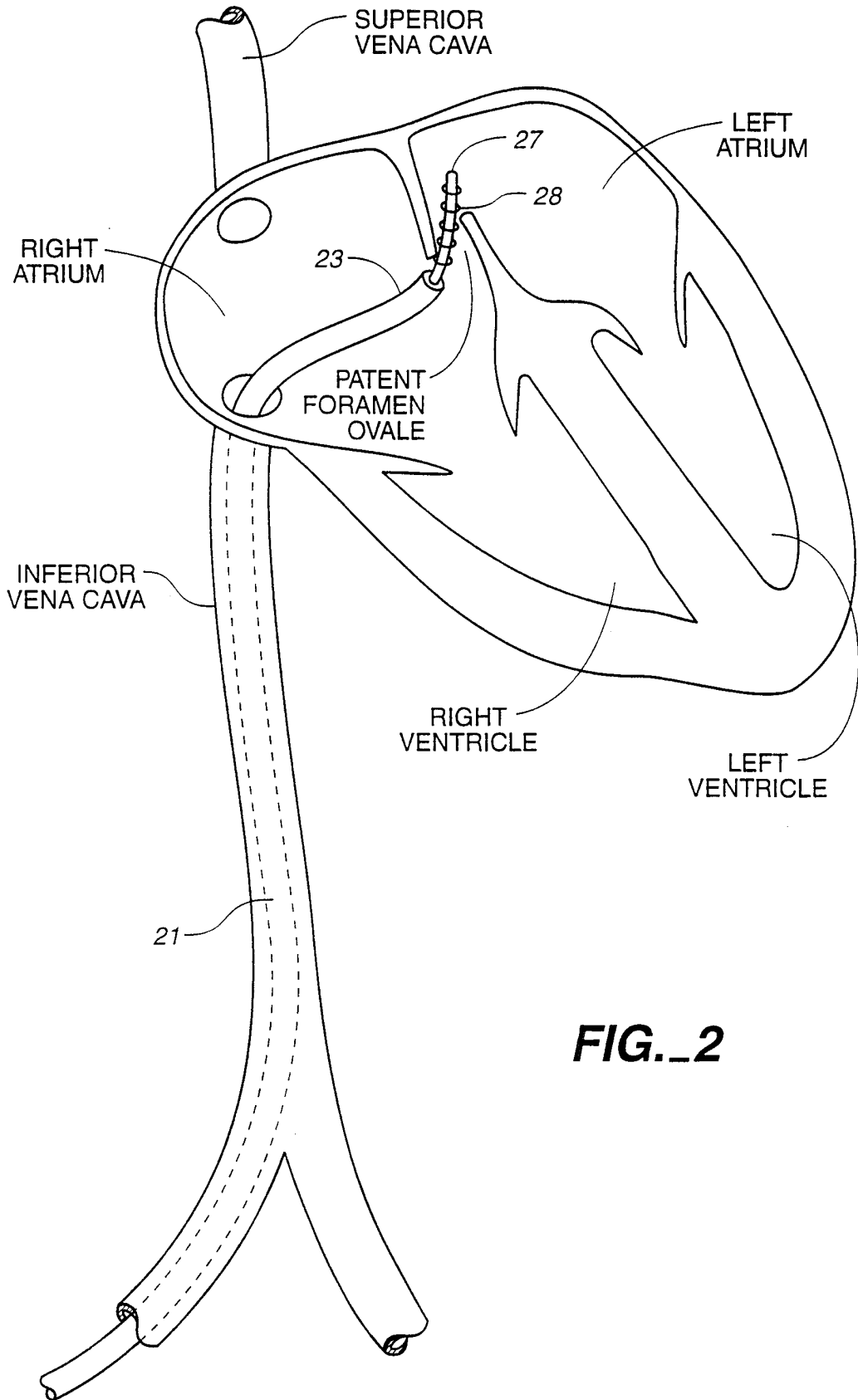


14. The method of abrading a patent foramen ovale of claim 12 wherein the abrading is accomplished by translating the distal end of the foramen ovale catheter through the patent foramen ovale.
- 5 15. The method of abrading a patent foramen ovale of claim 12 wherein the abrading is accomplished by rotating the distal end of the foramen ovale catheter in the patent foramen ovale.
16. A method of training a person to perform the method of abrading a patent foramen ovale comprising the steps of demonstrating or instructing the performance of the method of claim 12.
- 10 17. The method of training a person of claim 16 further comprising the step of claim 13.

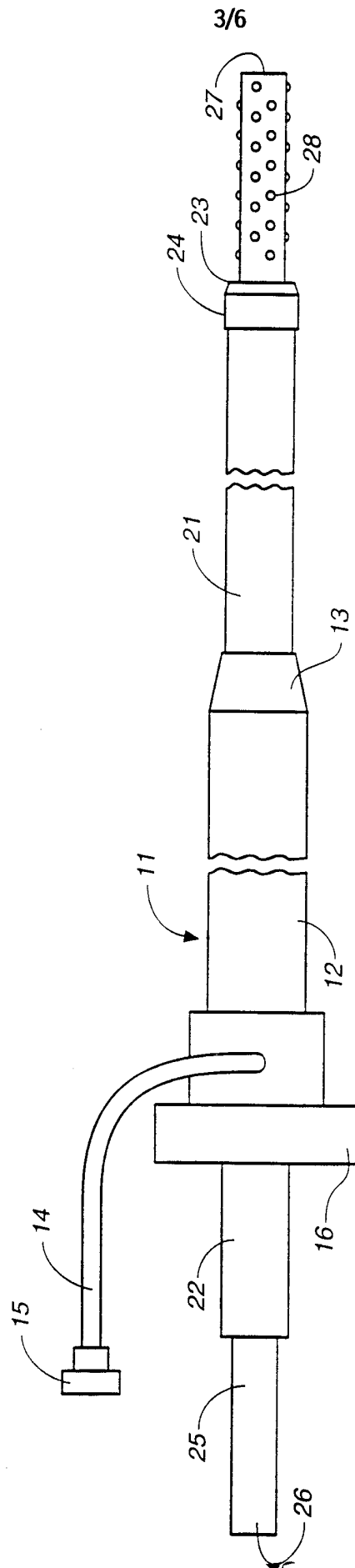


**FIG. 1**

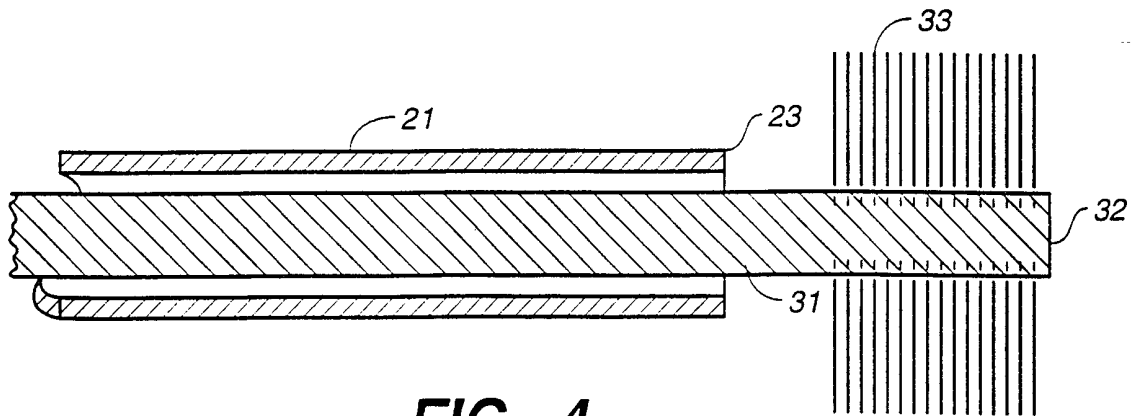
2 / 6



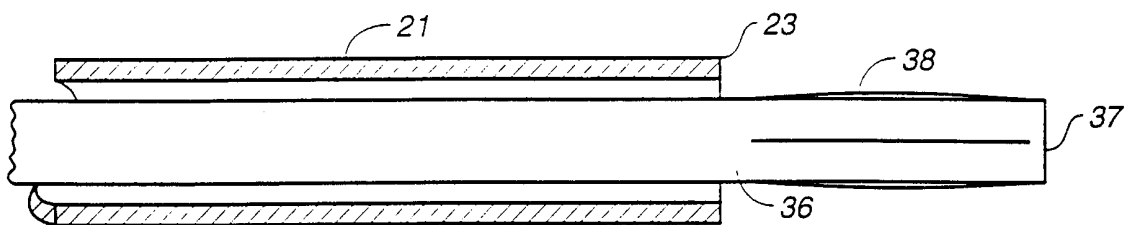
**FIG..2**



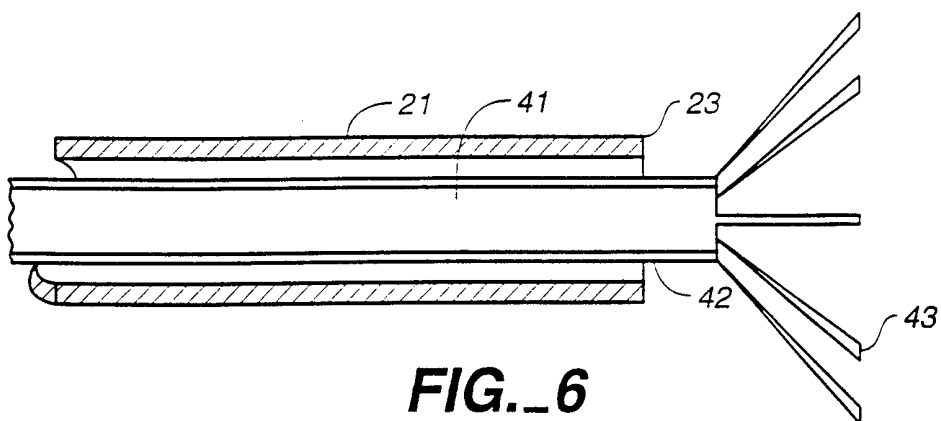
**FIG. 3**



**FIG.\_4**

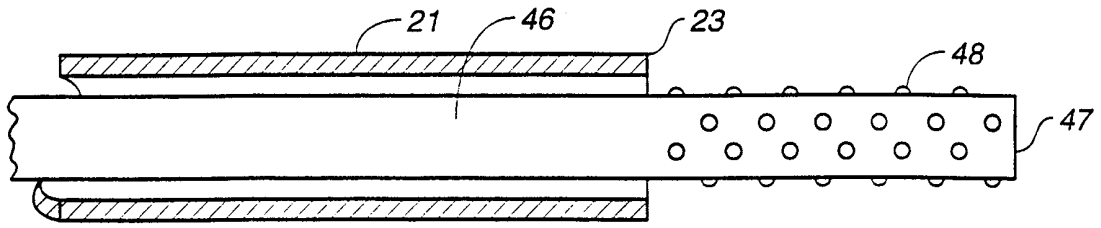


**FIG.\_5**

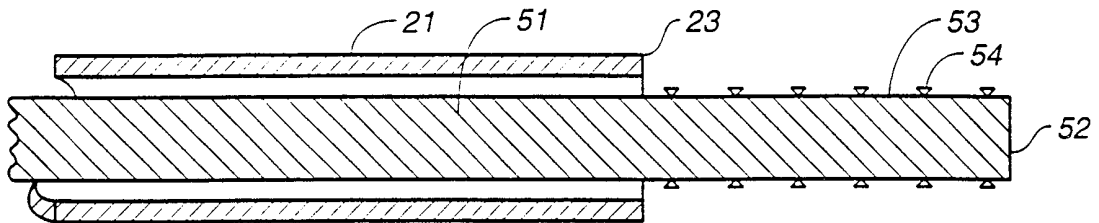


**FIG.\_6**

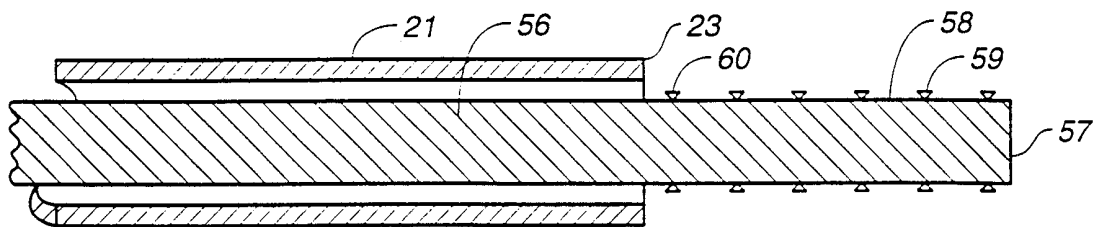
5 / 6



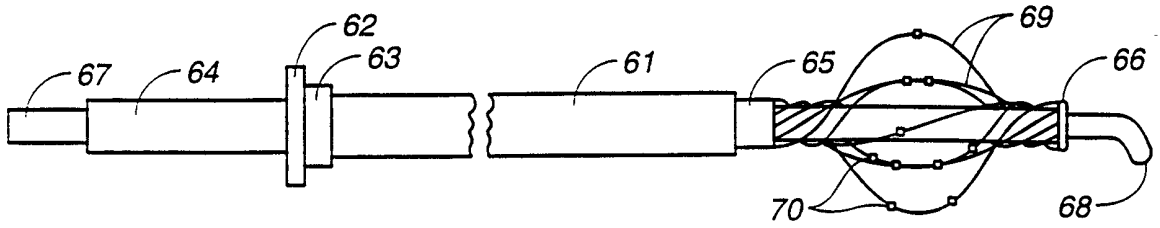
**FIG.\_7**



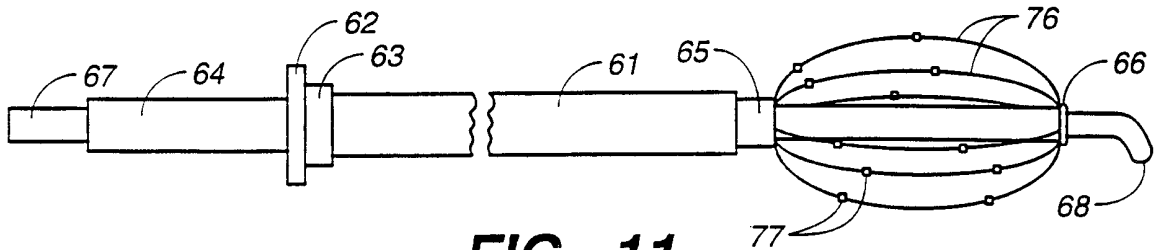
**FIG.\_8**



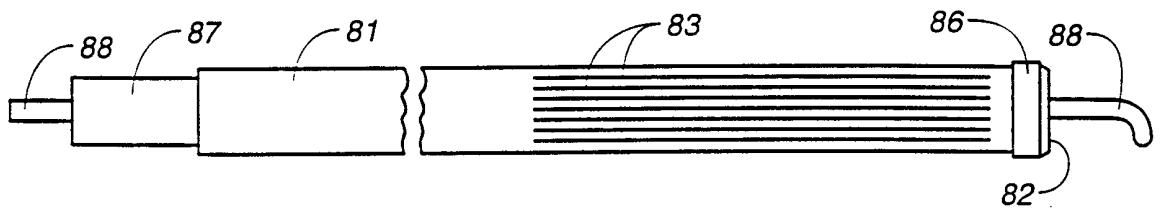
**FIG.\_9**



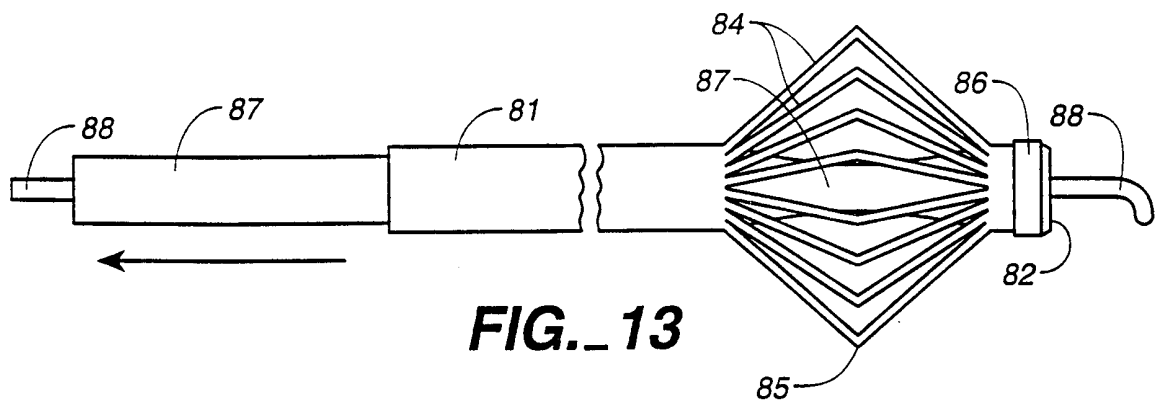
**FIG. 10**



**FIG. 11**



**FIG. 12**



**FIG. 13**

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/21437

<p><b>A. CLASSIFICATION OF SUBJECT MATTER</b>                  IPC(6) :A61B 17/22                  US CL :606/159, 167, 170, 180                  According to International Patent Classification (IPC) or to both national classification and IPC</p>		
<p><b>B. FIELDS SEARCHED</b>                  Minimum documentation searched (classification system followed by classification symbols)                  U.S. : 606/159, 167, 170, 180</p>		
<p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched                  NONE</p>		
<p>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)                  NONE</p>		
<p><b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b></p>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,571,122 A (KELLY et al) 05 November 1996, Figs. 1-5.	1-17
X	US 5,318,576 A (PLASSCHE, JR. et al) 07 June 1994, Figs. 1-6.	1-17
<p><input type="checkbox"/> Further documents are listed in the continuation of Box C.    <input type="checkbox"/> See patent family annex.</p>		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"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 05 DECEMBER 1998		Date of mailing of the international search report 13 JAN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer KEVIN TRUONG Telephone No. (703) 308-3767