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Samson

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[54] **SINGLE-LUMEN BALLOON CATHETER HAVING A DIRECTIONAL VALVE**

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[73] Assignee: **Target Therapeutics**, Fremont, Calif.

[21] Appl. No.: **976,197**

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[51] **Int. Cl.**[5] **A61M 25/00**

[52] **U.S. Cl.** **606/194**; 604/96; 604/249; 128/772

[58] **Field of Search** 606/192, 194; 604/33, 604/96, 99, 101–103, 246, 249, 170; 128/772

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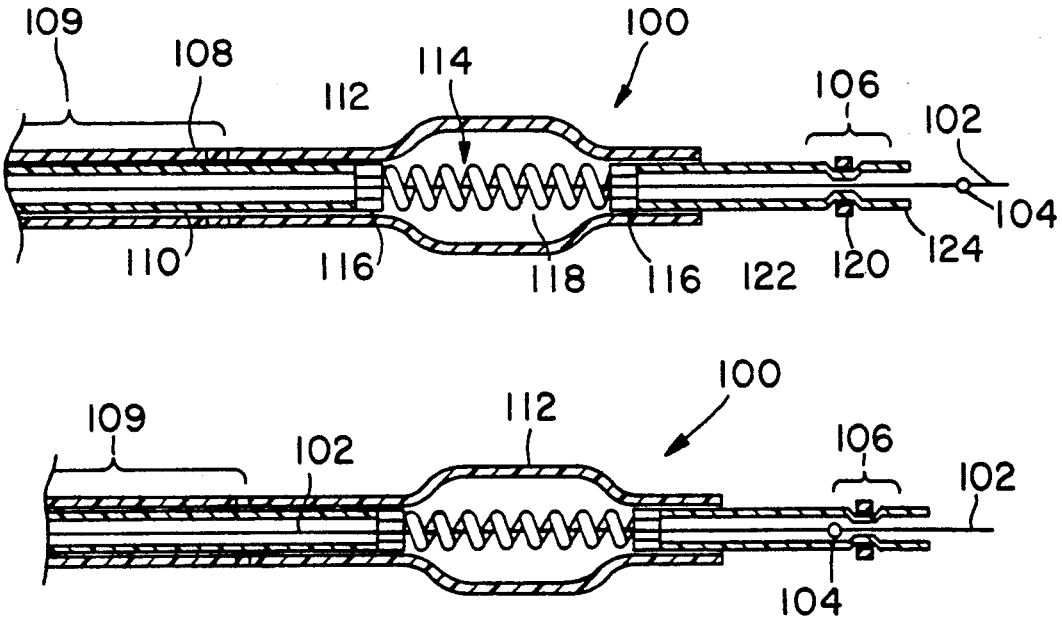
Primary Examiner—Ralph Lewis
Attorney, Agent, or Firm—Morrison & Foerster

[57] **ABSTRACT**

This invention is a single-lumen balloon catheter having a valve seat on the distal end of the catheter, distal of the balloon, which may be operated by a control wire having a valve plug disposed on the wire. The valve seat may be engaged by the valve plug from either direction, depending on the installation of the control wire. In either event, if the valve plug is installed distally of the valve seat in the catheter lumen, the valve is closed by pulling on the control wire (or moving the control wire in a proximal direction) and introducing fluid through the catheter lumen through the balloon. Alternatively, the guidewire, with its integral valve plug, may be introduced from the proximal end of the catheter and may traverse the body of the balloon to engage the valve seat in the distal end of the catheter. Pushing on the control wire will seat the valve, allowing the introduction of fluid through the catheter lumen to inflate the balloon. The latter arrangement allows the control wire to be interchanged with other guidewires a physician may wish to use. The balloon provided for in this invention is of a single length and does not change its axial length as it is inflated.

24 Claims, 2 Drawing Sheets



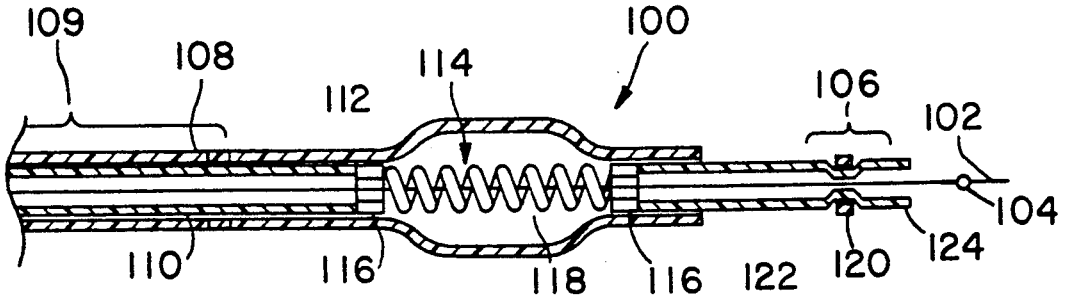


FIG. 1A

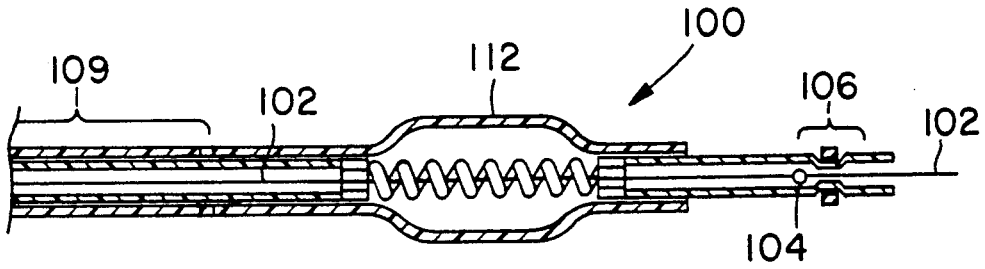


FIG. 1B

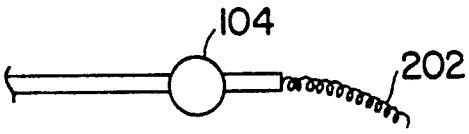


FIG. 2

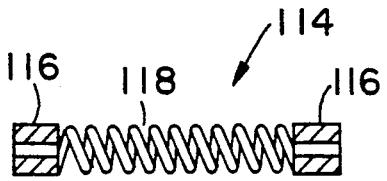


FIG. 3A

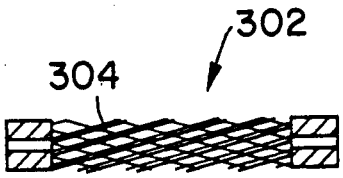


FIG. 3B

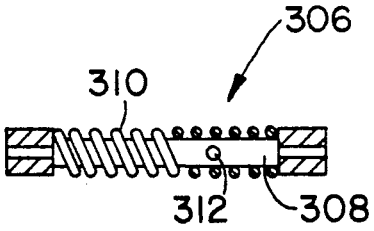


FIG. 3C

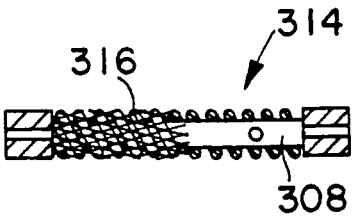


FIG. 3D

SINGLE-LUMEN BALLOON CATHETER HAVING A DIRECTIONAL VALVE

FIELD OF THE INVENTION

This invention is a single-lumen balloon catheter having a valve seat on the distal end of the catheter, distal of the balloon, which may be operated by a control wire having a valve plug disposed on the wire. The valve seat may be engaged by the valve plug from either direction, depending on the installation of the control wire. In either event, if the valve plug is installed distally of the valve seat in the catheter lumen, the valve is closed by pulling on the control wire (or moving the control wire in a proximal direction) and introducing fluid through the catheter lumen through the balloon. Alternatively, the guidewire, with its integral valve plug, may be introduced from the proximal end of the catheter and may traverse the body of the balloon to engage the valve seat in the distal end of the catheter. Pushing on the control wire will seat the valve, allowing the introduction of fluid through the catheter lumen to inflate the balloon. The latter arrangement allows the control wire to be interchanged with other guidewires a physician may wish to use. The balloon provided for in this invention is of a single length and does not change its axial length as it is inflated.

BACKGROUND OF THE INVENTION

Angioplasty is an excellent method for treating a wide variety of vascular diseases. In particular, it has been used extensively for opening stenoses in coronary arteries. The process has been increasingly used for treatment of stenosis in other parts of the vascular system.

One of the more well known and widely practiced forms of angioplasty makes use of a dilatation catheter which has an inflatable balloon at is distal end. Using fluoroscopy, the physician guides the catheter through the vascular system until the balloon is properly positioned. By applying a fluid through the separate inflation lumen, the balloon is inflated. The balloon's inflation causes the artery to stretch and presses the lesion or stenose into the artery wall, thereby reestablishing after deflation of the balloon, increased blood flow through the artery.

In order to treat very tight stenoses, i.e., those having small openings, increasingly small catheter diameters are desirable. significantly more flexible catheters are also desired in that otherwise very tight areas of stenosis will not be approachable. Although flexible and narrow of diameter, a good catheter must also be easily introduced and easily advanced through the tortuous path of the vascular system.

There are a variety of dilatation catheter types. Many use multiple lumens. For instance, a catheter may use a separate guidewire lumen so that a guidewire can be used to establish the path to the stenosis. The catheter may then be fed over the guidewire until the balloon is positioned over the stenosis. The catheter obviously has a separate lumen to allow introduction of and removal of fluid for the balloon.

Other catheter designs include those which act as their own guidewire, thereby eliminating the need for a separate guidewire lumen. Elimination of the need for the separate lumen means that the profile of the catheter can be somewhat smaller. Typical of such integral designs are U.S. Pat. No. 4,606,247, to Fogarty et al., which shows a catheter having an evertible balloon at is distal tip. The distal.tip of the catheter is placed near the stenosis to be treated. The balloon is extended beyond the distal tip to a position within the stenosis and then inflated to press the lesion back into the wall of the vessel. The balloon contains a passageway in the middle having a plug of some elastomeric material through which a guidewire may be placed. The plug retains the pressure of the fluid on the balloon, whether the guidewire is present or not.

Another "over-the-wire" catheter is shown in U.S. Pat. No. 5,085,636, to Burns. The Burns device utilizes a balloon having a port for introducing fluid into the balloon and simultaneous device for not allowing fluid to pass through the catheter when a guidewire is present in the vicinity of the balloon. The fluid seal is distendible and does not allow fluid past the guidewire.

My U.S. Pat. No. 5,171,221, entitled "Single Lumen Low Profile Valved Balloon Catheter" discloses a single lumen balloon catheter having a catheter using a flexible guidewire which extends axially through the lumen beyond the open end of an intermediate balloon segment. The guidewire is axially movable within the lumen and has two discrete portions of different diameters. The first diameter, distal on the guidewire, is smaller that a second more proximal diameter on the guidewire. The larger guidewire meshes with the diameter of the lumen just proximal of the balloon thereby sealing it on the proximal end. Simultaneously at the distal end of the balloon a valve member mounted on the guidewire blocks the distal opening of the catheter.

None of the prior art shows a device in which a control wire having a valve plug mounted thereon, which meshes with a valve seat mounted within the lumen and in which the balloon maintains a constant axial length during its distension.

SUMMARY OF THE INVENTION

This invention is a single lumen valved balloon catheter assembly with a single lumen having a proximal end, an open distal end, a valve seat section located towards the distal end of the catheter having both distal and proximal valve surfaces. The catheter body has a balloon section proximal of the valve section having an inflatable balloon. The balloon segment or section includes therein a balloon inner member, the interior of which is generally colinear with the lumen in the catheter body, and which balloon inner member allows fluid communication between the catheter lumen and the interior of the balloon. The invention also includes a flexible guidewire extending axially through the lumen beyond the open end, the guidewire being axially movable within the lumen and having a valve plug disposed near the distal end of the guidewire. The valve plug is of such a size and configuration that is able to close the lumen to fluid flow upon engagement with either the proximal or distal surface of the valve seat. The guidewire and its valve seat are produced in such a fashion that the guidewire may be introduced into the catheter lumen from the distal end thereby allowing the valve plug to contact the distal valve seat or the guidewire may be installed from the proximal end thereby allowing the valve plug to contact the proximal valve surface. Optional, but very desirable, is a catheter body section proximal of the balloon section which is sufficiently stiff to permit use of the guidewire-valve plug in sealing the valve. Preferably, the catheter body section

is a multilayered, polymeric tubing that does not kink, "accordion", or stretch upon application of axial force on the guidewire. The most preferred combination of materials is a slippery material as the inner surface of the section surrounded by a high performance engineering polymer such as polyimide.

The catheter may be of a very small diameter or low profile and consequently is quite flexible in its operation.

The balloon inner member may be any of a number of devices allowing fluid communication between the catheter lumen and the interior of the balloon. For instance, the balloon inner member may be a coil, a braid, a braid or coil supported by a tube having holes through its wall, or a tube having holes through its wall.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A and 1B are partial, enlarged, semicross sectional depictions of the distal portion of the catheter made according to this invention.

FIG. 2 shows a close up side view of the distal portion of a guidewire suitable for use in this invention.

FIGS. 3A and 3B show side views of two variations of the balloon inner member.

FIGS. 3C and 3D show enlarged partial cross-sections of still further variations of the balloon inner member.

DESCRIPTION OF THE INVENTION

FIGS. 1A and 1B show the distal portion, generally designated (**100**), of a catheter assembly made according to one embodiment of the invention. FIG. 1A depicts the distal end of the catheter assembly when the guidewire has been inserted with the valve plug (**104**) distally of the valve section (**106**). FIG. 1B shows the same catheter assembly (**100**) with the guidewire (**102**) with a valve plug (**104**) positioned proximately of the valve region (**106**).

Referring to FIG. 1A, the catheter body generally is made up of an outer, thinwall tubing (**108**) and an inner tubing (**110**). The balloon body (**112**), having the balloon inner member (**114**), which balloon under member **114** is made up of balloon inner member end sections (**116**) and a fluid permeable member (**118**). Distally of balloon (**112**) is located the valving for the catheter. The valving is a valve section (**106**) which may be made up of a simple tube having a metal band (**120**) located so as to form a valve surface (**122**) proximally of the metal band (**120**) on the interior of the lumen and a valve surface (**124**) distally of the band (**120**).

The catheter (**100**) has a body section (**109**) proximal of the balloon section which desirably is made up of an outer tubing (**108**) which is strong and flexible and an inner tubing member (**110**). Although there are a number of materials which are suitable for service as the outer tubing, e.g., high density polyethylene (HDPE), low density polyethylene (LDPE), certain highly cross linked silicones, polyesters (including Nylon), polyvinyl chloride, high molecular weight polyurethanes, and various polyimides. Of those materials, a polyimide is the most desirable in that it has a substantial axial strength and is therefore quite "pushable" but also maintains the catheter lumen open even under the severest of pressure. The distal portion of this catheter body is preferably of a much more flexible material such as low density polyethylene.

The inner tubing member (**110**) is not a required portion of the inventive device but is desirable. The member (**110**) may be coextruded with the outer tubing (**108**) or may be a discrete member. Suitably lubricious materials include polysulfides and polyfluoroethylenes. Suitable polyfluoroethylenes include polytetrafluoroethylene, fluoroethylene copolymers having perfluoroalkoxy groups, copolymers of tetrafluoroethylene, hexafluoropropylene, and copolymers of ethylene and tetrafluoroethylene. Most preferred are copolymers of tetrafluoroethylene and hexafluoroethylene.

Although the balloon (**112**) may be made out of a variety of materials, I have found that the balloon is readily formed from a length of radiation-hardened polyolefin tubing. The chosen polyolefin may be low density polyethylene, high density polyethylene, polypropylene, polybutene, or interpolymers or mixtures of these polymers. In any event, a balloon may be formed by closing one end and applying about 20 to 45 pounds per square inch of pressure within the tube and heating the portion which is to form the balloon to a temperature of between 300°–350° F. Obviously, the length of the balloon formed is determined by the length of the tubing heated. After the balloon is produced in an appropriate size, the heat is removed, and the balloon is allowed to cool. The ends may be cut so to fit in the catheter assembly. Typically the balloon is squeezed to a size near that of the catheter lumen. The ratio of the collapsed diameter of the balloon to the diameter of the catheter just proximal of the balloon is no more than about 1.2 to 1 and preferably no more than about 1.1 to 1. The production of the balloon in this fashion results in a device in which the diameter of the balloon before inflation as compared to the diameter of the balloon after inflation may be about 1:6 or less. The balloon made in this fashion is also axially very certain in size. Unlike elastomeric balloons which may vary in length when inflated, this balloon is essentially isoaxial, particularly when the balloon inner members described herein are utilized. The balloon inner member assembly (**114**) shown in FIGS. 1A and 1B has two ends (**116**) and a coil spring (**118**). This construction will be described in more detail below.

Finally, the valve portion of the catheter assembly is preferably inserted into the portion of the balloon having relatively constant inner diameter. It is held in place by heat welding or gluing or other suitable process. The valve region (**106**) with its ring (**120**) and proximal valve surface (**122**) and distal valve surface (**124**) may be made by the following procedure. Other procedures are certainly acceptable but I have found that the following procedure produces an excellent result. A polymeric tube having an inside diameter larger than the guidewire is stretched over a mandrel such as a suitably sized stainless steel wire. The ends are locked over the mandrel by heating. A temperature of about 600° F. to appropriate when the chosen polymer is a polyimide. A ring having an appropriate inside diameter is slipped over the tubing. The locked ends of the tubing are cut off to allow the tubing to recover its original dimensions. Polyimide tubing recovers fully by heating it to about 550° F. The ring may be of gold, platinum, platinum-tungsten alloy, stainless steel, or other suitable and, preferably, radioopaque materials. The tubing, upon return to its former diameter, forms distal and proximal surfaces adjacent the ring which serve as valve surfaces for the plug residing on the guidewire.

This distal structure substantially eliminates the possibility of "accordioning" when the distal valve surface (**124**) is used as the valve seat.

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