US005902290A

United States Patent [19]

Peacock, III et al.

[11] **Patent Number: 5,902,290**

[45] **Date of Patent: *May 11, 1999**

[54] **CATHETER PROVIDING INTRALUMINAL ACCESS**

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[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

[21] Appl. No.: **08/805,896**

[22] Filed: **Feb. 24, 1997**

Related U.S. Application Data

[63] Continuation of application No. 08/589,910, Jan. 23, 1996, abandoned, which is a continuation of application No. 08/212,225, Mar. 14, 1994, abandoned.

[51] **Int. Cl.**[6] **A61M 25/00**

[52] **U.S. Cl.** **604/282**; 604/264

[58] **Field of Search** 604/96, 102, 264, 604/280, 282

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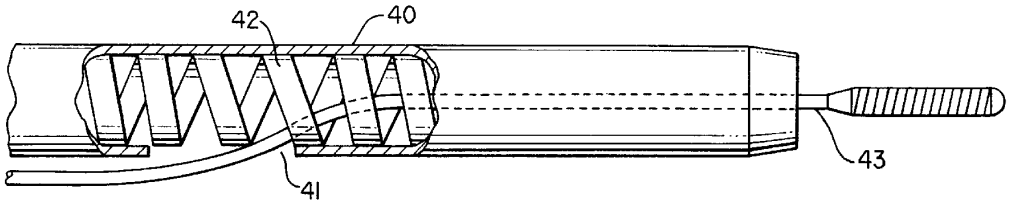
[57] **ABSTRACT**

An intraluminal catheter which provides access to distal locations within a patient's body lumen and which is provided with a flexible distal section having an inner lining, an outer jacket or coating and a helical coil between the lining and jacket. The distal section of the catheter is quite flexible yet it has sufficient transverse or radial rigidity to prevent significant distortion of the transverse cross-sectional shape of the catheter.

16 Claims, 3 Drawing Sheets



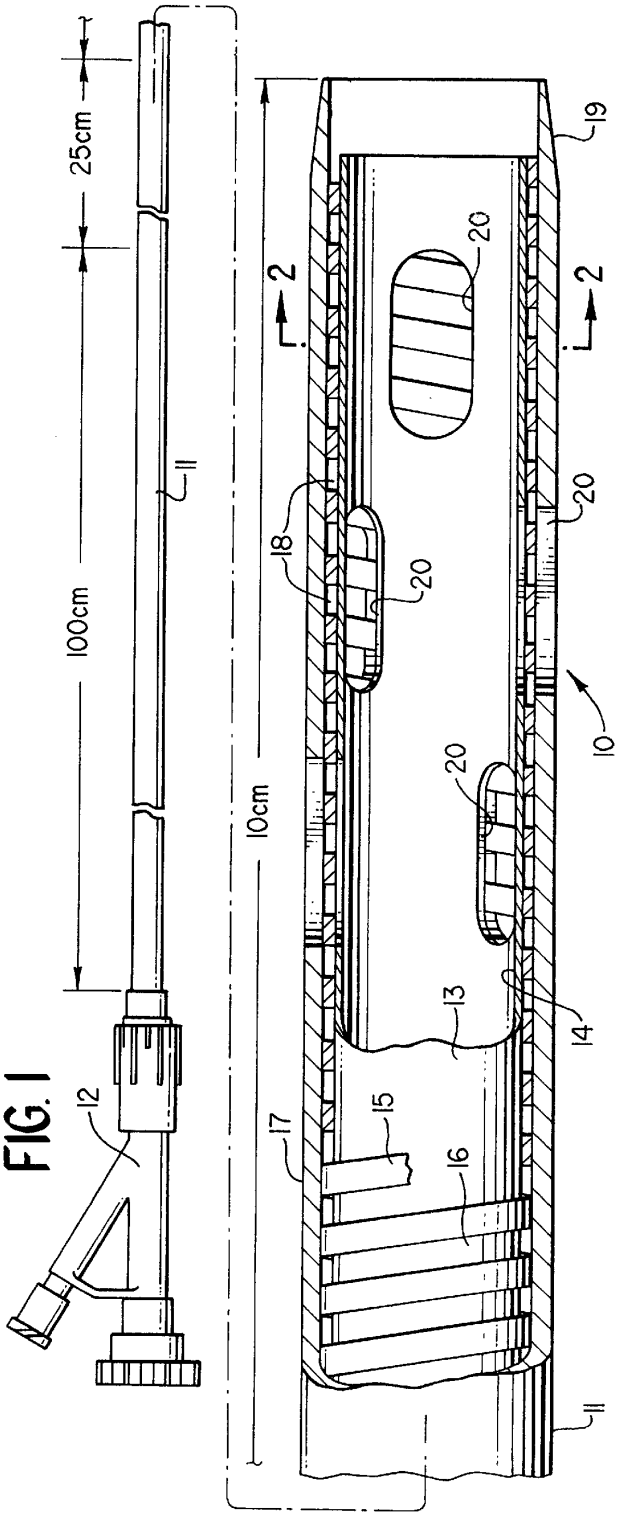


FIG. 1

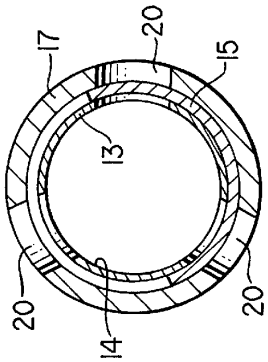
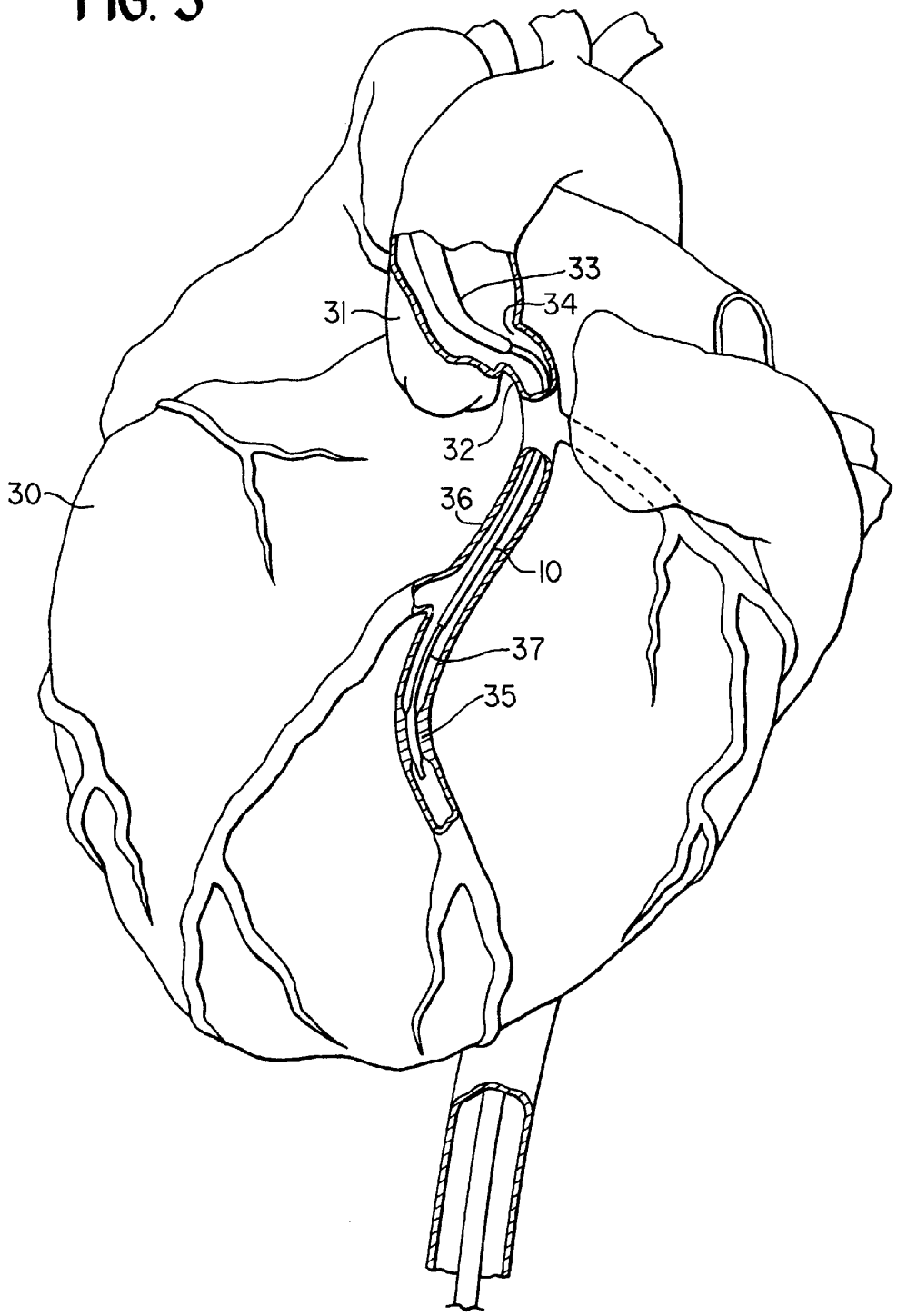


FIG. 2

FIG. 3



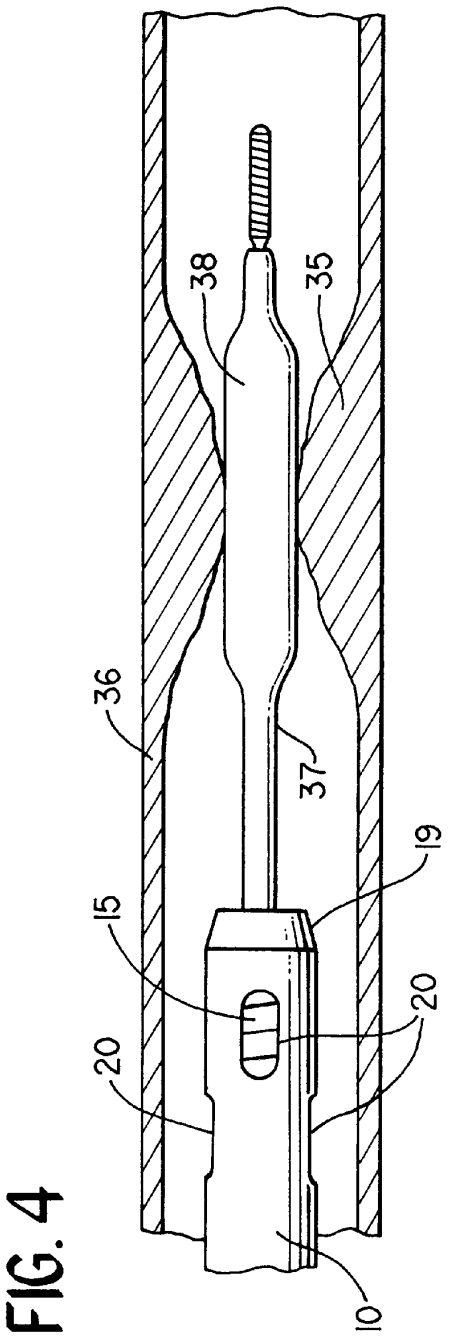


FIG. 4

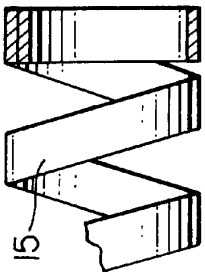


FIG. 6

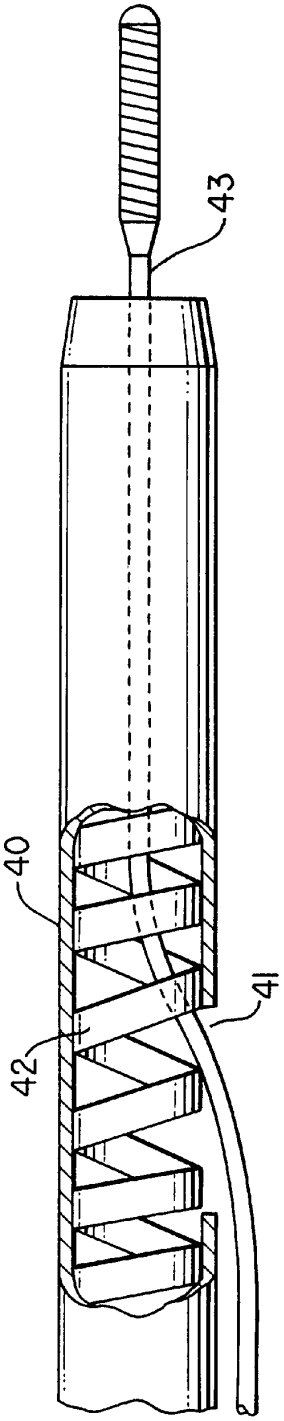


FIG. 5

CATHETER PROVIDING INTRALUMINAL ACCESS

This is a continuation of application Ser. No. 08/589,910, which was filed on Jan. 23, 1996, now abandoned which is a continuation of 08/212,225, filed Mar. 14, 1994 now abandoned.

FIELD OF THE INVENTION

This invention generally relates to intraluminal access catheters which are adapted to facilitate the advancement and withdrawal of intraluminal devices such as balloon dilatation catheters, guidewires and the like used in percutaneous transluminal coronary angioplasty (PTCA) procedures.

BACKGROUND OF THE INVENTION

In typical PTCA procedures, a guiding catheter having a preshaped distal tip is percutaneously introduced by a Seldinger technique into the cardiovascular system of a patient and advanced within the system until the preshaped distal tip of the guiding catheter is disposed within the ascending aorta adjacent the ostium of the desired coronary artery. The guiding catheter is relatively stiff because it has to be twisted or torqued from its proximal end, which extends outside the patient, to turn the distal tip of the guiding catheter so that it can be guided into the desired coronary ostium. A balloon dilatation catheter is introduced into and advanced through the guiding catheter and out the distal tip thereof into the patient's coronary artery until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion to be dilated. Once properly positioned, the balloon is inflated one or more times to a predetermined size with radiopaque liquid at relatively high pressures (e.g., generally 4–12 atmospheres) to dilate the stenotic region of the diseased artery. When the dilatations have been completed, the balloon is finally deflated so that the dilatation catheter can be removed from the dilated stenosis to allow the resumption of normal blood flow through the dilated artery.

There are several types of balloon dilatation catheters which are now widely available, including over-the-wire catheters, fixed-wire catheters, rapid exchange type catheters (which are a type of over-the-wire catheter) and perfusion type catheters (which may be either over-the-wire or fixed-wire catheters).

It is not uncommon during an angioplasty procedure to have to exchange the dilatation catheter once the dilatation catheter has been advanced within the patient's coronary artery. For example, if the physician determines that the inflated balloon size of the catheter is inappropriate for the stenosis to be dilated, the dilatation catheter will be withdrawn and an appropriately sized dilatation catheter will be advanced into the coronary artery to dilate the stenosis.

If the dilatation catheter employed is an over-the-wire type dilatation catheter, the catheter may be withdrawn from the patient with the guidewire remaining in place across the stenosis to be dilated so that access to this stenotic region is not lost. It should be noted that it may take the physician from about 15 minutes to up to two hours or more to first advance the guidewire into the patient's coronary artery and across the stenosis to be dilated and then advance the distal portion of the dilatation catheter having the balloon across the stenotic region.

However, when a fixed-wire dilatation catheter is withdrawn from the patient's coronary artery, in order to exchange the catheter for another sized fixed-wire catheter or another type catheter, access to the stenotic region is lost. It may take the physician an hour or more to advance a replacement fixed-wire catheter or a guidewire over which an over-the-wire dilatation catheter can be advanced through the patient's tortuous coronary anatomy in order to reach the arterial stenotic region in which the first fixed-wire dilatation catheter was located.

Exchange type catheters are described in U.S. Pat. No. 4,944,740 and U.S. Pat. No. 4,976,689 which are designed to facilitate the advancement and withdrawal of fixed-wire devices within a patient's coronary arteries without loss of access to the stenotic region. However, the commercial embodiments of these patents has been found to be relatively ineffective when they are advanced through highly tortuous coronary arteries and when using guiding catheters with small radii of curvatures, i.e. tight curvatures, such as found in guiding catheters having Amplatz configurations. Commercially available exchange type catheters have a tendency to collapse or kink when advanced through tight curvatures, thereby preventing the passage of the fixed-wire or other type of intravascular catheter through the inner lumen of the exchange catheter. In some instances the change in transverse cross-sectional shape of the inner lumen of commercially available exchange catheters from circular to oval shaped is sufficient to prevent or retard the passage of a dilatation catheter or guidewire through the exchange catheter.

What has been needed and heretofore unavailable is an exchange type catheter having a highly flexible distal end which has sufficient radial rigidity to maintain the cross-sectional shape of the inner lumen when the distal end is in a configuration with a small radius of curvature. The present invention satisfies that and other needs.

SUMMARY OF THE INVENTION

The present invention is directed to an improved intraluminal access catheter which is particularly suitable for facilitating the advancement and the withdrawal of intravascular devices such as fixed-wire and other types of dilatation catheters, guidewires and the like through a patient's coronary arteries.

The access catheter of the invention has an elongated proximal portion, a relatively short distal portion and an inner lumen extending therethrough which is adapted to facilitate the passage therethrough of guidewires, fixed-wire and over-the-wire dilatation catheter and other intravascular devices. The proximal portion of the catheter is sufficiently stiff to facilitate advancing the catheter through a guiding catheter and a patient's coronary artery. The distal portion is longitudinally flexible enough so as to be readily advanced through guiding catheters having distal ends with tight curvatures and tortuous coronary anatomy and it has sufficient radial rigidity so that the transverse cross-sectional shape of the inner lumen which extends through the distal portion is maintained even when the distal portion of the catheter is put into a configuration with one or more tight curvatures.

The flexible distal portion of the access catheter, which is dimensioned to be advanced through the a human patient's coronary artery, generally has a tubular shape and comprises an inner lining defining the inner lumen extending therethrough, which preferably has an inner lubricous surface, an outer plastic jacket and a supporting coil disposed between the inner tubular lining and an outer jacket. The supporting coil is a self supporting tubular structure and

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