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Bagaoisan et al.

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[54] **BALLOON ASSEMBLY WITH SEPARATELY INFLATABLE SECTIONS**

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[73] Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, Calif.

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[22] Filed: **Jul. 21, 1992**

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **604/96**; 604/101; 606/194

[58] **Field of Search** 604/96–103; 606/191–197

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,911,163	3/1990	Fina	606/192 X
4,990,139	2/1991	Jang	604/101
5,019,042	5/1991	Sahota	604/101
5,071,406	12/1991	Jang	604/96

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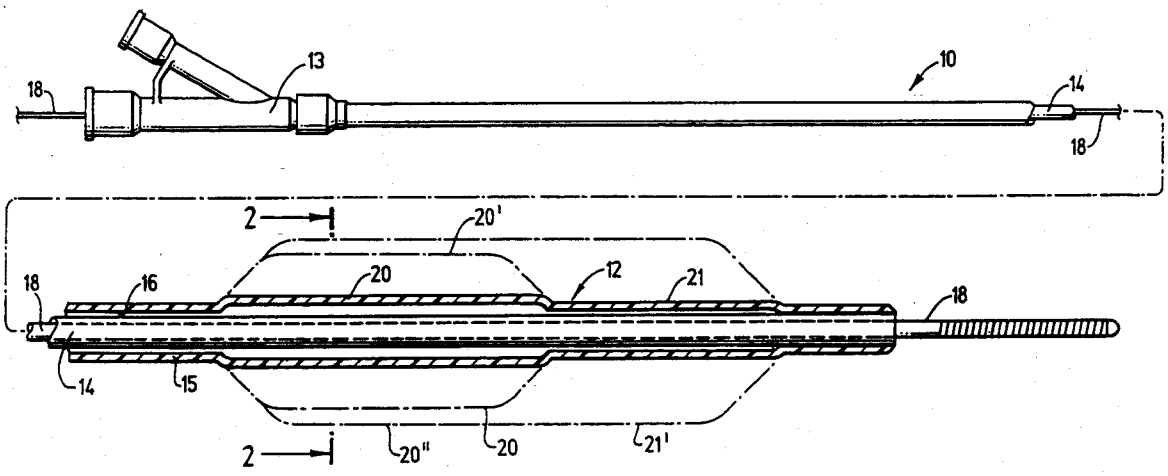
[57] **ABSTRACT**

A dilatation or other similar catheter for intraluminal use which has an elongated shaft and an inflatable member or section on the distal extremity of the catheter shaft which has multiple working sections, a first working section which elastically expands upon inflation to a first pressure within a first pressure range and a second working section which elastically expands upon inflation to a second pressure within a second pressure range which is at least in part higher than the first pressure range. The first working section may be inflated to secure the catheter within the body lumen and then the second working section may be inflated to dilatate the body lumen.

29 Claims, 3 Drawing Sheets



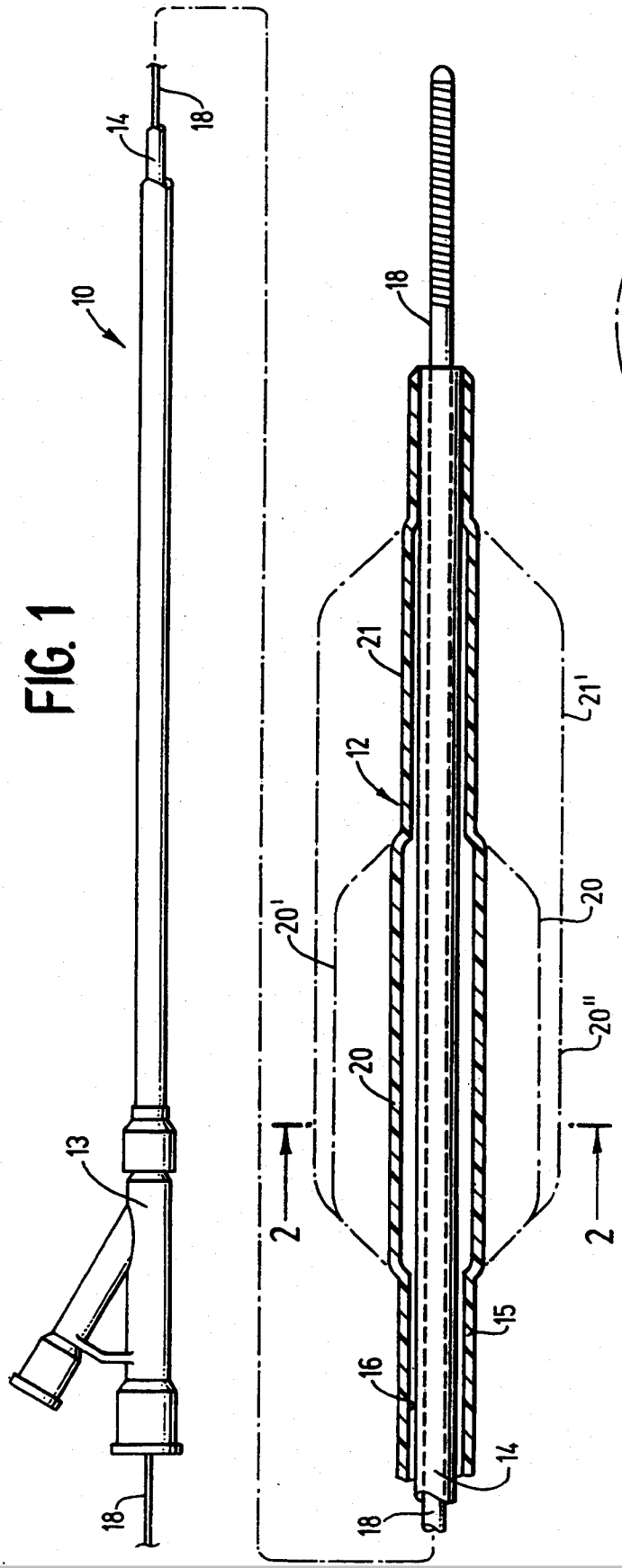


FIG. 1

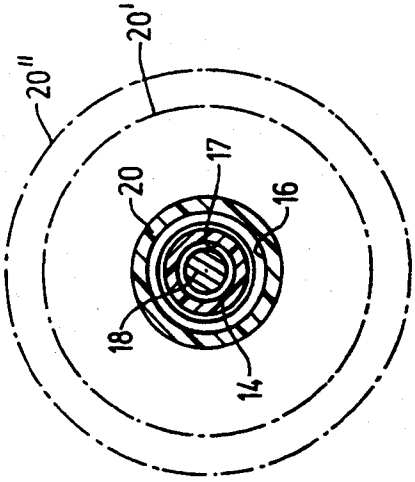


FIG. 2

FIG. 3

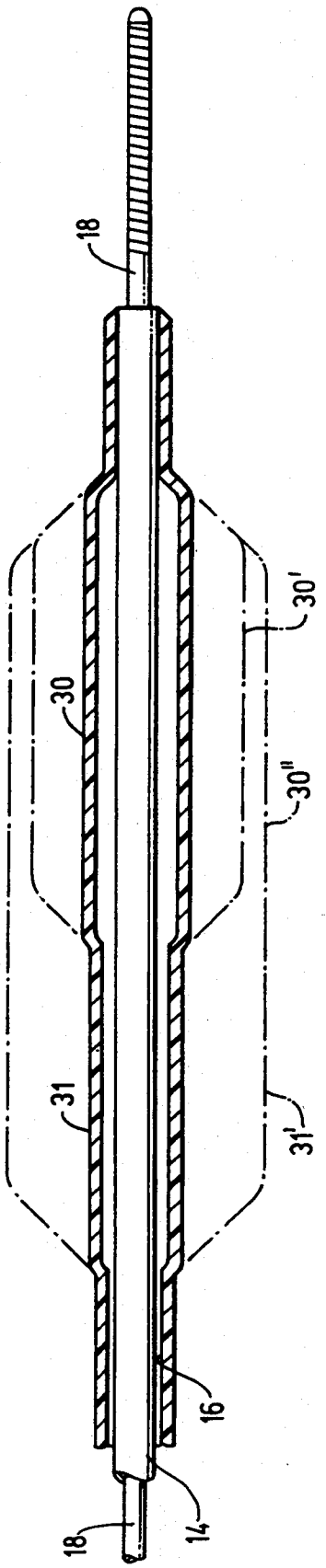
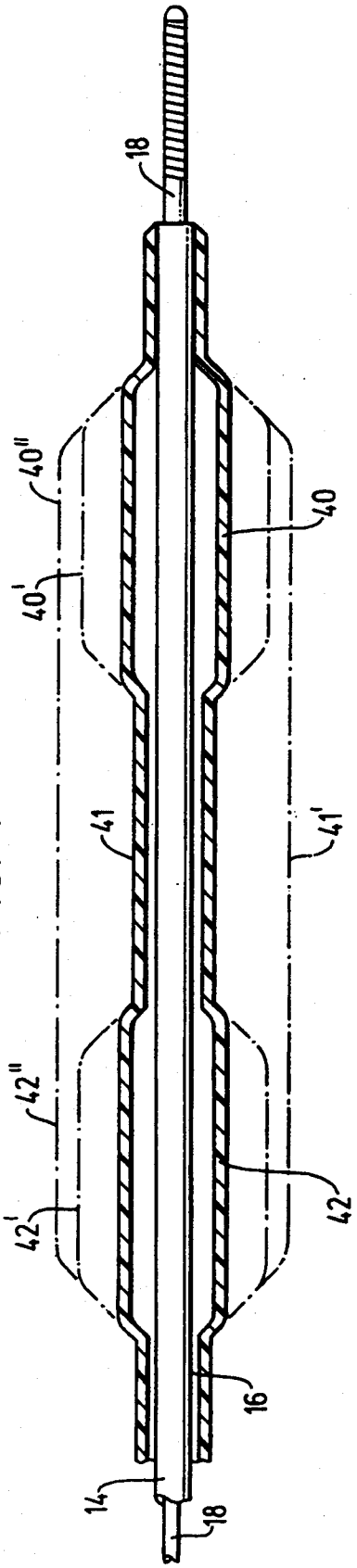


FIG. 4



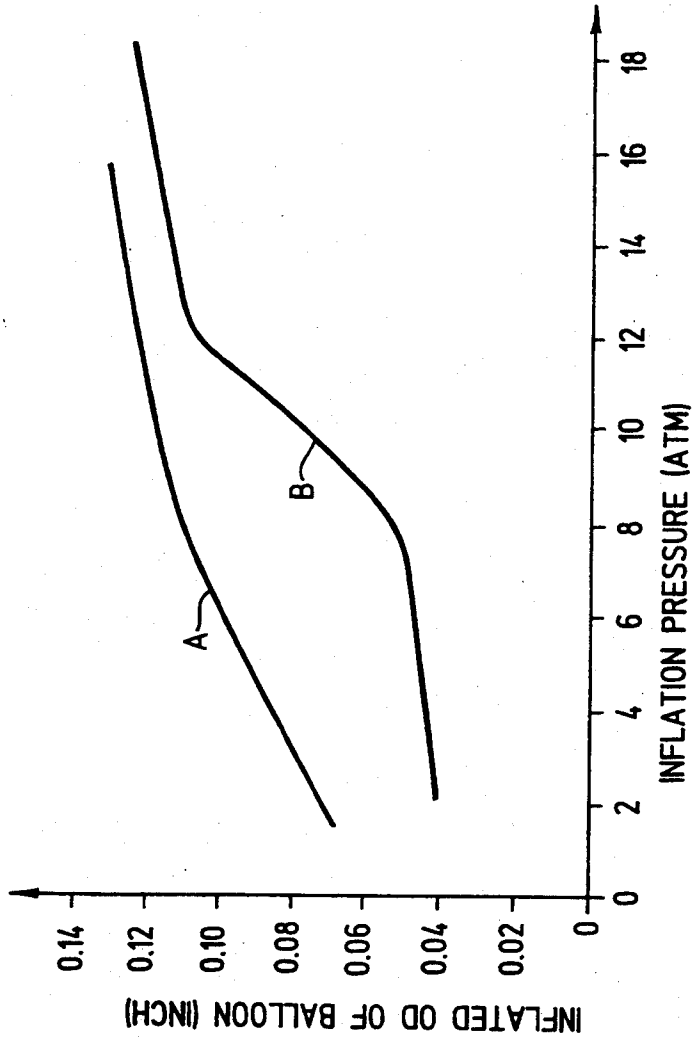


FIG 5.

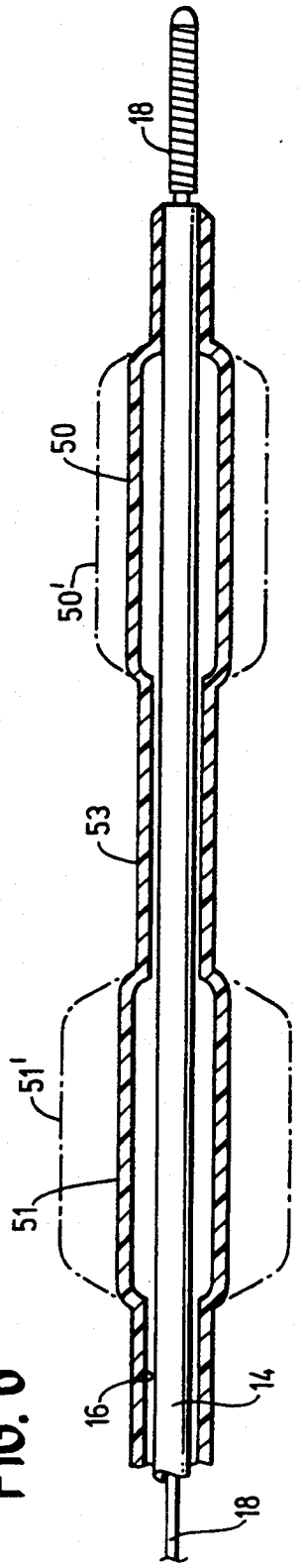


FIG. 6

BALLOON ASSEMBLY WITH SEPARATELY INFLATABLE SECTIONS

BACKGROUND OF THE INVENTION

The present invention is directed to a balloon assembly for catheters which are suitable for intraluminal procedures such a percutaneous transluminal coronary angioplasty (PTCA).

PTCA is a widely used procedure for the treatment of coronary heart disease. In this procedure, a balloon dilatation catheter is advanced into the patient's coronary artery and the balloon on the catheter is inflated within the stenotic region of the patient's artery to open up the arterial passageway and increase the blood flow through the artery. To facilitate the advancement of the dilatation catheter into the patient's coronary artery, a guiding catheter having a preshaped distal tip is first percutaneously introduced into the cardiovascular system of a patient by the Seldinger technique through the brachial or femoral arteries. The catheter is advanced therein until the preshaped distal tip of the guiding catheter is disposed within the aorta adjacent the ostium of the desired coronary artery. The guiding catheter is twisted or torqued from the proximal end, which extends out of the patient, to guide the distal tip of the guiding catheter into the ostium. A balloon dilatation catheter may then be advanced through the guiding catheter into the patient's coronary artery until the balloon on the catheter is disposed within the stenotic region of the patient's artery. The balloon is inflated to open up the arterial passageway.

One type of catheter frequently used in PTCA procedures is an over-the-wire type balloon dilatation catheter. Commercially available over-the-wire type dilatation catheters include the SIMPSON ULTRA-LOW PROFILE ®, the HARTZLER ACX ®, the HARTZLER ACX II ™, the PINKERTON 0.018 ™ and the ACS TEN ™ balloon dilatation catheters sold by the assignee of the present invention, Advanced Cardiovascular Systems, Inc. (ACS). Over-the-wire type dilatation catheters are described and claimed in U.S. Pat. No. 4,323,071 (Simpson-Robert).

When using an over-the-wire dilatation catheter, a guidewire is usually inserted into an inner lumen of the dilatation catheter before it is introduced into the patient's vascular system and then both are introduced into, and advanced through, the guiding catheter to its distal tip which is seated within the ostium. The guidewire is first advanced out the seated distal tip of the guiding catheter into the desired coronary artery until the distal end of the guidewire extends beyond the lesion to be dilatated. The dilatation catheter is then advanced out of the distal tip of the guiding catheter into the patient's coronary artery, over the previously advanced guidewire, until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion to be dilatated. Once properly positioned across the stenosis, 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 stenosed region of a diseased artery. After the inflations, the balloon is finally deflated so that the dilatation catheter can be removed from the dilatated stenosis to resume blood flow.

Fixed-wire type dilatation catheter systems are also utilized very frequently in PTCA procedures. This type of dilatation catheter has a guidewire or guiding member secured within the catheter and it provides low profiles, i.e. small transverse dimensions, because there is no inner tubular member which is characteristic of commercially available over-the-wire dilatation catheters. Commercially available fixed-wire dilatation catheters include the HARTZLER EXCEL ®, the HARTZLER LPS ® and the SLALOM ™ dilatation catheters sold by ACS. Fixed-wire dilatation catheters are disclosed and claimed in U.S. Pat. No. Re. 33,166 which is incorporated by reference into this application.

Another type of dilatation catheter, the rapid exchange type catheter, was introduced by ACS under the trademark ACS RX ® Coronary Dilatation Catheter. It is described and claimed in U.S. Pat. No. 5,040,548 (Yock), U.S. Pat. No. 5,061,273 (Yock) and U.S. Pat. No. 4,748,982 (Horzewski, et al.). This dilatation catheter has a short guidewire receiving sleeve or inner lumen extending through a distal portion of the catheter. The sleeve or inner lumen extends proximally from a first guidewire port in the distal end of the catheter to a second guidewire port in the catheter spaced proximally from the inflatable member of the catheter. A slit may be provided in the wall of the catheter body which extends distally from the second guidewire port, preferably to a location proximal to the proximal end of the inflatable balloon. The structure of the catheter allows for the rapid exchange of the catheter without the need for an exchange wire or adding a guidewire extension to the proximal end of the guidewire. This catheter has been widely praised by the medical profession, and it has met with much success in the marketplace because of the advantages of its unique design.

The perfusion type dilatation catheter was another type of dilatation catheter first introduced into the marketplace by ACS. This catheter, which can take the form of an over-the-wire, fixed-wire or a rapid exchange type catheter, has one or more perfusion ports proximal to the dilatation balloon in fluid communication with the guidewire receiving inner lumen extending to the distal end of the catheter. A plurality of perfusion ports are preferably provided in the catheter distal to the balloon which are also in fluid communication with the inner lumen extending to the distal end of the catheter. When the balloon of this dilatation catheter is inflated to dilatate a stenosis, oxygenated blood in the artery or the aorta, or both, depending upon the location of the dilatation catheter within the coronary anatomy, is forced to pass through the proximal perfusion ports, through the inner lumen of the catheter, and out the distal perfusion ports. The catheter provides oxygenated blood downstream from the inflated balloon to thereby prevent or minimize ischemic conditions in tissue distal to the balloon. The perfusion of blood distal to the inflated balloon allows for long term dilatations, e.g. 30 minutes or even several hours or more. This catheter has likewise been highly praised by the medical profession and has met with much commercial success. Commercially available perfusion type dilatation catheters include the STACK PERFUSION ® and the ACS RX PERFUSION ™ dilatation catheters which are sold by ACS.

It is not uncommon with all types of dilatation catheters to have some difficulty in properly positioning the inflatable member or balloon on the distal ends of these catheters within the stenotic region of a patient's artery or other body lumen or, if properly positioned within the stenosis, to have difficulty in maintaining the posi-

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