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Solar

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[54] **METHOD OF RAPID CATHETER EXCHANGE**

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[73] Assignee: **Pameda N.V.**, Netherlands Antilles

[21] Appl. No.: **966,693**

[22] Filed: **Oct. 26, 1992**

Related U.S. Application Data

[62] Division of Ser. No. 859,220, Mar. 30, 1992.

[51] **Int. Cl.**[6] **A61M 5/178;** A61M 29/00; A61F 2/06

[52] **U.S. Cl.** **604/164;** 623/1; 604/96; 606/194

[58] **Field of Search** 606/191-199; 604/96, 164; 623/1

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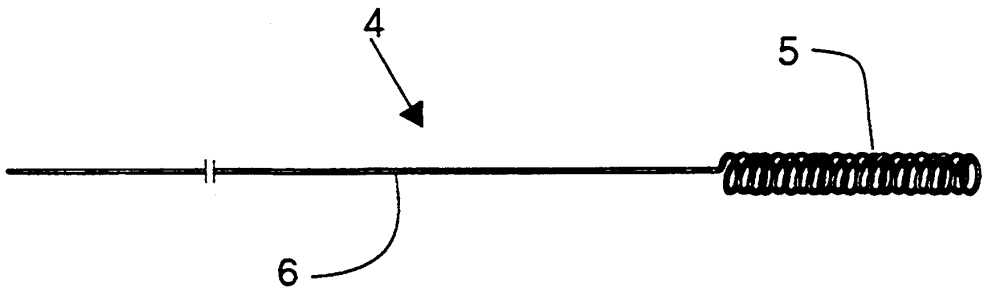
Primary Examiner—Randall L. Green
Assistant Examiner—Elizabeth M. Burke
Attorney, Agent, or Firm—Cowan, Liebowitz & Latman

[57] **ABSTRACT**

The invention relates to a rapid exchange catheter system comprising a exchange member having proximal and distal ends, the distal end of the rigid shaft being integral with the proximal end of the exchange member, such that said shaft is adapted to advance the exchange member distally to a desired location wherein the exchange member is positioned concentrically to a catheter shaft.

7 Claims, 3 Drawing Sheets



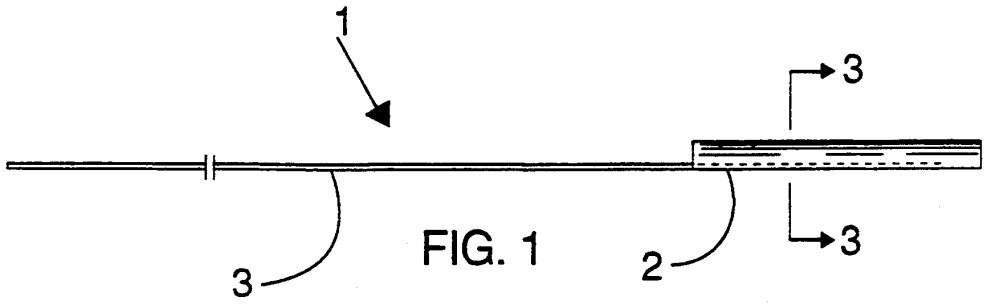


FIG. 1

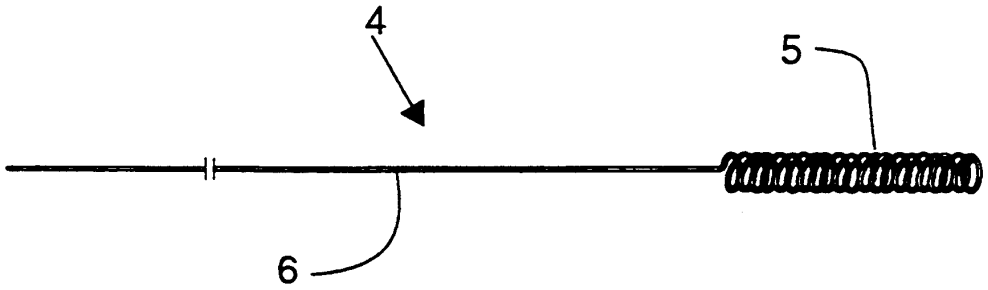


FIG. 2

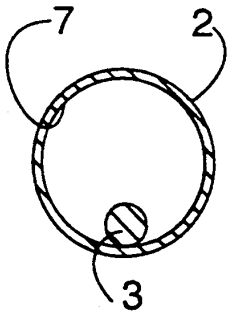


FIG. 3

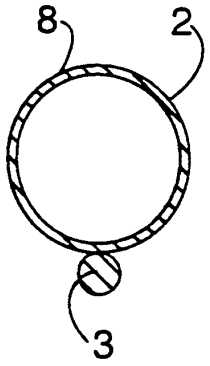


FIG. 4

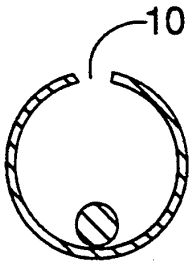


FIG. 5

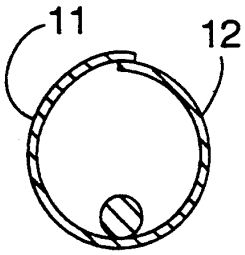


FIG. 6

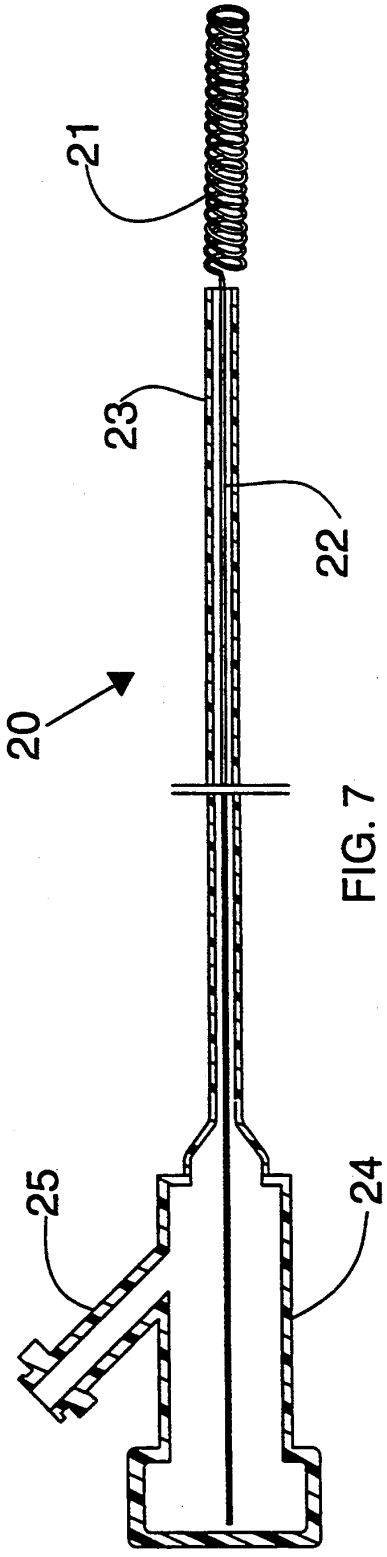


FIG. 7

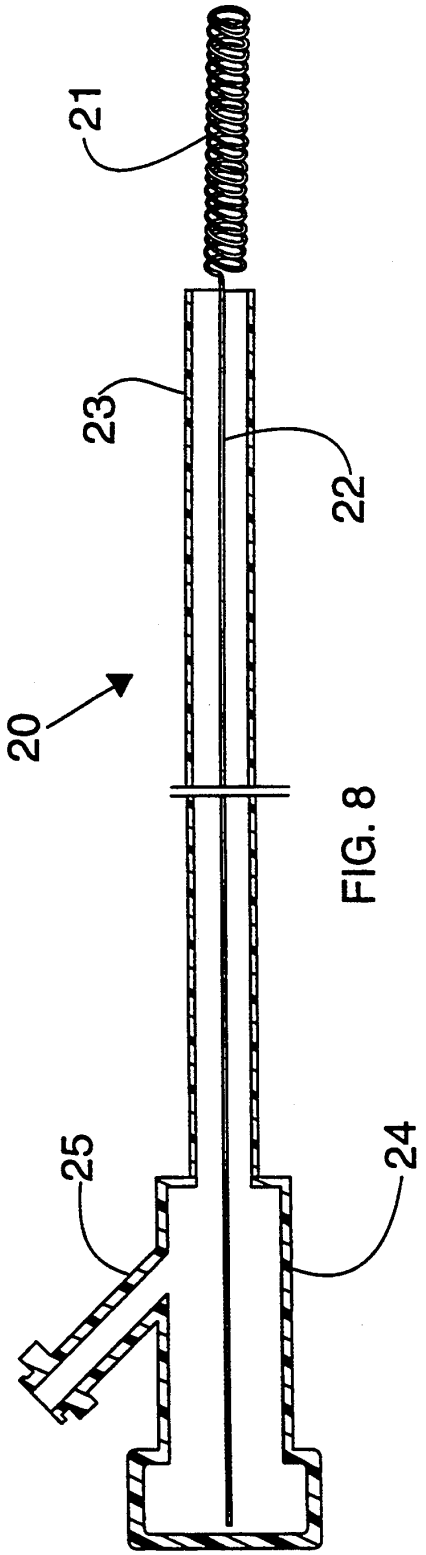


FIG. 8

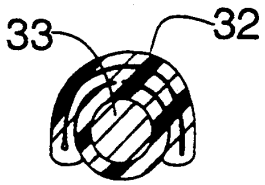


FIG. 9

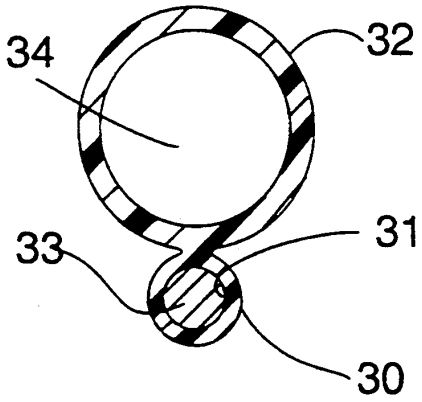


FIG. 10

METHOD OF RAPID CATHETER EXCHANGE

CROSS-REFERENCE TO RELATED APPLICATION

This application is a divisional of co-pending U.S. patent application Ser. No. 07/859,220, filed Mar. 30, 1992.

FIELD OF THE INVENTION

This invention relates to a rapid exchange catheter system. More particularly, this invention relates to a rapid exchange catheter system comprising one or more balloon dilatation catheters and an exchange facilitator consisting of an elongated exchange member and a rigid shaft.

BACKGROUND OF INVENTION

In the utilization of catheters to diagnose and treat various medical disorders, it is very often required that more than one device be used during the procedure. Because positioning of the catheter at the desired location may be difficult, time consuming, or critical or pose a high risk, techniques have been developed that facilitate exchange of catheter devices.

The most common technique for catheter exchange employs a very long guidewire called an exchange wire. In this technique the exchange wire is placed within a central lumen of a catheter that has been previously positioned within the body. To maintain the desired position, the exchange wire is advanced while the catheter is simultaneously withdrawn. Once the catheter is completely out of the body, it is removed from the exchange wire. A second catheter is then positioned over the exchange wire, and, once the catheter is completely on the exchange wire, it is then advanced to the desired site in the body. This over-the-wire technique for catheter exchange is considerably time consuming, and it requires at least two operators to effect the exchange. In addition, the very long exchange wire extends beyond the sterile field, which adds to the risk of contamination during the procedure.

U.S. Pat. No. 4,762,129 to Bonzel and U.S. Pat. No. 5,040,548 to Yock describe balloon angioplasty catheters that can be exchanged over a standard length guidewire. These catheters are called monorail catheters, and they are designed such that only a relatively short segment of the distal end of the catheter is advanced over the guidewire, i.e., the catheter has a lumen to receive the guidewire that extends from the distal tip of the catheter to a location proximal to the balloon. Since the length of the guidewire used is only about half that of an exchange wire, the catheter exchange can be done more quickly, and a single operator may do the exchange. However, since a much shorter segment of the catheter is concentric to the guidewire, the monorail-type catheters have diminished axial support for tracking the guidewire (trackability) and transmission of axial or longitudinal forces (pushability).

In addition to the drawbacks cited above, both of the catheter exchange techniques described above have two additional shortcomings—increased diameter of the catheters to accommodate the guidewire, and risk of vessel trauma resulting from repeated catheter passages. In a number of applications, over-the-wire catheters are too large to be placed at the desired location. In these applications, smaller catheters, whose diameters have been reduced by eliminating the guidewire lumen, have been required. Exchange with these prior art systems consisted essentially of starting over after the first catheter was removed. This is often time consuming, and there is an increased risk of complications resulting from vessel trauma. U.S. Pat. Nos. 4,944,740 and 4,976,689 addressed the trauma issue by providing an outer tubular sheath concentric to an inner catheter. However, this system would have very limited application in small blood vessels, as the system itself would occlude the blood vessel and cause ischemic complications. Moreover, the outer tubular sheath must be used as a system with its inner catheter; if another catheter or guidewire was used initially, this system could not make the exchange.

OBJECTS OF THE INVENTION

It is an object of this invention to provide an atraumatic rapid exchange catheter system.

It is also an object of this invention to provide a rapid exchange catheter system comprising an exchange member and a pushing shaft.

It is a further object of this invention to provide a rapid exchange catheter system comprising an exchange member, a pushing shaft, an expandable sheath membrane, and a hemostasic manifold.

It is a yet further object of this invention to provide a method for the rapid exchange of exchange members, such as catheters, guidewires and other devices.

These and other objects of the invention will become more apparent in the discussion below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **2** each represent lateral, longitudinal views of respective embodiments of the invention;

FIG. **3** represents a cross-sectional view of the embodiment of FIG. **1**;

FIGS. **4**, **5**, and **6** represent additional cross-sectional views of embodiments of the invention;

FIG. **7** represents an additional embodiment of the invention with the sheath collapsed;

FIG. **8** represents the embodiment of FIG. **7** with the sheath expanded; and

FIGS. **9** and **10** represent cross-sectional views of a further embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The rapid exchange catheter system (RECS) of this invention provides a very rapid, atraumatic means of exchanging one balloon dilatation catheter or other device for another balloon dilatation catheter or other device. The RECS is comprised of (1) a distal exchange member, preferably radiopaque, and (2) a rigid shaft or wire attached to the exchange member. Optionally the RECS may also comprise (3) a membrane sheath, which is folded around and attached along the length of the rigid shaft, and (4) a hemostatic manifold in fluid connection with the membrane sheath.

The RECS is used by, first, placing the exchange member over the proximal portion of the shaft of a catheter, e.g., a balloon dilatation (PTCA) catheter, or a guidewire or other device, that is to be withdrawn from a patient. Then, the exchange member is advanced distally along the shaft until the exchange member is positioned at the target site, i.e., adjacent to or across a stenosis, by pushing the rigid wire. The catheter, guidewire, or other device is withdrawn, and then, if a mem-

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