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Ramzipoor

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[54] **GUIDEWIRE REPLACEMENT DEVICE WITH FLEXIBLE INTERMEDIATE SECTION**

Attorney, Agent, or Firm—Heller, Ehrman, White & McAuliffe

[75] Inventor: **Kamal Ramzipoor**, Union City, Calif.

[57] **ABSTRACT**

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

A guidewire replacement device having a proximal shaft section, a distal shaft section and a flexible intermediate shaft section which facilitate the articulation of the distal shaft section with respect to the proximal shaft section. The intermediate shaft section has an aperture for the egress or exit of an in-place guidewire during a guidewire exchange. The proximal end of an in-place guidewire is inserted through the distal guidewire port in the distal end of the distal shaft section, through the distal section and out the aperture in the intermediate shaft section. The exchange device is advanced through the inner lumen of a guiding catheter over the in-place guidewire until the distal end of the exchange device extends through the proximal guidewire port of a rapid exchange type intraluminal catheter. Once the guidewire exchange device is properly placed, the in-place guidewire can then be withdrawn from the patient. The replacement guidewire can then be advanced through the inner lumen of the proximal shaft section, the guidewire passageway of the intermediate section, the inner lumen of the distal section into the guidewire receiving inner lumen of the intraluminal catheter. The guidewire exchange device may then be removed from the patient.

[21] Appl. No.: **616,449**

[22] Filed: **Mar. 15, 1996**

[51] **Int. Cl.**⁶ **A61B 5/00**

[52] **U.S. Cl.** **600/585**; 604/95; 604/280

[58] **Field of Search** 128/772, 658, 128/657; 604/95, 96, 280, 281, 282, 283

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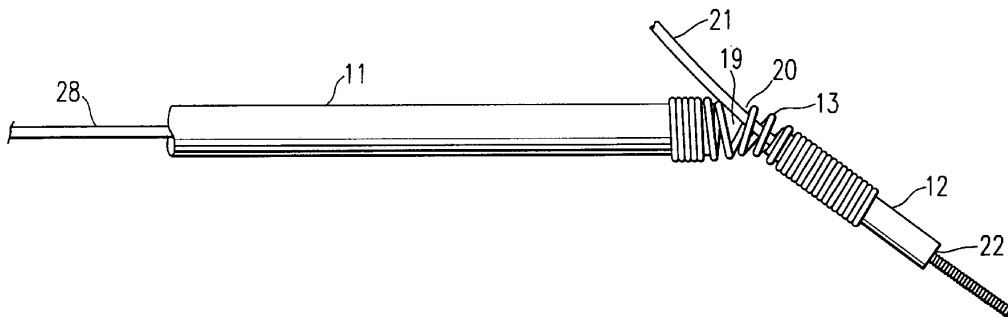
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Primary Examiner—Max Hindenburg
Assistant Examiner—Pamela S. Wingood

10 Claims, 3 Drawing Sheets



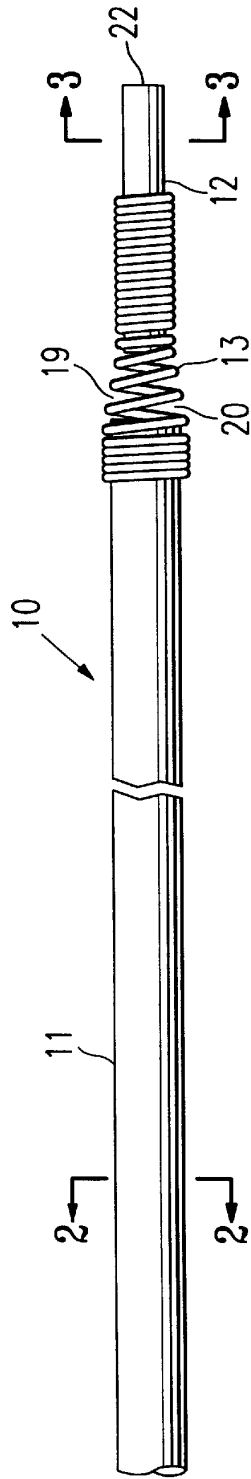


FIG. 1

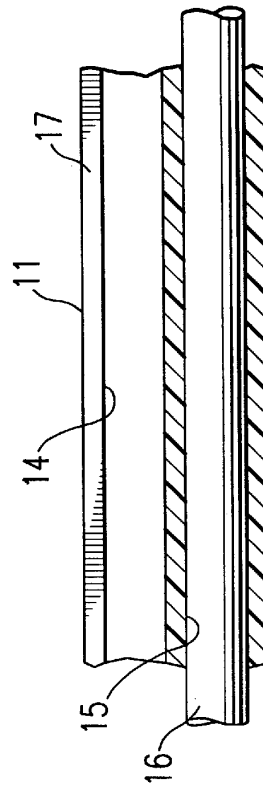


FIG. 4



FIG. 3

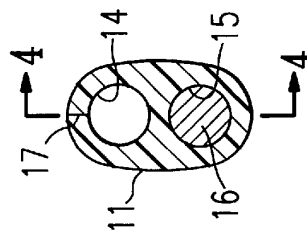


FIG. 2

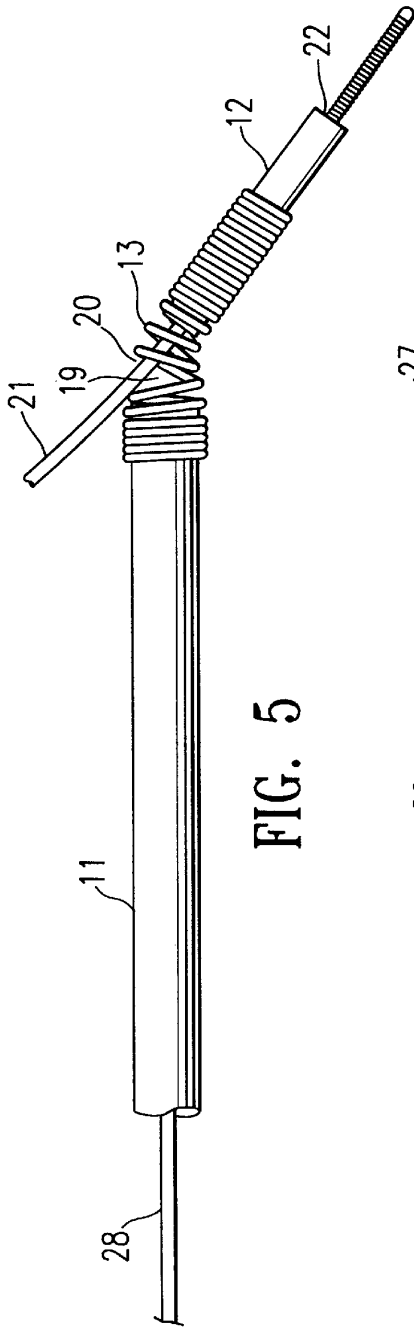


FIG. 5

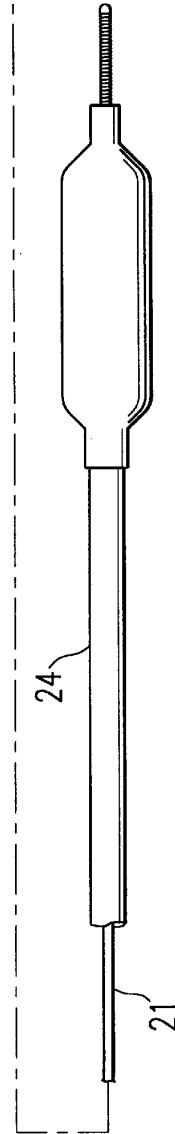
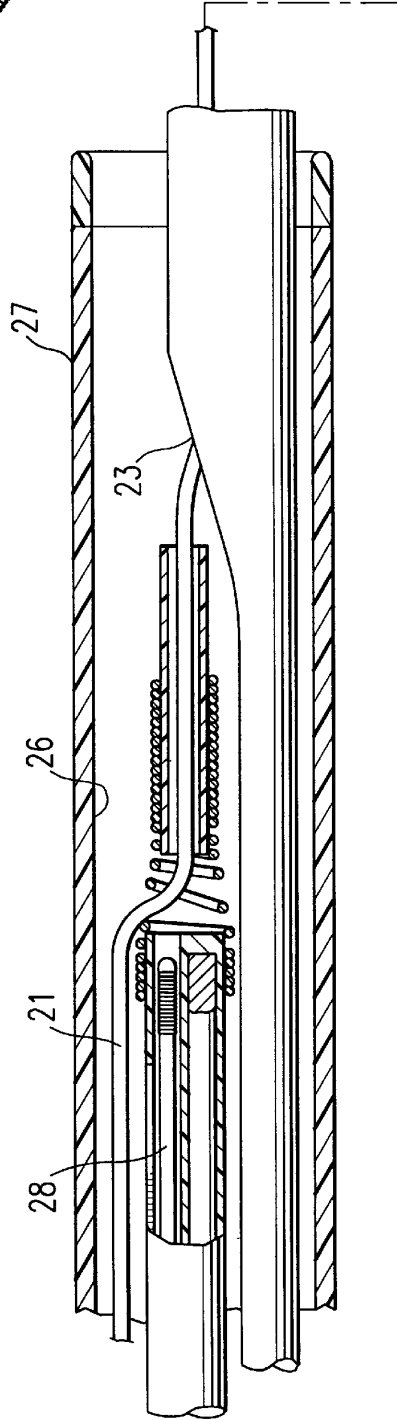


FIG. 6

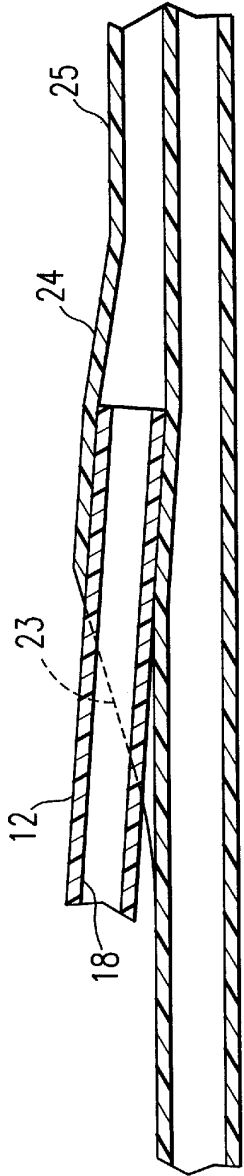


FIG. 7

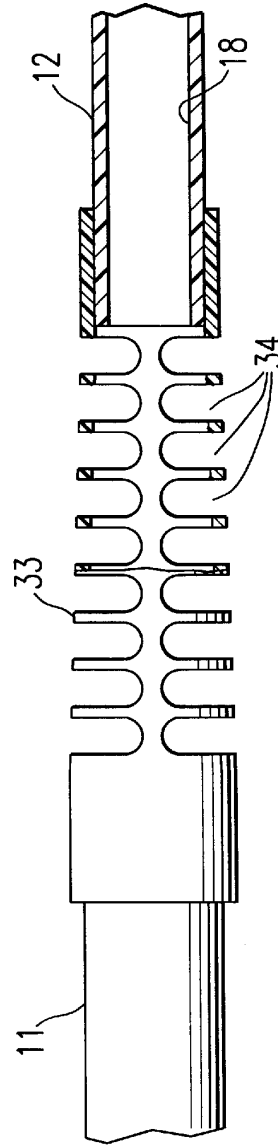


FIG. 8

GUIDEWIRE REPLACEMENT DEVICE WITH FLEXIBLE INTERMEDIATE SECTION

BACKGROUND OF THE INVENTION

This invention generally relates to intravascular procedures, such as percutaneous transluminal coronary angioplasty (PTCA), and particularly to the exchange of guidewires during such procedures.

In typical PTCA procedures, a dilatation catheter is advanced over a guidewire, which is slidably disposed within an inner lumen of the dilatation catheter, 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 across the lesion, the flexible, relatively inelastic balloon on the dilatation catheter is inflated to a predetermined size with radiopaque liquid at relatively high pressures (e.g., generally 4–20 atmospheres or more) to dilate the stenosed region of the diseased artery. One or more inflations of the balloon may be required to complete the dilatation of the stenosis. After the last dilatation, the balloon is deflated so that the dilatation catheter can be removed from the dilated stenosis and blood flow can resume through the dilated artery.

One significant improvement in dilatation catheters has been the introduction of rapid exchange type dilatation catheters. These catheters have a short guidewire receiving sleeve or inner lumen extending through the distal portion of the catheter which extend from a distal guidewire port in the distal end of the catheter to a proximal guidewire port spaced proximal to the proximal end of the dilatation balloon. The proximal guidewire port is usually located at least about 10 cm and usually not more than about 50 cm from the distal guidewire port. A slit is preferably provided in the catheter wall in fluid communication with the guidewire receiving inner lumen which extends from the second guidewire port, preferably to a location proximal to the proximal end of the inflatable balloon to aid in the removal of the catheter from a guidewire upon withdrawal of the catheter from the patient. The structure of the catheter allows for the rapid exchange of the catheter without the need for the use of an exchange wire or adding a guidewire extension to the proximal end of the guidewire. The design of this catheter has been widely praised by the medical profession and has met with much commercial success in the market place because of its unique design. The rapid exchange type dilatation catheters of the assignee of the present invention, Advanced Cardiovascular Systems, Inc., have had a significant impact in the market for rapid exchange type dilatation catheters. Such products include dilatation catheters sold under the trademarks ALPHA, STREAK and ELIPSE.

Rapid exchange type dilatation catheters are described and claimed in U.S. Pat. No. 5,040,548 (Yock), U.S. Pat. No. 5,061,273 (Yock), U.S. Pat. No. 5,300,085 (Yock), U.S. Pat. No. 5,350,395 (Yock), U.S. Pat. No. 4,748,982 (Horzowski et al.), U.S. Pat. No. 5,154,725 (Leopold) and U.S. Pat. No. 5,346,505 (Leopold) which are incorporated herein in their entirety by reference.

However, there is one significant inconvenience with the use of rapid exchange type dilatation catheter systems, namely, the inability to remove a guidewire already in place within a patient's vasculature during an angioplasty procedure without losing access to the vascular location. There has been no convenient way in which a replacement guidewire might be advanced through the vasculature and into the short guidewire receiving inner lumen in the distal extremity of a rapid exchange type dilatation catheter. These

instances occur when there is a need to replace an in-place guidewire with another guidewire having a different structure, e.g. from a floppy-type design with a separate shaping ribbon to an intermediate or standard with a core wire which extends to the distal tip of the guidewire. The need to withdraw an in-place guidewire also occurs when the distal tip of the in-place guidewire needs to be reshaped to change the angle of attach to a branch coronary artery.

What has been needed and heretofore unavailable is a convenient means to withdraw an in-place guidewire from a rapid exchange type dilatation catheter and either replace the in-place guidewire with another guidewire or to reposition the in-place guidewire within the rapid exchange type dilatation catheter. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

This invention is directed to a guidewire exchange device for use with rapid exchange type catheters and to the use of this device, particularly during an intravascular procedure such as angioplasty.

The guidewire exchange device of the invention generally comprises an elongated shaft with proximal and distal ends, a guidewire receiving inner lumen extending therein from the proximal end to a guidewire port in the distal end of the catheter. The catheter shaft has an elongated proximal section, a relatively short distal section and an intermediate section which is capable of transmitting push from the proximal shaft section to the distal shaft section and which is sufficiently axially flexible to allow the distal shaft section to be deflected away from the longitudinal axis of the proximal shaft section, i.e. to facilitate the articulation of the distal shaft section with respect to the proximal shaft section. This allows the proximal end of an in-place guidewire to be back loaded through the distal shaft section and out an aperture or opening provided in the flexible intermediate shaft section. The guidewire exchange device can be advanced over an in-place guidewire until the distal end of the distal shaft section of the device is seated in the proximal guidewire port of a rapid exchange type catheter. Preferably, the distal shaft section is advanced well into the guidewire receiving inner lumen of the rapid exchange type catheter. In this manner, the in-place guidewire can be readily removed from the patient by pulling on the proximal extremity thereof which extends out the proximal end of a guiding catheter without loss of access to the vascular location within the patient. A replacement guidewire can then be readily advanced through the guidewire lumen in the proximal shaft section, the guidewire passageway through the intermediate shaft section, through the inner lumen of the distal shaft section and then into the guidewire lumen of the rapid exchange type dilatation catheter. At this point the guidewire exchange device may be withdrawn. However, it may be desirable to leave the guidewire exchange device connected to the rapid exchange type dilatation catheter in the event the replacement guidewire needs to be replaced.

In the embodiment of the invention wherein the distal portion of the distal tubular member of the exchange device is adapted to be inserted into and be advanced through essentially the entire length of the relatively short guidewire receiving inner lumen of the readily exchangeable catheter is particularly suitable for use with a rapid exchange type dilatation catheters having perfusion ports, as described in the previously discussed McInnes et al. applications incorporated herein, which allow blood to pass through the guidewire receiving inner lumen. When using rapid

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