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Verbeek

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[54] RAPID EXCHANGE HIGH PRESSURE TRANSITION FOR HIGH PRESSURE CATHETER WITH NON-COMPLIANT BALLOON

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[73] Assignee: Medtronic, Inc., Minneapolis, Minn.

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[51] Int. Cl.^{6} A61M 29/00

[52] U.S. Cl. 604/103; 604/96; 606/194

[58] Field of Search 604/96–104, 282; 128/898; 606/191–200, 108; 600/201, 204, 207

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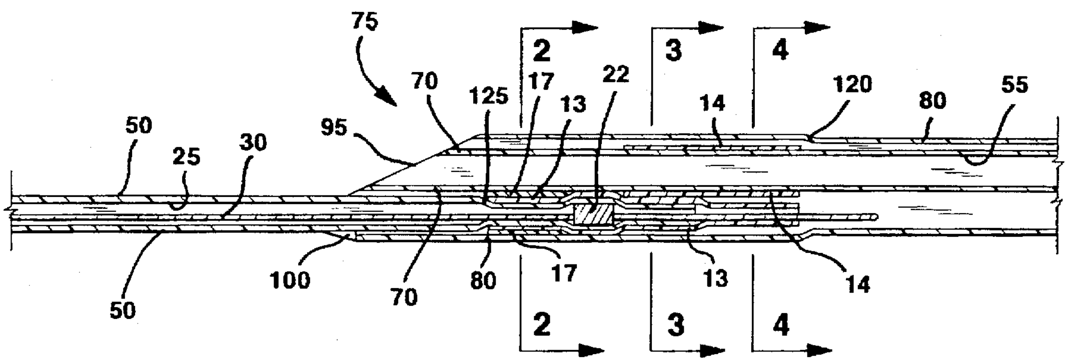
Attorney, Agent, or Firm—Dianne M.F. Plunkett; Harold R. Patton

[57] ABSTRACT

A medical catheter is provided which includes a core wire extending longitudinally through inflation tubing. The inflation tubing defines an inflation lumen. The distal end of the inflation tubing extends longitudinally through a tubular first reinforcement band which terminates distal to the distal end of the inflation tubing. An inner lumen tube defines a guidewire lumen, the inner lumen tube being biaxial with the inflation tubing and running longitudinally along the outer diameter of the inflation tubing. The inner lumen tube extends longitudinally through a shim tube which has a longitudinal slit running along its top side. The inner lumen tubing which has the shim coaxially bonded thereon extends longitudinally through a shaft tube. The inflation tube with the first reinforcement band coaxially bonded thereon also extends longitudinally through the shaft tube. The shaft tube is bonded to the inner lumen tube and to the inflation tube. A metal piece may be bonded to the inflation tube. An inflatable balloon is mounted at the distal end of the shaft tube, the balloon is in fluid communication with the inflation lumen.

22 Claims, 3 Drawing Sheets



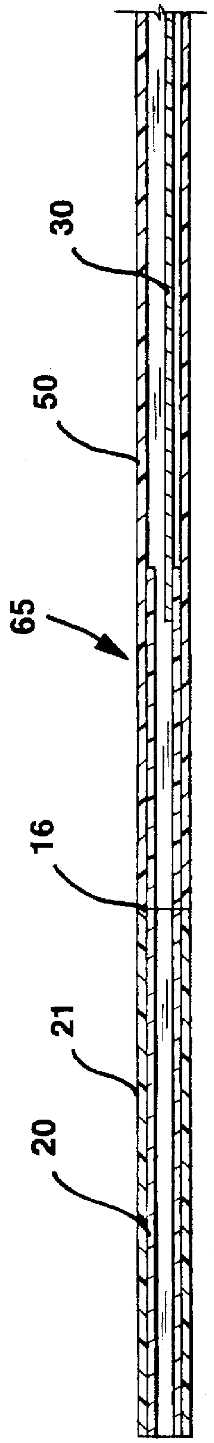


FIG.1A

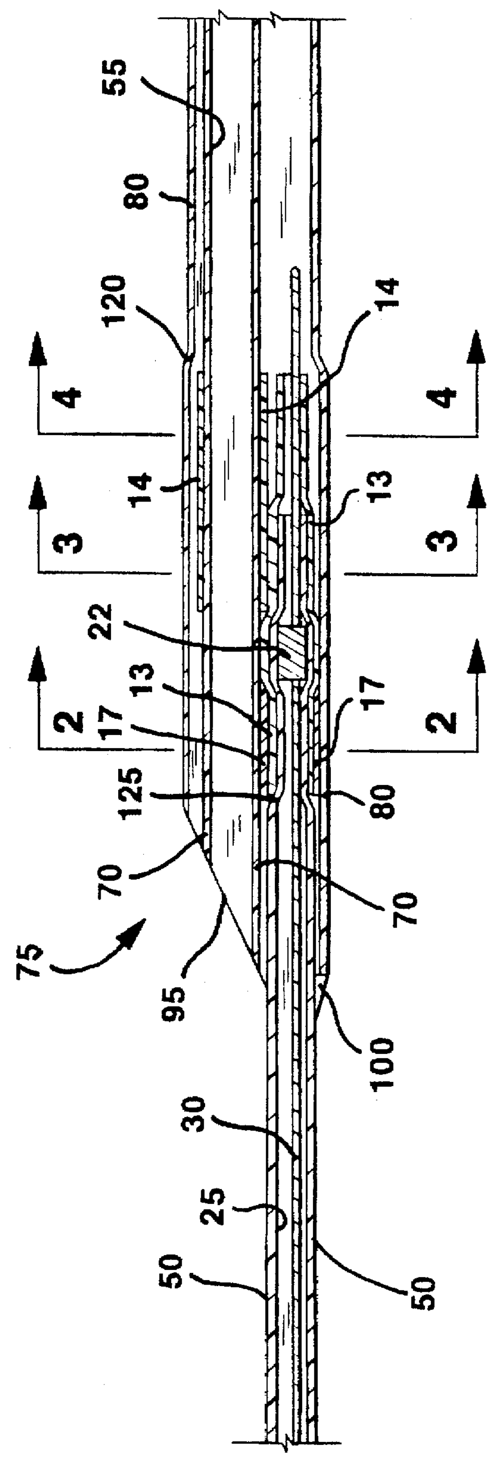


FIG. 1B

FIG.1

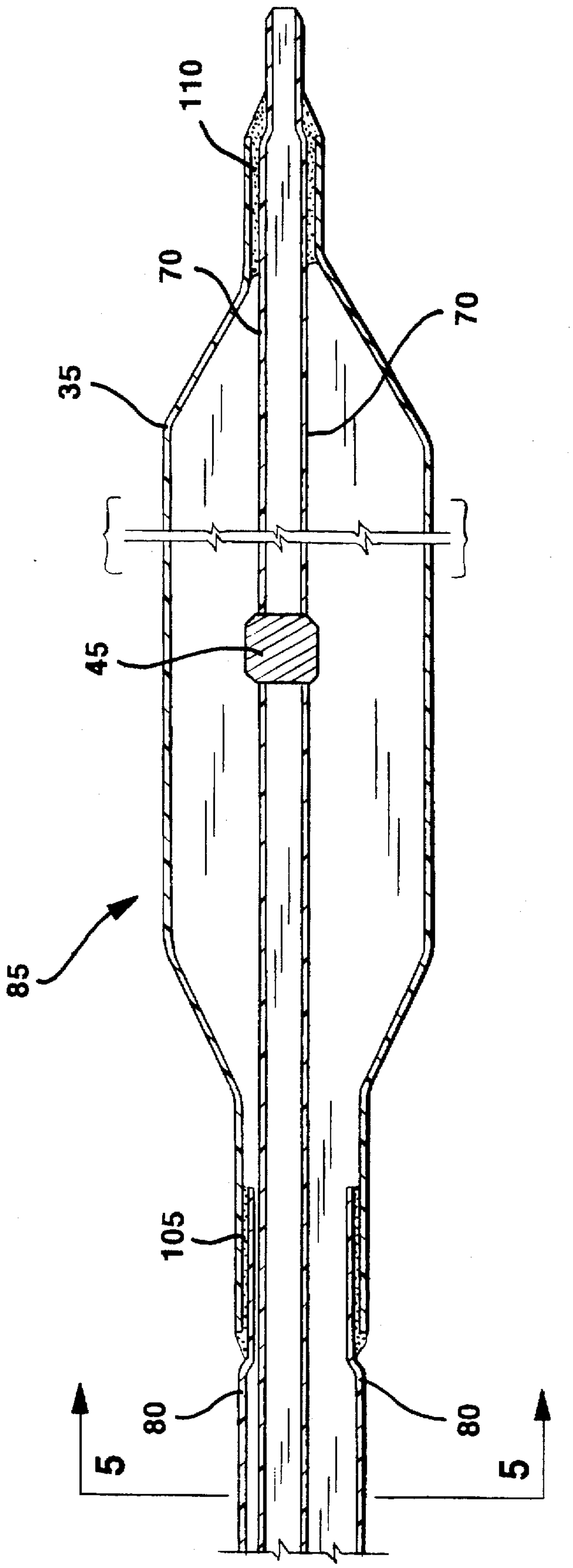


FIG. 1C

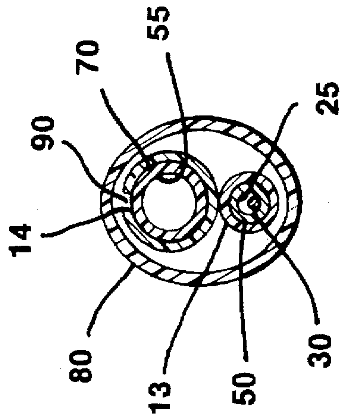


FIG. 3

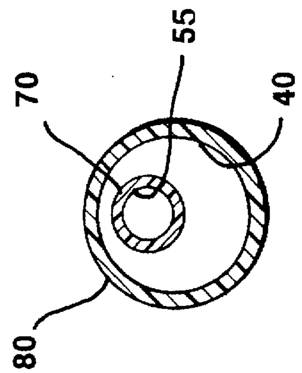


FIG.5

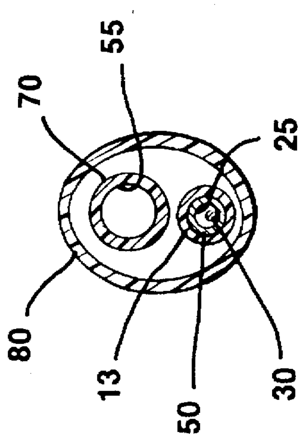


FIG. 2

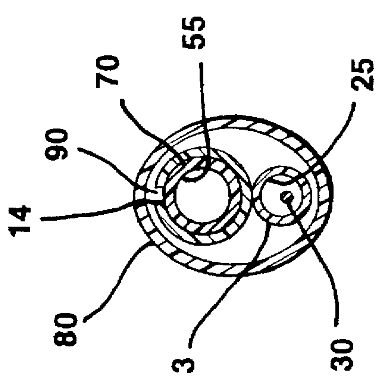


FIG. 4

RAPID EXCHANGE HIGH PRESSURE TRANSITION FOR HIGH PRESSURE CATHETER WITH NON-COMPLIANT BALLOON

FIELD OF THE INVENTION

The present invention relates to angioplasty catheters, and more particularly, to a shaft transition section for a rapid exchange high pressure balloon catheter.

BACKGROUND OF THE INVENTION

One of the therapeutic procedures applicable to the present invention is known as percutaneous transluminal coronary angioplasty (PTCA). This procedure can be used, for example, to reduce arterial build-up of .cholesterol fats or atherosclerotic plaque. Typically a first guidewire of about 0.038 inches in diameter is steered through the vascular system to the site of therapy. A guiding catheter, for example, can then be advanced over the first guidewire to a point just proximal of the stenosis. The first guidewire is then removed. A balloon catheter on a smaller 0.014 inch diameter second guidewire is advanced within the guiding catheter to a point just proximal of the stenosis. The second guidewire is advanced into the stenosis, followed by the balloon on the distal end of the catheter. The balloon is inflated causing the site of the stenosis to widen. The original catheter can then be withdrawn and a catheter of a different size or another device such as an atherectomy device can be inserted.

Conventional angioplasty balloons fall into high, medium, and low pressure ranges. Low pressure balloons are those that have burst pressures below 6 atmospheres (6.1×10^5 Pascals). Medium pressure balloons are those that have burst pressures between 6 and 12 atm (6.1×10^5 and 1.2×10^6 Pa). High pressure balloons are those that have burst pressures above 12 atm (1.2×10^6 Pa). Burst pressure is determined by such factors as wall thickness and tensile strength, for example.

High pressure balloons are desirable because they have the ability to exert more force and crack hard lesions. High pressure balloons are also useful in stent deployment. A biocompatible metal stent props open blocked coronary arteries, keeping them from reclosing after balloon angioplasty. A balloon of appropriate size and pressure is first used to open the lesion. The process is repeated with a stent crimped on a high pressure balloon. The stent is deployed when the balloon is inflated. A high pressure balloon is useful for stent deployment because the stent must be forced against the artery's interior wall so that it will fully expand thereby precluding the ends of the stent from hanging down into the channel encouraging the formation of thrombus.

Rapid exchange catheters are those which have shorter guidewire lumens passing from the distal end of the catheter through the balloon and opening to the exterior of the catheter somewhere proximal to the balloon. Catheter exchanges over the guidewire are easier to accomplish because they can be done with a single operator rather than two operators as required by over-the-wire catheters.

The catheter shaft area where the proximal end of the guidewire lumen begins is known as the transition area. Maintaining flexibility, a low profile and a strong bond in the transition area is difficult when high pressures of greater than 450 psi (31 bar) are used. With such pressures, parts could delaminate and separate. Typically, the area having the least bond strength, with the exception of the balloon area, is at the transition section where components meet and the tubing is necked down and/or weakened by heat.

U.S. Pat. Nos. 5,328,472 and 5,410,797 to Steinke et at. disclose flexible biaxial tubes which form the transition region. The rated burst pressure for this product is 10 bar with a transition area capable of 14 bar.

U.S. Pat. No. 5,545,134 to Hilaire et al. discloses a tube which comprises in its upper part a channel with a substantially circular cross-section which, once drawn, constitutes the second inner duct for the passage of a guide-wire, and in its lower part a second channel with a cross-section having substantially the shape of a crescent or kidney, which progressively disappears by stretching.

U.S. Pat. No. 5,549,556 to Ndondo-Lay et al in FIG. 6 and U.S. Pat. No. 5,549,557 to Steinke et al in FIG. 2 disclose a biaxial guidewire and inflation lumen. The inflation lumen being defined by a spring coil and an inflation lumen jacket with a central core wire. Such a transition construction withstands pressures of up to 400 psi.

What is needed is a rapid exchange catheter with a shaft transition that can reliably withstand internal pressure of at least 450 psi (31 bar) without leaking or rupturing which is relatively easy, consistent and reliable to manufacture.

SUMMARY OF THE INVENTION

The above features and advantages of the present invention, as well as others, are accomplished by providing a medical catheter comprising a core wire extending longitudinally through inflation tubing. The inflation tubing defines an inflation lumen. The distal end of the inflation tubing extends longitudinally through a tubular first reinforcement band which terminates distal to the distal end of the inflation tubing. An inner lumen tube defines a guidewire lumen, the inner tureen tube being biaxial with the inflation tubing and running longitudinally along the outer diameter of the inflation tubing. The inner lumen tube extends longitudinally through a shim tube which has a longitudinal slit running along its top side. The inner lumen tubing which has the shim coaxially bonded thereon extends longitudinally through a shaft tube. The inflation tube with the first reinforcement band coaxially bonded thereon also extends longitudinally through the shaft tube. The shaft tube is bonded to the inner lumen tube and to the inflation tube. A metal piece may be bonded to the inflation tube. An inflatable balloon is mounted at the distal end of the shaft tube, the balloon is in fluid communication with the inflation lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a longitudinal cross section of the proximal end of the shaft of the present invention;

FIG. 1B is a longitudinal cross-section of the transition section;

FIG. 1C is a longitudinal cross-section of the balloon;

FIG. 2 is a cross-section taken along the lines 2—2 of FIG. 1B before heat shrinking;

FIG. 3 is a cross-section taken along the lines 3—3 of FIG. 1B before heat shrinking;

FIG. 4 is a cross-section taken along the lines 4—4 of FIG. 1B before heat shrinking; and

FIG. 5 is a cross-section taken along the lines 5—5 of FIG. 1C.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a 6 French compatible, rapid exchange catheter with a transition that can reliably

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