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Fugoso et al.

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[54] **FLEXIBLE CATHETER**

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

[52] **U.S. Cl.** **604/524**; 604/526

[58] **Field of Search** 604/523, 524, 604/264, 96, 526; 600/435

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,960,410	10/1990	Pinchuk	604/96
5,328,472	7/1994	Steinke et al.	604/102
5,410,797	5/1995	Steinke et al.	29/435
5,454,795	10/1995	Samson	604/282
5,460,608	10/1995	Lodin et al.	604/96
5,599,326	2/1997	Carter	604/282
5,690,613	11/1997	Verbeek	604/103
5,702,373	12/1997	Samson	604/280 X

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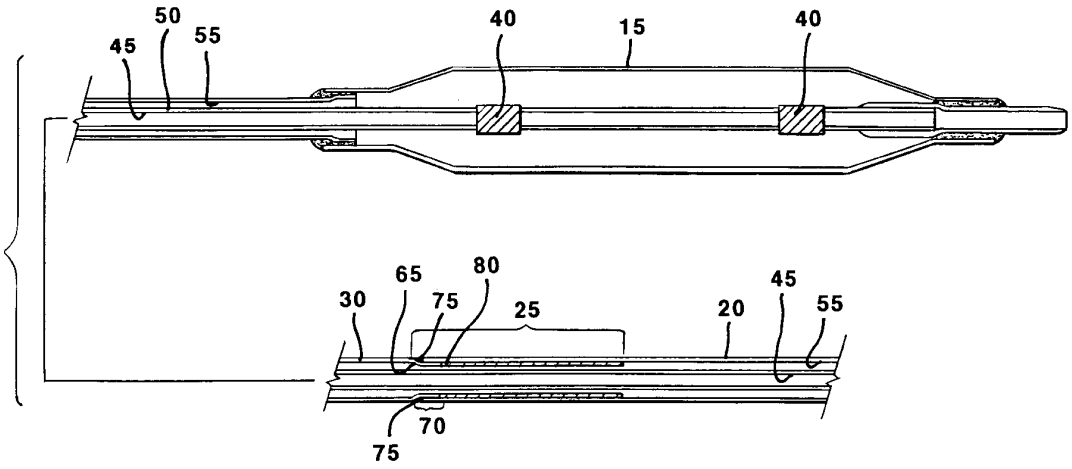
[57] **ABSTRACT**

A medical catheter comprising a distal shaft having a greater flexibility than the proximal shaft. The proximal shaft has a helical end portion of reduced outer diameter which is integral with and extending from the distal end of the proximal shaft. The helical end portion slidingly fits within a portion of the proximal end of the distal shaft. The helical end portion is bonded to at least a portion of the distal shaft to form a fluid-tight seal. The pitch of the helical end portion may be constant or variable. The helical turns may be abutting or spaced apart. A guidewire shaft centrally extends longitudinally through the proximal and distal shaft such that fluid can be transmitted through the proximal and distal shaft, exterior to the guidewire shaft.

21 Claims, 3 Drawing Sheets



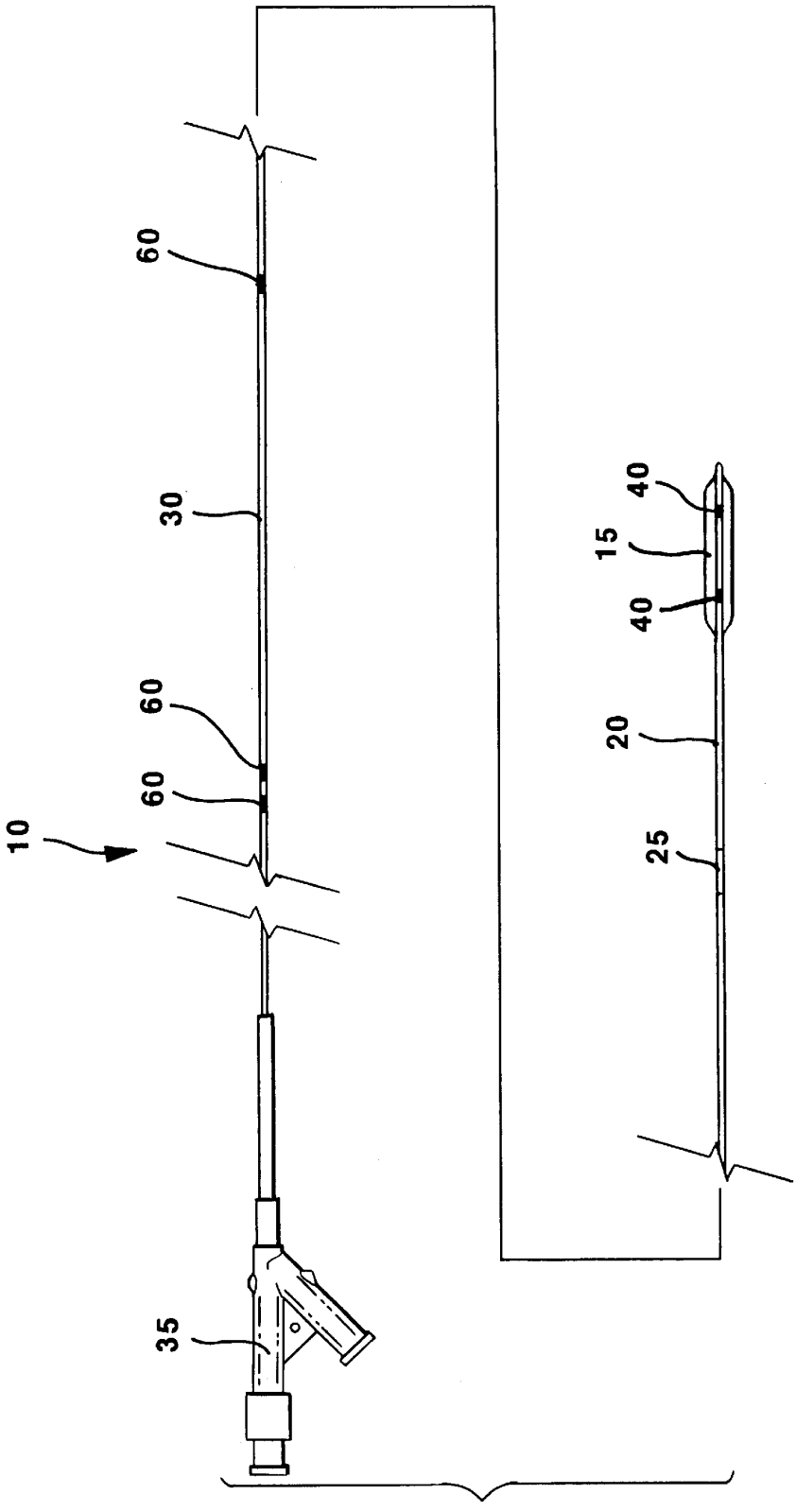


FIG.1

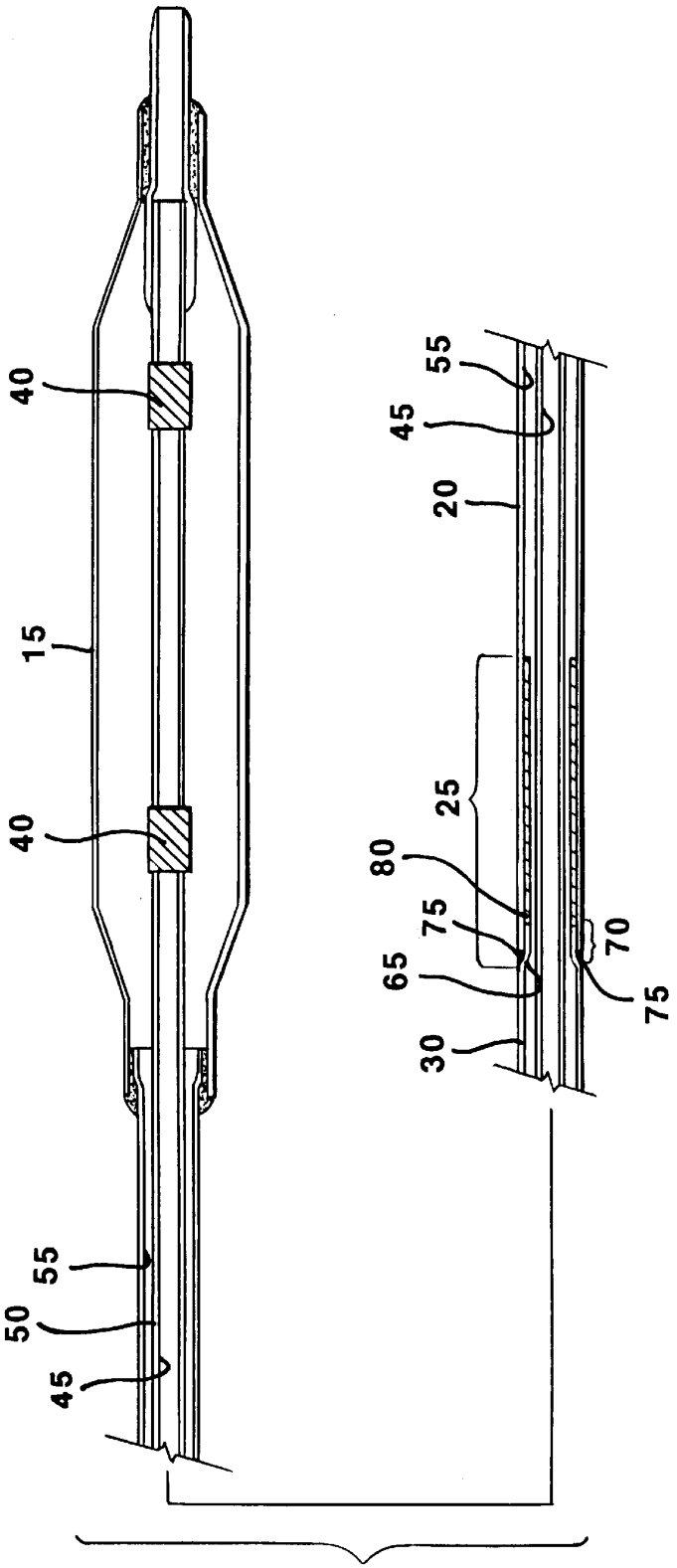


FIG.2

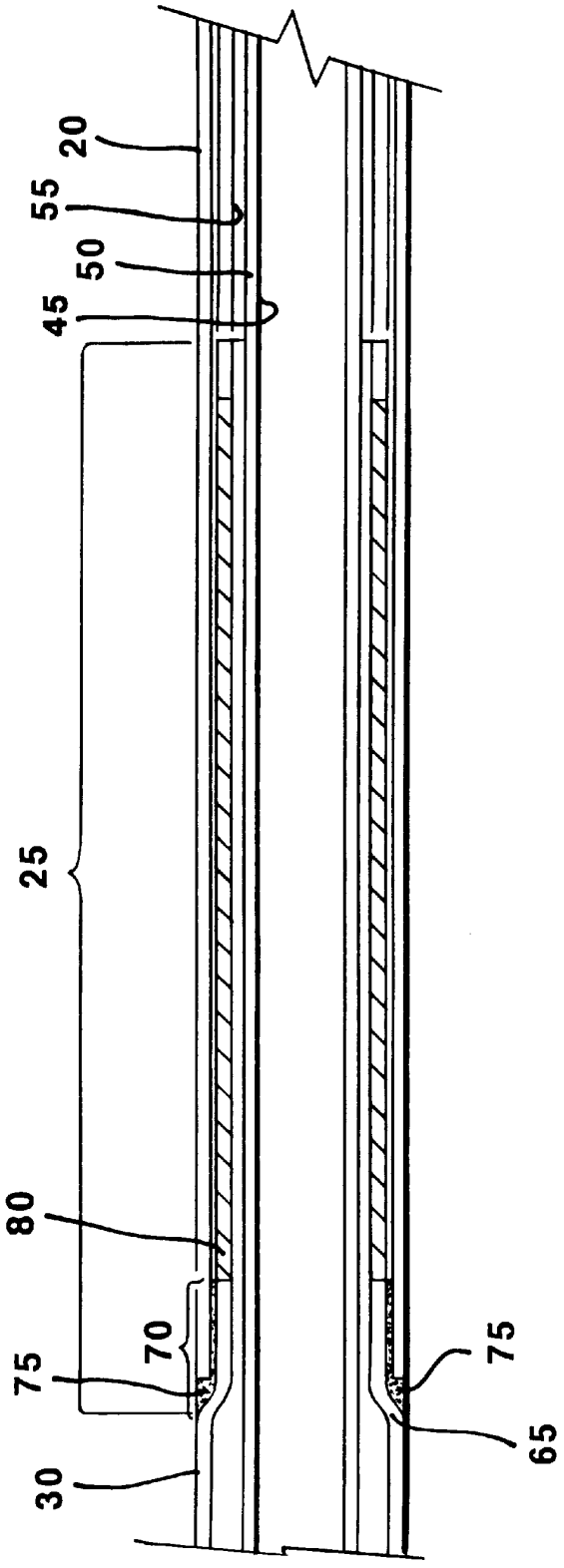


FIG.3

FLEXIBLE CATHETER

FIELD OF THE INVENTION

The present invention relates to a catheter of constant outer diameter having a flexible, non-kinking shaft and more particularly to a catheter having a flexible distal shaft portion and a stiffer proximal shaft portion.

BACKGROUND OF THE INVENTION

Percutaneous transluminal coronary angioplasty (PTCA) is used to increase the lumen diameter of a coronary artery partially or totally obstructed by a 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 dilatation of the occlusion, however, can form flaps, fissures and dissections which threaten reclosure of the dilated vessel or even perforations in the vessel wall.

Although the dimensions in the above example are suited to the coronary arteries, any body lumen can be treated by percutaneous transluminal angioplasty (PTA), including the vas deferens, ducts of the gallbladder, prostate gland, trachea, bronchus and liver. The body lumens range in diameter from small coronary vessels of 3 mm or less to 28 mm in the aortic vessel. The invention applies to acute and chronic closure or reclosure of body lumens.

It is advantageous for catheter shafts to have a stiff proximal end for pushability and a more flexible distal end for better tracking through tortuous lesions. Abutting stiff tubular materials to more flexible tubular materials results in a point at which kinking can occur. What is needed is a transition area therebetween to provide a smooth transition between the stiff proximal section and the more flexible section of the catheter shaft and thereby reduce kinking.

U.S. Pat. No. 4,960,410 to Pinchuk for "Flexible Tubular Member for Catheter Construction" discloses a spirally cut tubular member which extends through the balloon to the distal end of the catheter. The tubular member includes a first relatively stiff tube that is spirally cut along a distal portion and also includes a second more flexible tube that covers the spirally cut distal portion of the stiff tube to make a distal portion of the tubular member more flexible than a proximal portion of the elongated tubular member.

U.S. Pat. No. 5,599,326 to Carter for "Catheter with Multi-Layer Section" discloses an interior stiffener comprising a spirally cut tube member and an exterior tube member.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a smooth, flexible and kink-resistant transition between the catheter shaft stiff proximal end and the more flexible distal end while retaining a uniform outer diameter between the proximal shaft portion and the distal shaft portion. The present invention is accomplished by providing an apparatus comprising a distal shaft having a greater flexibility than the proximal shaft. The proximal shaft has a helical end portion of reduced outer diameter which is integral with and extending from the distal end of the proximal shaft. The helical end portion slidingly fits within a portion of the proximal end of the distal shaft. The helical end portion is bonded to at least a portion of the distal shaft to form a fluid-tight seal. The pitch of the helical end portion may be constant or variable. The helical turns may be abutting or spaced apart. A guidewire shaft centrally extends longitudinally through the proximal and distal shaft such that fluid can be transmitted through the proximal and distal shaft, exterior to the guidewire shaft.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view of the catheter of the invention;

FIG. **2** is a cross-section of the distal end of the catheter of FIG. **1**; and

FIG. **3** is a cross-section of the transition section of the catheter of FIG. **2**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, Applicant's catheter **10** is comprised of a balloon **15**, distal shaft **20**, transition **25**, proximal shaft **30** and manifold **35**. The spirally cut transition **25** is designed to provide a smooth transition between the stiff proximal shaft **30** and the more flexible distal shaft **20**. This reduces kinking and prevents guidewire lockup or damage, especially during backloading the guidewire into the catheter. In instances where the catheter is deep into the guide catheter, the flexible transition allows the catheter to bend with the bends in the guide catheter instead of butting against the wall of the guide catheter, thus increasing the trackability of the distal section which is out in the torturous vessel. A conventional over-the-wire design consists of a guidewire shaft **50** which defines a guidewire lumen **45** running the length of the catheter **10**. The guidewire shaft **50** is coaxially disposed within the proximal shaft **30**. The inner diameter and the outer diameter of the distal end of the proximal shaft **30** is necked down at **65**. The transition **25** beginning at the neck **65** and ending at the distal end of the proximal shaft **30** is approximately 1 inch (2.54 cm) long. The outer diameter of the proximal shaft **30** before necking is approximately 0.041 inches (1.04 mm). After necking **65**, the outer diameter of the proximal shaft **30** is greater than 0.0315 inches (0.800 mm), preferably 0.034 inches (0.86 mm) which will yield optimum in/deflation times. The inner diameter of the proximal shaft **30** after necking down is approximately 0.029 inches (0.737 mm).

The distal end of the proximal shaft **30** is spirally cut into a coil to define the transition **25**. A constant pitch of 24 degrees with 2 coils per mm is preferred. Other pitches or variable pitches may be preferred in certain alternate applications. Smaller angles lead to less flexibility due to more coils per the specified distance and vice versa. An example of this would be using this type of transition in place of a strain relief at the proximal end of the catheter next to the manifold. In this application, fewer coils per the specified distance would be more desirable. The more distal you move down the catheter toward the balloon, the more coils per the specified distance, thus the more flexible the transition. To create the spiral cut, a 0.0280 inch mandrel is inserted into the distal end of the proximal shaft **30** which is then cut using any conventional means such as a razor blade maintained at a fixed angle to the cutting surface. This can be done manually with a fixture maintaining the razor at a fixed angle while the catheter section is rotated using a motorized device with a mounting chuck. The operator holds the razor

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