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United States Patent [19]

Sutton

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[54] **FLEXIBLE CATHETER**

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[21] Appl. No.: **701,569**

[22] Filed: **Aug. 22, 1996**

Related U.S. Application Data

[63] Continuation of Ser. No. 564,984, Nov. 30, 1995, abandoned, which is a continuation of Ser. No. 344,821, Nov. 23, 1994, abandoned.

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

[52] **U.S. Cl.** **604/282**; 604/264; 604/280

[58] **Field of Search** 604/95, 282, 264, 604/270, 280, 281

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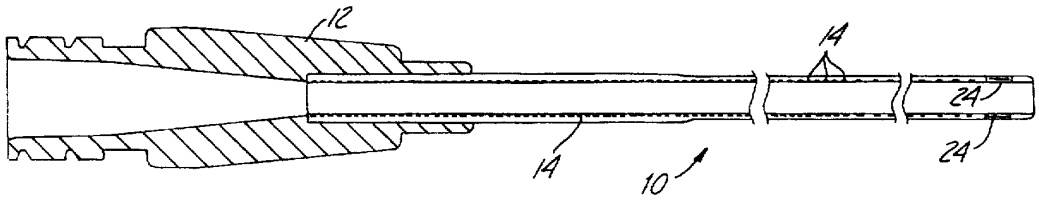
[57] **ABSTRACT**

The invention provides a catheter capable of delivering drugs or other fluids to a desired remote location in a bodily passageway, such as a small, tortuous artery. The catheter of the invention includes inner and outer tubular layers, and a continuous helical wire coil disposed between the tubular layers along substantially the entire length of the catheter. To enhance trackability and pushability, the wire coil is constructed to provide regions of differing flexibility to the catheter. The wire coil in a first portion of the catheter has a first coil pitch and the wire coil in a second section of the catheter has a second coil pitch which is larger than the first coil pitch to provide the second section of the catheter with greater flexibility than the first section.

20 Claims, 2 Drawing Sheets



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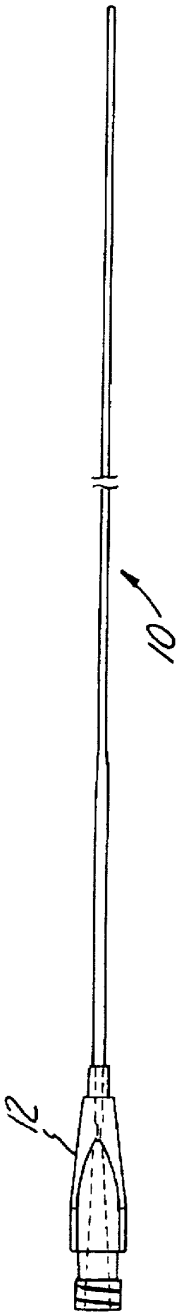

Fig. 1

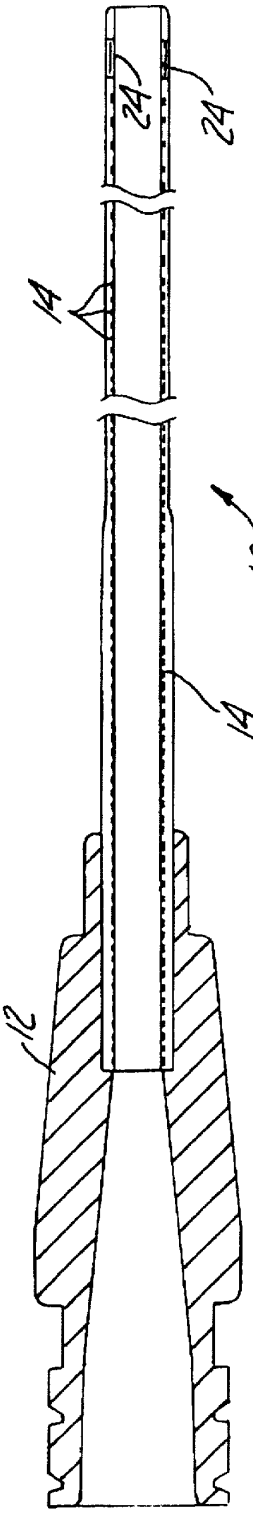

Fig. 2

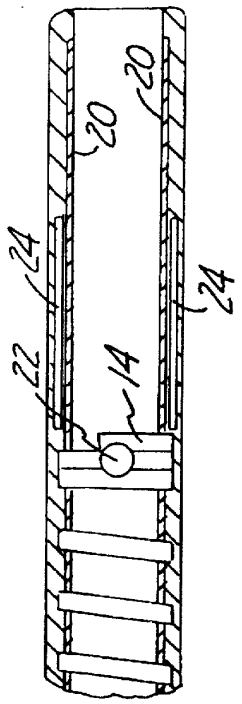

Fig. 3

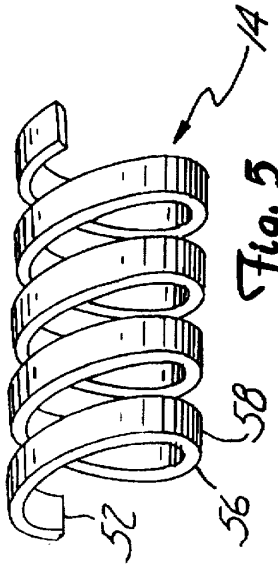

Fig. 5

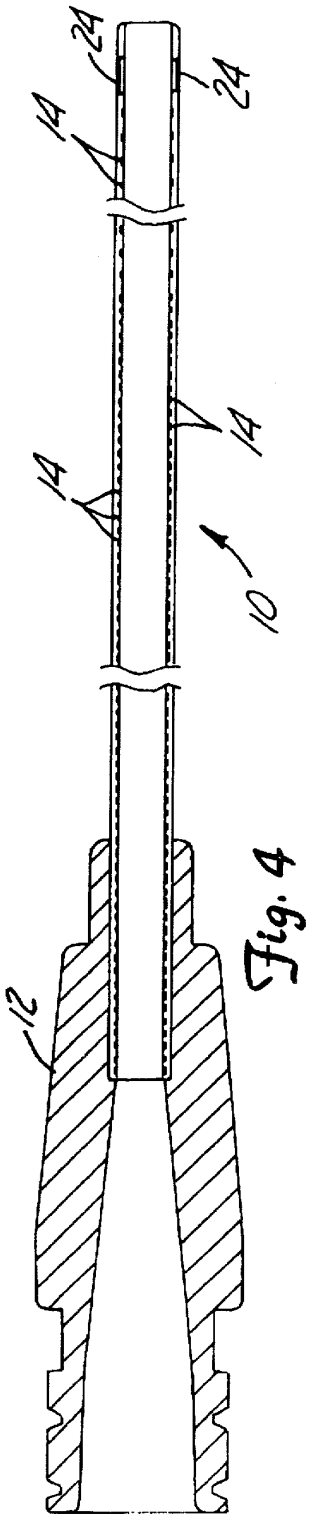

Fig. 4

FLEXIBLE CATHETER

This application is a continuation of application Ser. No. 08/564,984, filed Nov. 30, 1995 now abandoned, which is a continuation of application Ser. No. 08/344,821, filed Nov. 23, 1994 now abandoned.

FIELD OF THE INVENTION

This invention relates to catheters used in medical procedures.

BACKGROUND OF THE INVENTION

Catheters find a variety of applications in medical procedures for providing access to selected locations within a bodily passageway or cavity. A particularly common application of catheters is for intravascular access for the administration of drugs, fluids or occlusive devices. Infusion catheters typically are introduced in combination with a guiding catheter and a guide wire.

Infusion catheters are typically placed percutaneously via the femoral artery, although other arterial or venous entries are also used. Infusion catheters have many applications in the peripheral, coronary and neurovasculature. These include delivery of chemotherapy drags, delivery of blood thinning agents to break down blood thrombosis, infusion of contrast media for fluoroscopic imaging, or delivery of devices for treating aneurysms and arteriovenous malformations. In all these applications, the ability to access very selective and remote arterial or venous locations is critical.

Important performance characteristics of infusion catheters utilized for these and similar purposes include distal flexibility, pushability over a guide wire, luminal fluid carrying capacity, kink-resistance, frictional characteristics of inner and outer surfaces, and distal tip radiopacity.

Prior art infusion catheters typically consist of tubes made of a polymeric materials, sometimes in combination with metallic reinforcement. Such catheters of the prior art, while providing adequate means to access vascular sites, have distinct disadvantages. Often they are fabricated from polymers which soften somewhat when inserted into a body (due to the effects of temperature). In some applications (such as smaller, more tortuous arteries) it is desirable to construct the catheter from very flexible materials to facilitate advancement of catheters into such difficult access locations. As a result, however, such catheters can become more difficult to manipulate, have a tendency to kink and buckle, lack axial energy transmission (i.e., poor pushability) and can also tend to bind against the guiding catheter and/or guide wire. Catheter designs intended to minimize such deficiencies often must do so at the expense of flexibility, resulting in poor trackability (i.e., ability of the catheter to follow and conform to the curves of a guide wire without causing the guide wire to straighten out).

Catheters have been made which provide different regions of flexibility - - - i.e., a stiffer proximal section and a more flexible distal section. Examples of such catheters include U.S. Pat. No. 4,464,176, which describes a catheter made of two layers of tubing, one of the layers being more flexible than the other and extending distally beyond the end of the other layer by a considerable distance. U.S. Pat. No. 4,739,768 shows a similar structure, and further suggests the use of three layers of tubing to construct a catheter with three different degrees of flexibility. Utilizing solely the thickness of the catheter wall to control flexibility requires, however, that the stiffer portion of the catheter be necessarily proportionally thicker. Others have addressed this problem by

constructing a catheter from two lengths of tubing of dissimilar materials, one being more flexible than the other (see, e.g., U.S. Pat. No. 4,842,590). Such constructions introduce additional manufacturing complexity, however, in joining such lengths in a consistently reliable fashion. Others have utilized dissimilar metal reinforcing materials to achieve differing flexibility - - - e.g., relatively stiffer wire braiding in the proximal portion and a relatively more flexible helical coil in the distal portion. Again, the use of such differing materials requires careful quality control in manufacturing, to assure proper performance at the junction of the dissimilar materials.

There is, therefore, a need for catheters that provide a variable degree of flexibility in a relatively small size (i.e., diameter) to facilitate access to remote locations through sometimes lengthy and tortuous passageways. As the pushability of catheters generally decreases with smaller size and greater flexibility, there is a need for such flexible, small catheters that have excellent pushability and trackability and are without introducing manufacturing complexities.

SUMMARY OF THE INVENTION

The invention provides a catheter capable of delivering drugs or other fluids to a desired remote location in a bodily passageway, such as a small, tortuous artery. The catheter of the invention includes inner and outer tubular layers, and a continuous helical wire coil disposed between the tubular layers along substantially the entire useable length of the catheter. To enhance both trackability and pushability, the wire coil is constructed to provide regions of differing flexibility to the catheter. The wire coil in a first (typically proximal) portion of the catheter has a first coil pitch (i.e., the distance, measured center to center along the length of the catheter, from one turn of the wire coil to the next adjacent turn), and the wire coil in a second (typically distal) section of the catheter has a second coil pitch which is larger than the first coil pitch to provide the second section of the catheter with greater flexibility than the first section. The first, less flexible section therefore typically has greater pushability, and typically comprises a substantial portion of the length of the catheter, with the second, more flexible (and therefore typically less pushable) portion comprising a distal section of at least, e.g., about 5 cm, and preferably about 15–30 cm. Desirably the pitch of the wire coil in the second portion is at least about 25% larger than in the first portion, and preferably at least about 50% larger.

The wire coil preferably terminates very close to the distal end of the catheter, desirably within a distance of not more than about five times the outer diameter of the tubular layers (and preferably not more than the actual diameter of such layers), measured at the distal end of the wire coil. In a preferred embodiment one or both ends of the wire coil are secured by a weld attaching at least two (preferably three) adjacent turns of the coil to one another. A radiopaque marker may be provided, disposed between the tubular layers at the distal end of the catheter (either positioned just distally of the distal end of wire coil, or positioned over this distal end portion of the wire coil). Preferably the wire coil is made from a metal wire having a generally rectangular cross-section. In a preferred embodiment, the width of the wire, in cross-section, is at least twice its thickness. In some applications, the wire coil may include three distinct regions of differing pitch (and therefore flexibility). Also, a third tubular layer may be disposed along a proximal section of the inner and outer tubular layers (desirably between such layers), to provide such proximal section with greater stiffness.

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