US006199262B1

(12) **United States Patent**
**Martin**

(10) **Patent No.: US 6,199,262 B1**
(45) **Date of Patent: Mar. 13, 2001**

(54) **METHOD OF MAKING A GUIDING CATHETER**

(75) Inventor: **Brian B. Martin**, Boulder Creek, CA (US)

(73) Assignee: **Medtronic, Inc.**, Minneapolis, MN (US)

( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/258,657**

(22) Filed: **Feb. 26, 1999**

**Related U.S. Application Data**

(62) Division of application No. 08/915,360, filed on Aug. 20, 1997, now Pat. No. 5,902,287.

(51) **Int. Cl.**[7] ..... **B23P 11/00**

(52) **U.S. Cl.** ..... **29/525.15**; 156/293; 156/257; 264/544; 604/532; 604/525

(58) **Field of Search** ..... 264/544, 264; 604/526, 532, 525; 156/256, 257, 293, 73.1, 308.2, 308.4; 29/469.5, 525.15

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | | |
|---|---|---|---|---|
| 3,752,617 | * | 8/1973 | Burlis et al. . | |
| 4,469,483 | | 9/1984 | Becker et al. . | |
| 4,576,772 | * | 3/1986 | Carpenter . | |
| 4,590,028 | * | 5/1986 | Rosenkrantz et al. | 264/154 |
| 4,761,871 | * | 8/1988 | O'Connor et al. | 29/431.2 X |
| 4,776,846 | | 10/1988 | Wells . | |
| 4,822,345 | | 4/1989 | Danforth . | |
| 4,909,787 | | 3/1990 | Danforth . | |
| 4,976,691 | | 12/1990 | Sahota . | |
| 5,368,564 | | 11/1994 | Savage . | |
| 5,378,234 | | 1/1995 | Hammerslag et al. . | |
| 5,437,632 | | 8/1995 | Engelson . | |
| 5,453,099 | | 9/1995 | Lee et al. . | |
| 5,456,674 | | 10/1995 | Bos et al. . | |
| 5,470,322 | | 11/1995 | Horzewski et al. . | |
| 5,772,641 | * | 6/1998 | Wilson . | |
| 5,849,035 | * | 12/1998 | Pathak et al. . | |
| 5,868,718 | * | 2/1999 | Pepin et al. . | |
| 5,902,287 | * | 5/1999 | Martin . | |
| 6,110,164 | * | 8/2000 | Vidlund . | |

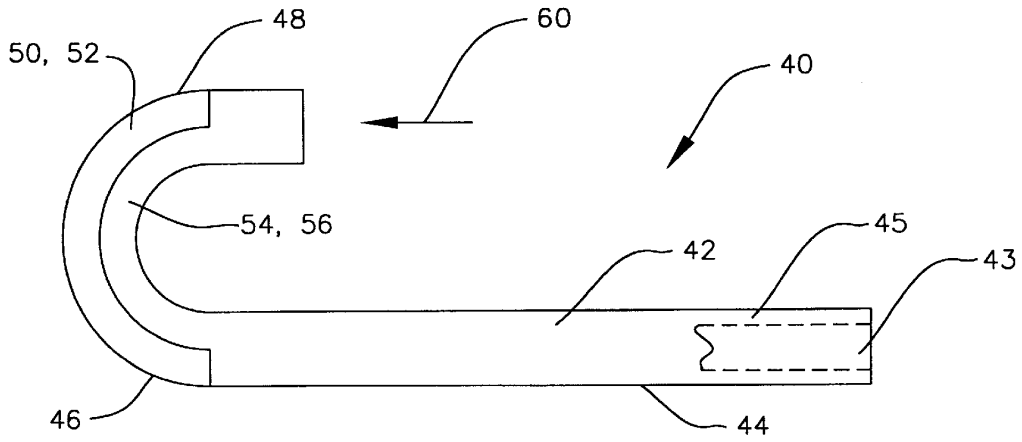
* cited by examiner

*Primary Examiner*—S. Thomas Hughes
*Assistant Examiner*—Steven A Blount

(57) **ABSTRACT**

A method of making a catheter, including an elongated tube structure having a proximal end and at least one preset curved portion proximate a distal end. The preset curved portion includes a first material located generally along an outer surface of the preset curved portion and a second material located generally along an inside surface of the preset curved portion. The first material preferably has a greater stiffness than the second material, so that the catheter is capable of assuming a generally straight configuration without plastic deformation.

**15 Claims, 3 Drawing Sheets**



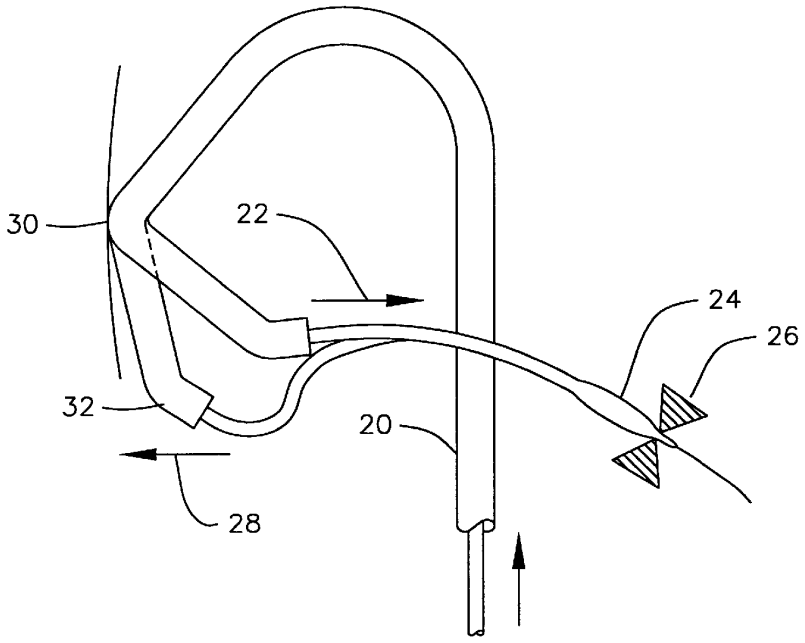



FIG. 1

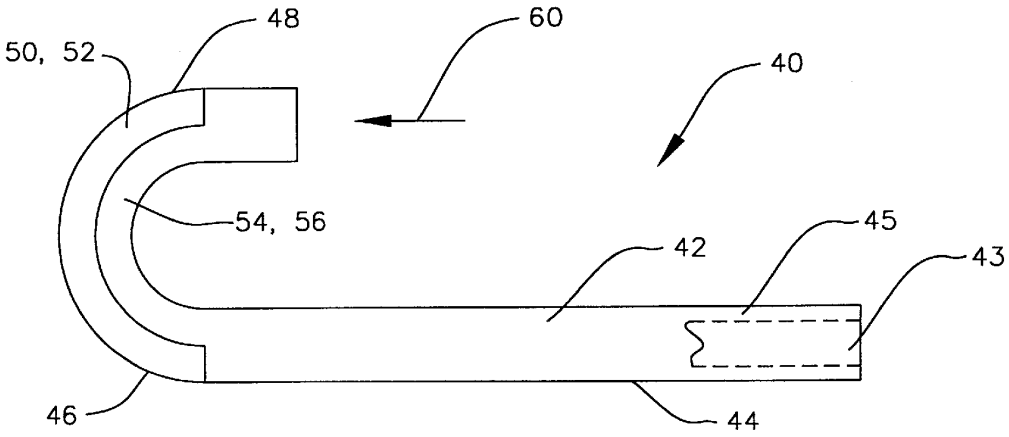



FIG. 2

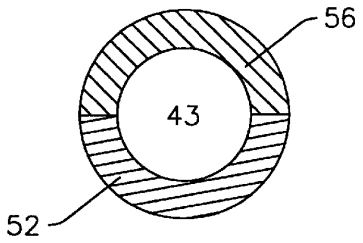



FIG. 3

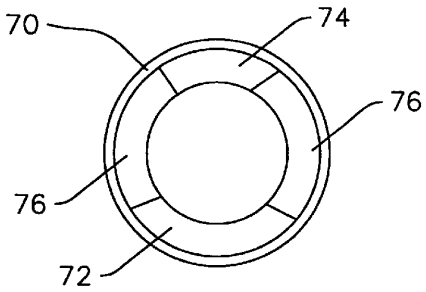



FIG. 5B

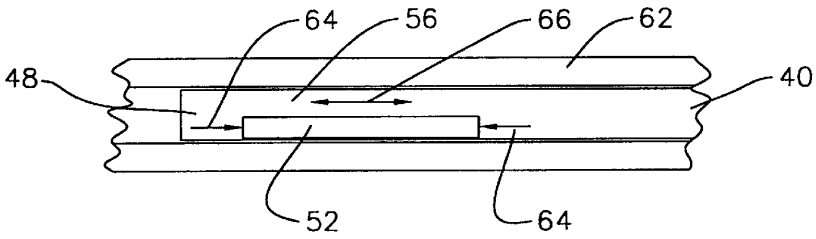



FIG. 4

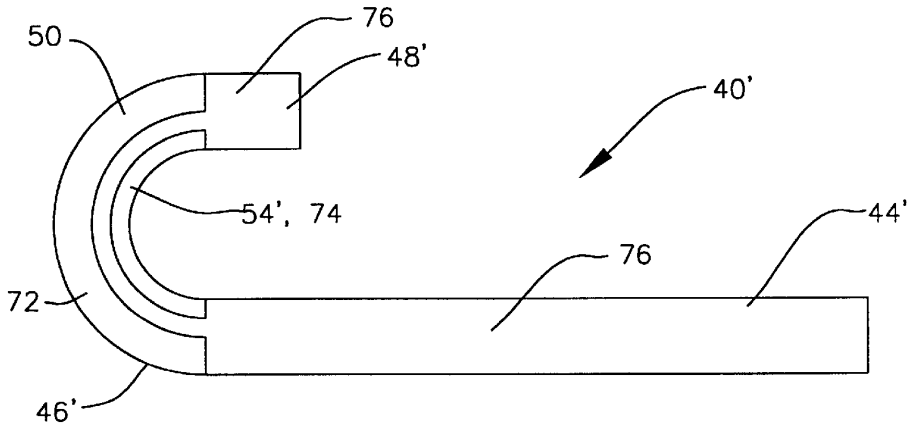



FIG. 5A

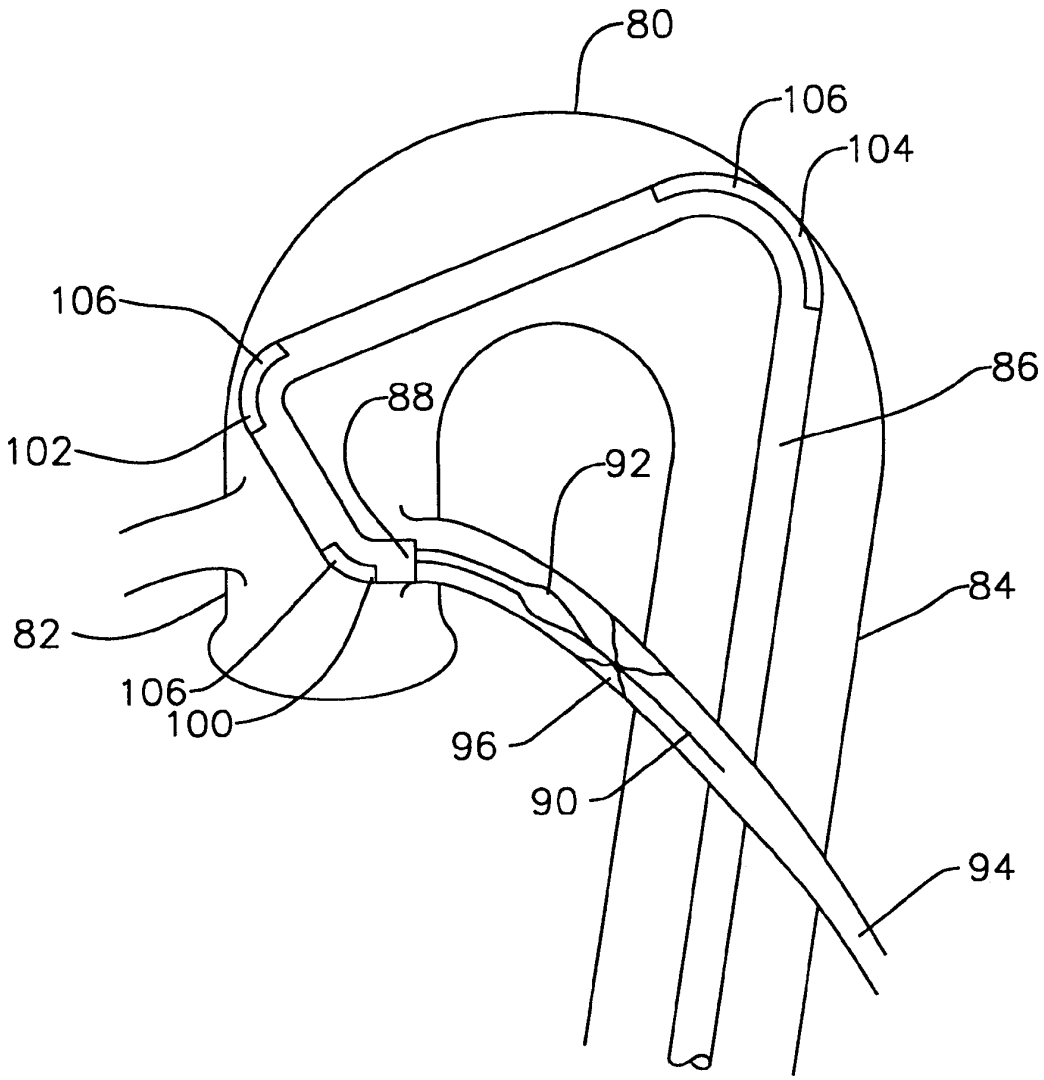



FIG. 6

# METHOD OF MAKING A GUIDING CATHETER

This is a division of application Ser. No. 08/915,360, filed Aug. 20, 1997, now U.S. Pat. No. 5,902,287, which is incorporated herein by reference.

## FIELD THE INVENTION

The present invention relates to a guiding catheter that combines stiffness that resists bending stress or torque and elasticity that permits straightening without plastic deformation.

## BACKGROUND OF INVENTION

Medical catheters generally comprise elongated tube like members which may be inserted into the body either percutaneously, or via a body orifice, for any of a wide variety of diagnostic and therapeutic purposes. Such medical applications generally require the use of a catheter having the ability to turn corners, such as in ocular irrigation or aspiration applications, or to negotiate twists and turns, such as in certain cardiovascular applications.

Catheters are typically introduced to the patients body through an introducer sheath. The catheter must generally be straightened to fit through the introducer sheath. Therefore, the catheter must be constructed so that it is elastically resilient enough to go through the introducer sheath without plastic deformation, yet resilient enough to meet the performance needs of the particular medical procedure.

For some applications, an inner catheter having a preformed shape is straightened and placed in an outer guiding sheath. When the inner catheter is extended or the outer sheath withdrawn, the inner catheter assumes its original shape. Again, the inner catheter must be constructed so that it is elastically resilient enough to straighten without plastic deformation, yet resume its original configuration when the outer sheath is removed.

For example, percutaneous translumenal coronary angioplasty (PTCA) requires manipulation of a catheter from a proximal position outside the patient's body through branched or tortuous portions of the patients arterial system for purposes of alleviating an obstruction by inflating a balloon. This particular procedure has been performed with increasing frequency over the past years in preference to open heart bypass surgery.

FIG. **1** illustrates the typical configuration of a conventional left coronary guiding catheter **20** with a dilation balloon **24** in the aorta when engaged with a stenosis **24** in the left main coronary artery during the performance of left coronary artery PTCA. The application of force **22** to advance a dilation balloon across the region of stenosis **26** increases the bending stress **28** on the bend **30** of the guiding catheter **20**. The pre-bent configuration of the guiding catheter **20**, in this situation a left Judkin's configuration, is unable to overcome the resistance at the stenosis **24**, causing distal end **32** to back away from the entrance of the left main coronary artery and the angioplasty balloon catheter **24** to prolapse in the accenting aorta, precluding further progress.

Inability to advance the angioplasty balloon across the coronary stenosis because of instability of the guiding catheter and subsequent prolapse of the angioplasty balloon catheter represents one of the most common reasons for failure during the performance of a coronary angioplasty procedure. The guiding catheter disengages in this circumstance because of its flexibility. The guiding catheter has



intrinsic flexibility because it must conform to the configuration of the aorta and aortic arch, which contain both linear and curved segments, during introduction. Insertion of the guiding catheter requires that it be advanced over a guidewire up the aorta, which is relatively straight, and then over the aortic arch, which, as the name implies, is curvilinear.

The stability afforded by guiding catheters typically relates to the limited intrinsic stiffness of these catheters. The stiffness of these prior guiding catheters is subject to a "warm-up" phenomenon (becoming more flexible as they remain in the body and equilibrate to body temperature) and thus varies inversely with the temperature of the device. Hence, these catheters tend to be particularly stiff on introduction into the body, when flexibility is preferable, and yet relatively flexible and hence unstable following exposure to body temperatures during balloon catheter manipulation across a coronary stenosis when rigidity is preferable.

U.S. Pat. No. 4,909,787 (Danforth) discloses a catheter having a closed chamber eccentrically disposed along almost the entire length of the housing such that it virtually encompasses the housing. The catheter preferably contains a relatively elastic segment disposed preferentially along the outer circumference of the curvature of the catheter. The chamber may be filled with a fluid. The catheter is capable of asymmetric elongation when hydrostatic pressure is applied to the chamber, resulting in the development of bending stress and increased rigidity on the distal end as desired by the operator.

U.S. Pat. No. 5,456,674 (Bos et al.) discloses a catheter with variable longitudinal properties. The catheters are manufactured by simultaneously conveying a plurality of streams of different materials to a molding nozzle and merging the streams together to form a catheter. The catheter is manufactured with varying properties along its longitudinal axis corresponding to properties of the constituent streams of materials.

## SUMMARY OF THE INVENTION

The present invention relates to a catheter comprising an elongated tube structure having a proximal end and at least one preset curved portion proximate a distal end. The preset curved portion comprising a first material located generally along an outer surface on the outer radius of the preset curved portion and a second material located generally along an inner surface on the inner radius of the preset curved portion. The present catheter is particularly useful as a guiding catheter that combines stiffness to resist bending stress and elasticity to permit straightening without plastic deformation.

The first material preferably has a modulus of elasticity greater than the modulus of elasticity of the second material. Alternatively, the modulus of elasticity of the second material may be greater than a modulus of elasticity of the first material. The first material preferably has a first stiffness greater than a second stiffness of the second material. A third material may be interposed between the first and second materials. The third material preferably has a third stiffness less than the first stiffness, but greater than the second stiffness.

The preset curved portion is capable of assuming a generally straight configuration without plastic deformation. The cross sectional area of at least a portion of the preset curved portion is about 50% of the first material and about 50% of the second material. The first and the second materials are preferably coextruded structure. Alternatively,

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.