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Osborn

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[54] **APPARATUS FOR UNIFORMLY IMPLANTING A STENT**

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

[21] Appl. No.: **111,173**

[22] Filed: **Aug. 24, 1993**

[51] **Int. Cl.**[6] **A61M 29/02**

[52] **U.S. Cl.** **606/108**; 606/194; 604/101

[58] **Field of Search** 606/108, 194, 195, 192, 606/198; 604/96, 101, 103

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Primary Examiner—Michael H. Thaler
Attorney, Agent, or Firm—Fulwider Patton Lee & Utecht

[57] **ABSTRACT**

An improved system for uniformly implanting a stent in a body lumen comprising an intravascular catheter having an elongated catheter body and at least one inflation lumen contained therein, the catheter body including proximal and distal ends, a balloon near the distal end of the catheter for expanding the stent, an elastic sleeve surrounding and in contact with the balloon for controlling the radial expansion of the balloon and either restraining bands or a pair of control balloons to control the expansion of the balloon so that controllable expansion characteristics of the stent are achieved.

15 Claims, 3 Drawing Sheets

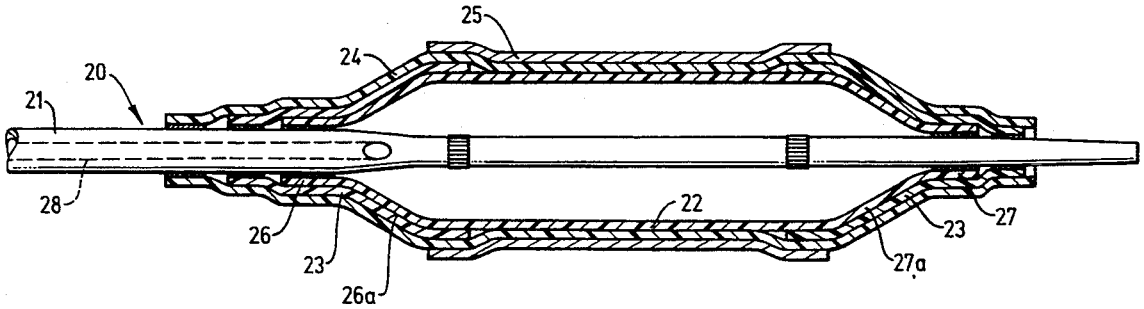


FIG. 1

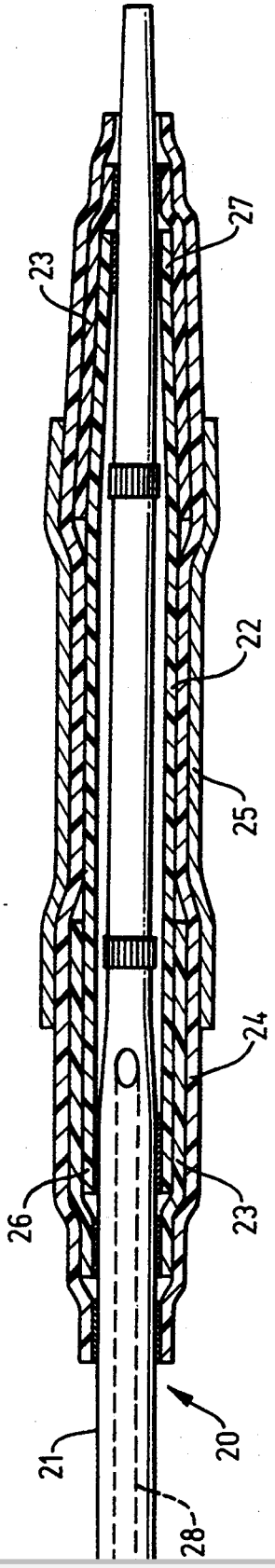


FIG. 2

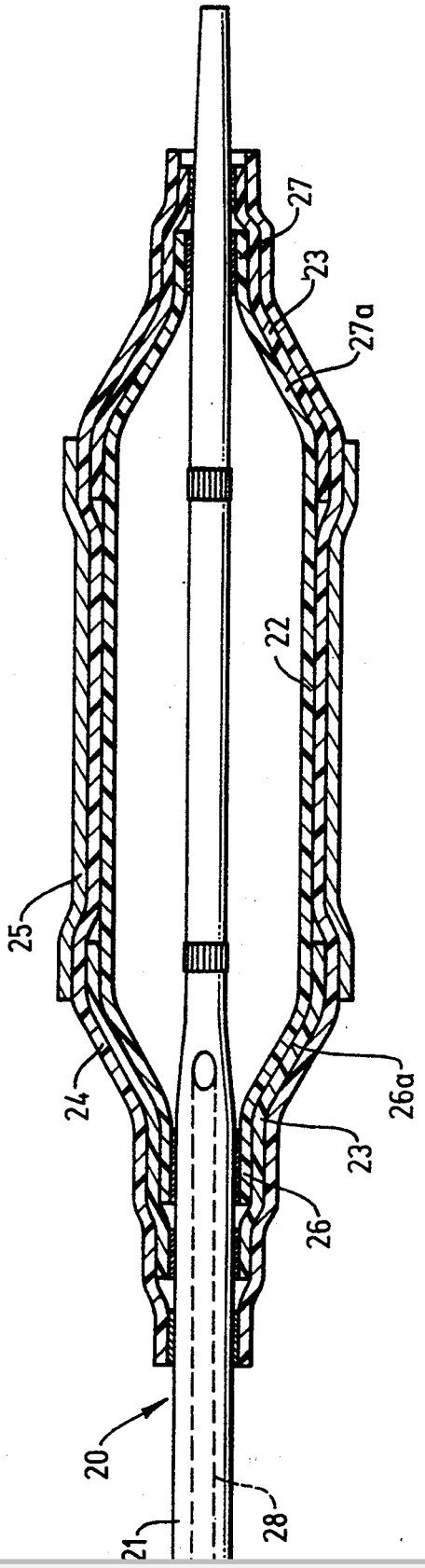


FIG. 3

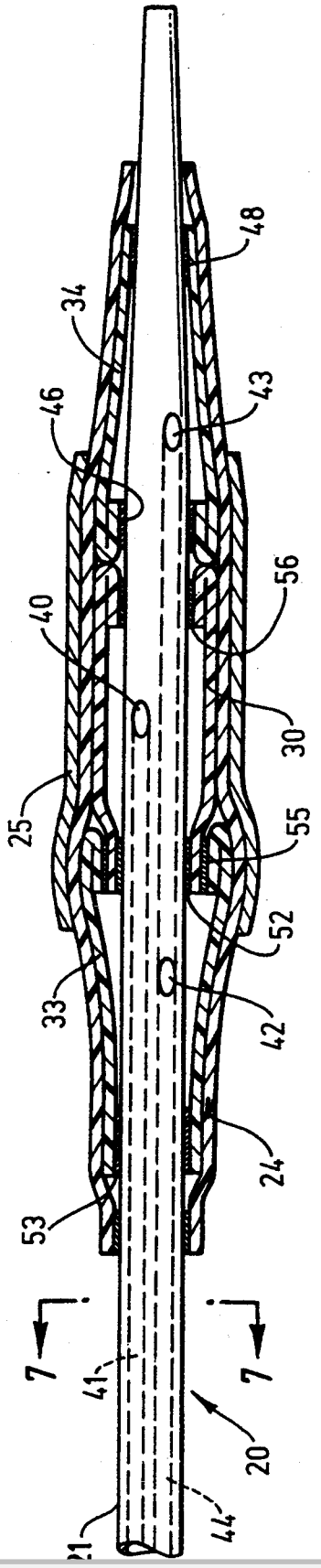


FIG. 4

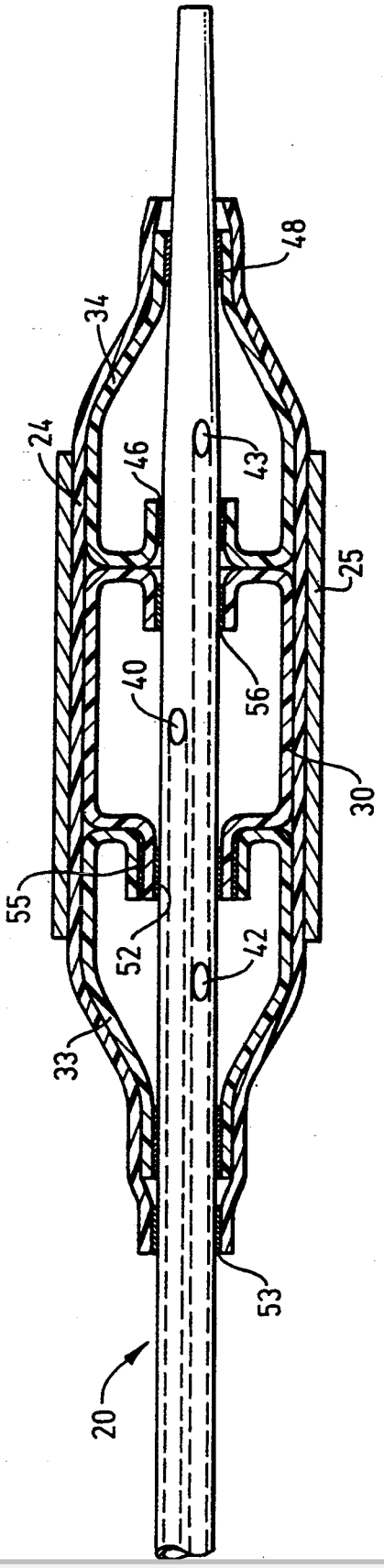


FIG. 5

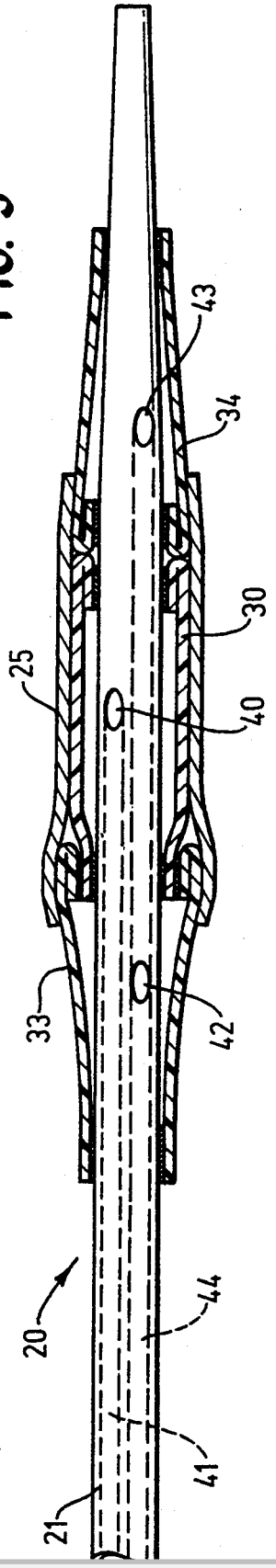


FIG. 7

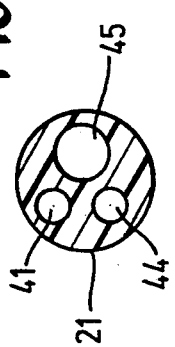
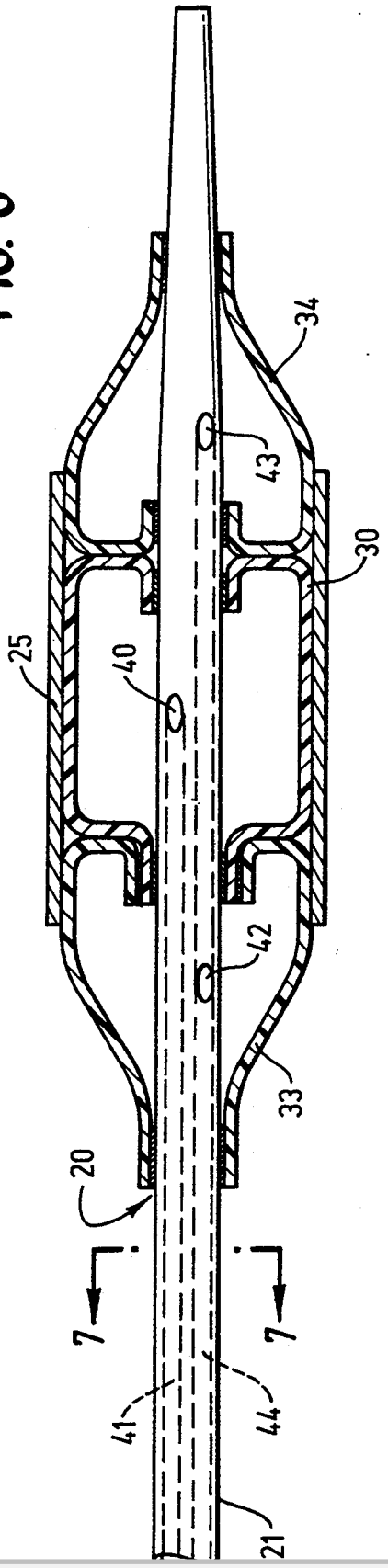


FIG. 6



APPARATUS FOR UNIFORMLY IMPLANTING A STENT

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to improvements in methods and apparatus for uniformly implanting a stent and, more particularly, to improved uniform stent implantation systems wherein radial expansion is controlled.

2. Description of Related Art

In typical percutaneous transluminal coronary angioplasty (PTCA) procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient through the brachial or femoral arteries and advanced through the patient's vasculature until the distal end of the guiding catheter is in the ostium of the desired coronary artery. A guidewire and a dilatation catheter having a balloon on the distal end of the dilatation catheter are introduced through the guiding catheter with the guidewire sliding within the dilatation catheter. First, the guidewire is passed through the guiding catheter and into the patient's coronary vasculature. Second, the dilatation catheter is advanced over the previously passed guidewire until the dilatation balloon is properly positioned across a lesion. Once in position across the lesion, a preformed balloon carried by the catheter is inflated to a predetermined size with a liquid at relatively high pressures (e.g., greater than about 4 atmospheres) to radially compress the atherosclerotic plaque of the lesion against the inside of the artery wall and thereby dilate the lumen of the artery. The balloon is then deflated to a small profile, so that the dilatation catheter can be withdrawn from the patient's vasculature and blood flow resumed through the dilated artery. The PTCA procedure is also typically performed with the use of a guiding catheter, wherein a conventional over-the-wire system is employed.

In such angioplasty procedures, there may be restenosis of the artery, which necessitates either another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the dilated area. To assist in the prevention of restenosis and to strengthen the dilated area, a physician can implant an intravascular prothesis, generally called a stent, to maintain vascular patency inside the artery at the site of the lesion. Stents are also used to repair vessels having a flap or dissection or to generally strengthen a weakened section of a vessel. The stent is expanded to a larger diameter, often by the balloon portion of the dilatation catheter. Stents delivered to a restricted coronary artery, expanded to a larger diameter by a balloon catheter, and left in place within the artery at the site of the dilated lesion are shown, for example, in U.S. Pat. No. 4,740,207 (Kreamer) and U.S. Pat. No. 5,007,926 (Derbyshire).

Although stents have been used effectively for some time, the effectiveness of a stent can be diminished if it is not uniformly implanted within the artery. For example, balloons having a stent placed upon them tend to have non-uniform radial expansion due to the increased restriction the stent imposes on the working length of the balloon. Consequently, the balloon expands first at the proximal and distal balloon ends along the path of least resistance, i.e., towards the distal and proximal ends of the balloon, which expands the balloon in a "dog bone" fashion looking uniform radial expansion

Thus, when the balloon expands in this "dog bone" fashion, the proximal and distal regions of the balloon over expand to form a characteristic "dog bone" shape, the stent is not expanded uniformly and the stent may be improperly implanted.

Accordingly, those concerned with the design, development, and use of stent implantation systems have long recognized the desirability and need for further improvements in systems for uniformly implanting a stent in order to maximize stent performance. In this regard, what has been needed and, heretofore unavailable, is a stent delivery system which controls the radial expansion of the stent along its entire length to ensure uniform expansion.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention provides an improved method and apparatus for controlling the radial expansion of a catheter balloon used to deliver a stent, in order to enhance uniform implantation of the stent.

More particularly, the present invention comprises a catheter having first means on the catheter for expanding a stent, second means cooperating with the first means to control the radial expansion characteristics of the first means, and third means for controlling the radial expansion of the proximal and distal ends of the first means. In this way, the stent is more uniformly expanded to its implantation diameter and properly placed within the vasculature of a patient.

In one embodiment, by way of example and not necessarily by way of limitation, a balloon catheter includes an elongated catheter body and a balloon member on the distal end of the catheter. The balloon member has a proximal end and a distal end with each end having tapered balloon segments. Elastic restraining bands surround each of these distal and proximal tapered segments of the balloon. These restraining bands exert a resistive force in response to the resistive force created by the addition of the stent on the balloon. An uneven expansion is created in the balloon by the existence of the stent, thus the restraining bands help to offset this force. In order to further control the radial expansion of the balloon, a coaxial elastic sheath or sleeve surrounds and is in contact with the balloon member and the restraining bands. This results in only radial displacement along the entire length of the balloon. A stent, which is placed over the working length of the balloon, is therefore, uniformly expanded as the balloon is inflated, since radial expansion of the balloon is more precisely controlled.

During inflation of the balloon, the elastic restraining bands exert a force at the proximal and distal ends of the balloon equal and opposite to that generated by the combined resistance of the sleeve and the stent tending to deform the balloon. In this way, the uneven expansion (end effects) are limited when the balloon is expanded which, in turn, inhibits a "dog boning" deformation at the proximal and distal regions of the balloon. Further, as the balloon inflates, the sleeve surrounding the balloon distributes the radial forces evenly over an extended area, which then controls the radial expansion of both the balloon and the surrounding stent carried on the balloon.

In an another embodiment, a catheter includes an elongated catheter body and three balloons at the distal end of the catheter. The three balloons comprise a pair

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