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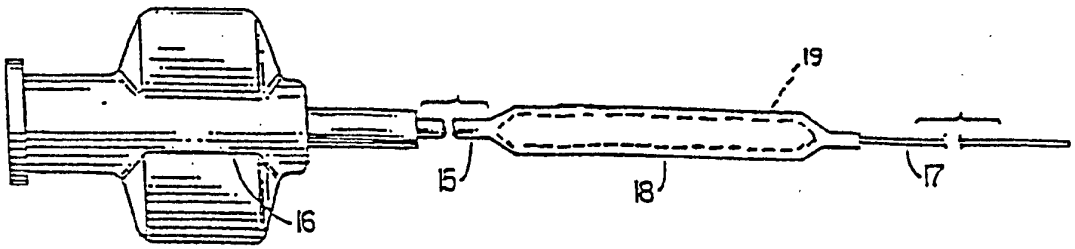

(57) Abstract

This invention is a flexible plastic inflatable medical dilatation balloon (18) and balloon catheter (15) that is both radiopaque and translucent. The balloon (18) is extruded from a compounded polymer containing radiopaque materials. The quantity of radiopaque material is chosen so that the resulting balloon is, as noted, visible under various forms of x-ray diagnosis, and optically translucent.

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RADIOPAQUE BALLOON CATHETERS

This invention relates to balloons and to balloon catheters which are useful in medical dilatation procedures and is more particularly concerned with the development of a radiopaque dilatation balloon formed from a polymer compounded with radiopaque material which is visible under x-ray diagnosis and optically translucent.

Balloon catheters are finding increasing use in medical procedures such as percutaneous transluminal angioplasty, percutaneous transluminal coronary angioplasty, percutaneous transluminal nephrostomy, ureteral dilatation, biliary duct dilatation, percutaneous transluminal renal angioplasty, and the like. Balloons for use in these procedures have been prepared from a variety of polymeric materials which are blood and tissue compatible. Among those materials that have been employed include materials such as poly(vinylchloride), polyethylene, poly(ethylene terephthalate), polyurethanes and the like, homopolymers or copolymers of olefins, polyethylene/vinyl acetate copolymers, and the like.

It is desirable in balloon catheter structures for the balloon to be radiopaque, i.e. visible under various forms of x-ray diagnosis, so that the positioning of the balloon within a patient can be precisely determined. It is also advantageous that the balloon be optically translucent, thus allowing a surgeon to visually inspect for air bubbles which may form in the balloon. Removal of these air bubbles is a necessary step in the preparation of the balloon catheter prior to its insertion in a patient.

Despite the obvious advantages associates with a catheter balloon which is radiopaque and translucent, development of such balloons has, to date, escaped the art. Although several types of catheters have been developed which employ a radiopaque material in their construction, there have been no balloon catheters

developed in this manner.

One proposed solution is described in U.S. Patent No. 5,181,921, issued to Makita et al., which reports on the use of a radiopaque plating on the outside surface of a catheter balloon. This plating, however, prevents a surgeon from visually inspecting the balloon for air bubbles which must be removed from the balloon prior to use.

Also disclosed in Makita et al. is the injection of a radiopaque die into the balloon. This is currently the only technique being used to see an inflated catheter balloon under x-ray. However, due to the viscosity of the radiopaque die, significant preparation time is required to remove air bubbles from the balloon.

Prior to inflation with a radiopaque die, the prior art teaches the use of a radiopaque marker band, or bands, around the catheter shaft. This facilitates precise location of the balloon portion of the catheter within the body cavity or vasculature and enables visualization under x-ray diagnostics.

Advantageously, balloon catheters according to the present invention overcome the disadvantage of the prior art by providing a balloon which is radiopaque and optically translucent thus allowing precise positioning of the balloon under various forms of x-ray diagnosis and easy removal of air bubbles formed in the balloon.

Accordingly, and in contrast to the prior art, the present invention provides a radiopaque balloon configuration for a balloon catheter. More specifically, by incorporating radiopaque material into the polymer from which the balloon is formed, a catheter balloon is provided which is both translucent and radiopaque. Thus, with the balloon catheter of this invention, balloon catheter procedures can be performed more effectively, with less preparation time for removal of air bubbles from the balloon, with decreased inflation and deflation time

and voids the requirement for radiopaque marker bands.

Accordingly, it is the object of this invention to overcome the preparation time and the expense associated with the prior art, using a balloon design that incorporates radiopaque material directly in the polymer from which a balloon is formed.

It is a further object of this invention to provide a catheter balloon design that is radiopaque and translucent thus allowing a surgeon to visually observe and easily remove air bubbles which may form within the balloon.

It is also an object of this invention to provide a balloon catheter employing a radiopaque balloon thus alleviating the need for a radiopaque marker band, or bands, around the catheter shaft.

Yet a further object of this invention is to provide a balloon catheter with decreased inflation and deflation time in that a lower viscosity saline solution, or the like, may be utilized as opposed to the higher viscosity radiopaque dies currently needed.

Furthermore, an object of this invention is to provide a radiopaque balloon design capable of production via standard plastic melt processing techniques such as extrusion.

These objects, and other objects which will become apparent from the description which follows, are achieved by radiopaque balloons and the balloon catheters of the invention and by the methods for their preparation. Thus, in its broadest aspect, the invention comprises radiopaque balloons and balloon catheters for use in medical dilatation procedures wherein the materials employed for the preparation of the balloons can be altered during their processing and preparation into a balloon configuration that is radiopaque and translucent.

The invention comprises an inflatable and collapsible balloon wherein the balloon contains, as an additive, radiopaque material. Preferably, the balloon material is

a polymeric material, and the radiopaque material is compounded with the polymeric material and is present at a level which causes the balloon to be both radiopaque and translucent.

Figure 1 and Figure 2 show two different sized balloons.

Figure 3 shows a typical balloon catheter (one hub shown).

The invention will now be described by reference to various specific embodiments. It is to be understood that these embodiments are described for purposes of illustration only and are not to be construed as limiting.

The principal novelty in medical dilatation balloons and balloon catheters of the invention lies in the use of a compounded polymer containing radiopaque material to form radiopaque and translucent balloons and balloon catheters.

The radiopaque balloons and balloon catheters of the invention are prepared in a conventional manner using conventional equipment and employing any of the conventional elastomeric materials used in the fabrication of dilatation balloon catheters. Accordingly, any of the polymeric materials such as poly(vinylchloride), styrenic polymers such as "KRATON", polyacrylates, polyolefins, polyamides, polyesters, poly(ethylene terephthalate), fluoropolymers, silicones, and the like, conventionally employed in the art to prepare dilatation balloon catheters, can be employed to fabricate the dilatation balloon catheters of the instant invention.

Similarly, any of the commonly known radiopaque pacifiers such as barium sulfate, bismuth bicarbonate, bismuth trioxide and the like may be chosen for mixture with a desired polymer. The level of radiopaque material is chosen so that a resulting compounded polymer containing the radiopaque material will be translucent yet well visible under various forms of x-ray diagnosis.

Typically, the percentage by weight of radiopaque material in the compounded polymer is between 5 and 50%. Various mixtures which achieve the objectives of the present invention can be obtained through routine experimentation for different combinations of radiopaque and polymer materials. That is, radiopaque materials can be added to the polymer by the method described below, and the levels can be adjusted to achieve both a radiopaque and translucent material.

The actual dimensions of the balloons also depend upon the particular dilatation procedure for which the balloon and any attached catheter are to be employed. In general, the external diameter of the balloon can be of the order of about 2 mm to about 25 mm. The overall length of the inflated portion will be of the order of about 10 mm to about 150 mm. The walls of the balloon will have an average thickness in the range of about 0.01 mm to about 0.2 mm depending in part on the pressures to which the balloon is to be inflated in actual use. Accordingly, the materials included in the compounded polymer must be selected with these limits in mind.

Once the proper amounts of polymer and radiopaque material are chosen, they are placed in a tumbler (mixer) and tumbled for about 20 minutes. The blended mixture of polymer and radiopaque material is then passed through an extruder, and the extradite exits the extruder through a strand or string die of approximately 1/8 inches in diameter (depending on the desired pellet size). The strands exiting the extruder are continuous and pass through a water bath for cooling. The cooled extradite then enters a pelletizing machine which cuts the strands to the desired length of pellets.

The compounded polymer thus formed is then extruded to obtain a final shape, e.g. a tube, to be used in forming the balloon. In one preferred embodiment a balloon is formed from the compounded polymer in accordance with the

process disclosed in my U.S. Patent No. 5,195,970.

As will be obvious to one skilled in the art, the radiopaque dilatation balloons of the invention can be employed to replace dilatation balloons in the many types of balloon-catheter combinations currently employed in medical dilatation procedures. For example, in producing a typical dilatation balloon 10 of the kind shown overall in Figures 1 and 2, a tube is produced by extrusion of the aforesaid plastic materials using conventional melt processing equipment. The extruded balloon tube is formed by passing the tube over an appropriate sized mandrel. The tube may be further processed by various forming techniques. One preferred technique is by heating, stretching and inflating the tube within a mold to obtain a precise wall thickness and form as in Figures 1 and 2. Figure 3 shows a typical balloon catheter which define a tubular catheter body on shaft 15, a proximal inflating hub 16, and a guide wire 17 and which may or may not be incorporated into the catheter body which may or may not require additional proximal hubs, all being of generally conventional design. Catheter body 15 defines an inflatable and collapsible balloon 18 shown to be, as is conventional, in a tubular section of relatively larger diameter than the rest of the catheter body 15. Balloon 18 may be an integral part of the rest of the catheter body 15, or it may be separately manufactured, for example, by an extrusion process and then attached to the remainder of the catheter body 15. Balloon 18 may be entirely inflated to expand its diameter, and may also be collapsed to a minimum diameter.

The balloons of the invention possess properties which render them especially valuable in carrying out medical dilatation procedures such as angioplasty and the like. The radiopaque nature of the balloon allows a surgeon to precisely determine the location of the balloon in an artery, vein or like passageway involved in a medical

procedure. Additionally, since the radiopaque material is incorporated into the polymer which forms the balloon walls, the cumbersome, inefficient, and time-consuming procedure of injecting and removing a viscous radiopaque dye into the balloon may be avoided. Simple saline solution or the like may now be conveniently employed.

Moreover, the fact that balloons according to the present invention are radiopaque and optically translucent allows a significant decrease in preparation time for locating and removing air bubbles which may form within the balloon prior to insertion into the patient. Also, the balloon portion of the catheter can be precisely localized without the need of a radiopaque marker band, or bands, or similar locating device. Accordingly, the radiopaque balloons and balloon catheters of the present invention represent a significant advance in the art.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is defined in the claims below.

1. In an inflatable and collapsible balloon for use in a medical dilatation catheter, the improvement which comprises forming said balloon (18) from a polymer containing as an additive radiopaque material.

2. The balloon of claim 1 wherein said polymer contains an amount of said radiopaque material sufficient to cause said balloon (18) to be radiopaque and translucent.

3. The balloon of claim 1 wherein the radiopaque material is 5-50% by weight of compounded polymer.

4. The balloon of claim 1 wherein the said radiopaque material is selected from barium sulfate, bismuth subcarbonate and bismuth trioxide.

5. The balloon of claim 1 wherein the balloon is formed from a plastic material suitable for thermoplastic melt processing.

6. The balloon of claim 1 wherein said polymer is selected from poly(vinylchloride), polyethylene, ethylene copolymers, styrenic polymers, polyethylene/vinyl acetate copolymer, poly(ethylene terephthalate), nylon elastomers, silicone elastomers, fluoropolymer elastomers and polyurethanes.

7. The balloon of claim 1 for use in the dilatation catheter procedure consisting of angioplasty, percutaneous transluminal angioplasty, percutaneous transluminal coronary angioplasty, percutaneous transluminal nephrostomy, ureteral dilatation, biliary duct dilatation or percutaneous transluminal renal angioplasty.

8. A catheter having a catheter body (15), a portion of said body defining the balloon (18) of claim 1.

9. A method for producing the balloon of claim 1 comprising:

(a) blending mixture of polymer and radiopaque material to form a compounded polymer;

(b) extruding said mixture of polymer and radiopaque material through a die to form a compounded

polymer containing radiopaque material;

(c) allowing said compounded polymer to cool to a temperature to solidify; and

(d) extruding said compounded polymer to form a radiopaque and translucent balloon.

10. The method of claim 9 further comprising molding the balloon formed in step (d) so as to alter the dimensions of said balloon.

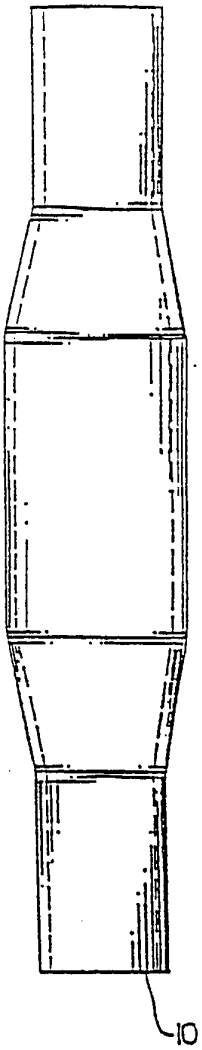

FIG.1

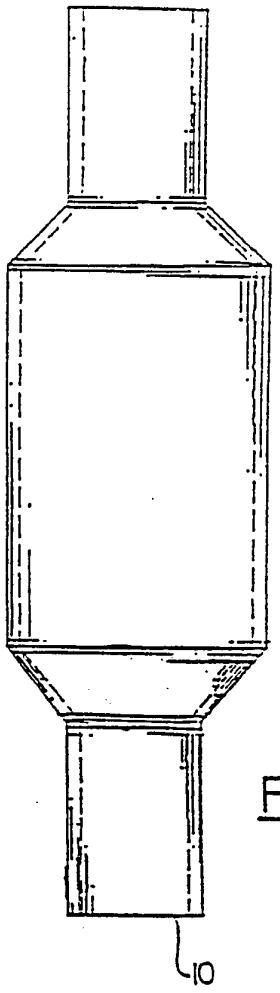

FIG.2

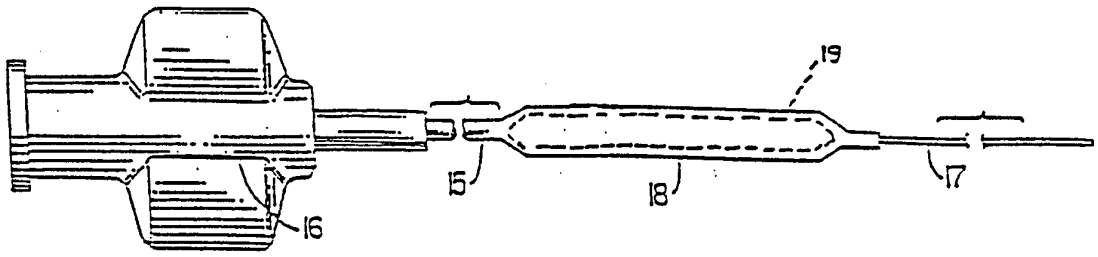

FIG.3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/13563

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00; B29C 47/60
US CL :264/211.23; 604/96; 606/191
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 264/176.1, 177.14, 177.17, 209.3, 211.23, 512, 514, 515; 604/96, 191, 264, 280; 606/191-198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US, A, 5,300,048 (DREWES, JR. ET AL.) 05 April 1994. See entire document.	1-10
Y	US, A, 4,921,483 (WIJAY ET AL.) 01 May 1990. See entire document.	1-8
Y	US, A, 4,898,591 (JANG ET AL.) 06 February 1990. See entire document.	1-8
X	US, A, 4,950,227 (SAVIN ET AL.) 21 August 1990. See entire document.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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