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[54] **METHOD OF MAKING MULTILUMEN
BALLOON CATHETER**

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[56]

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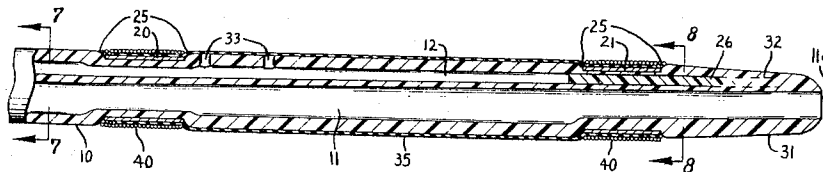
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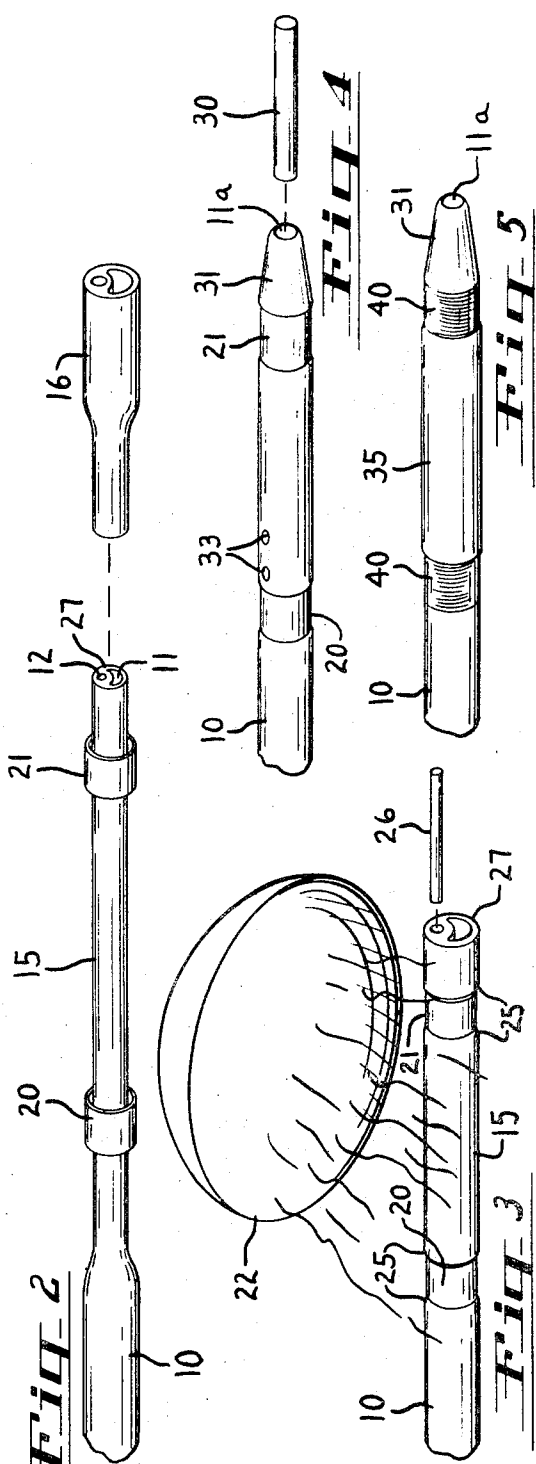
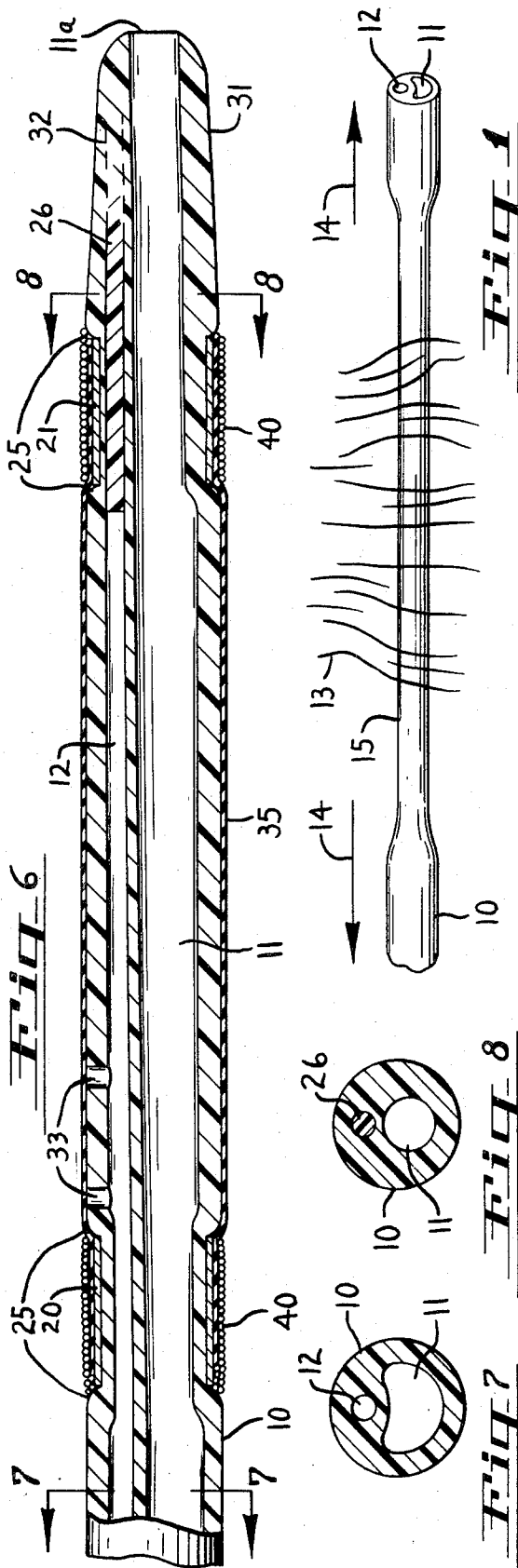
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ABSTRACT

A multilumen tube is extruded from a thermoplastic material having a memory characteristic. An end portion of the tube is heated sufficiently to soften the plastic and permit the end portion to be drawn out to a reduced diameter. A pair of metal ferrules is placed on the reduced end portion in predetermined positions spaced a short distance apart. Then the reduced portion is heated in relaxed condition causing it to reexpand and lock the ferrules in place. Balloon inflation openings are formed communicating with one of the lumens. A sleeve of balloon material is secured by bindings over the ferrules. In one embodiment the tube is limp and the balloon is utilized as a sail to flow carry the catheter through a vein into and through the heart and into the pulmonary artery.

8 Claims, 9 Drawing Figures





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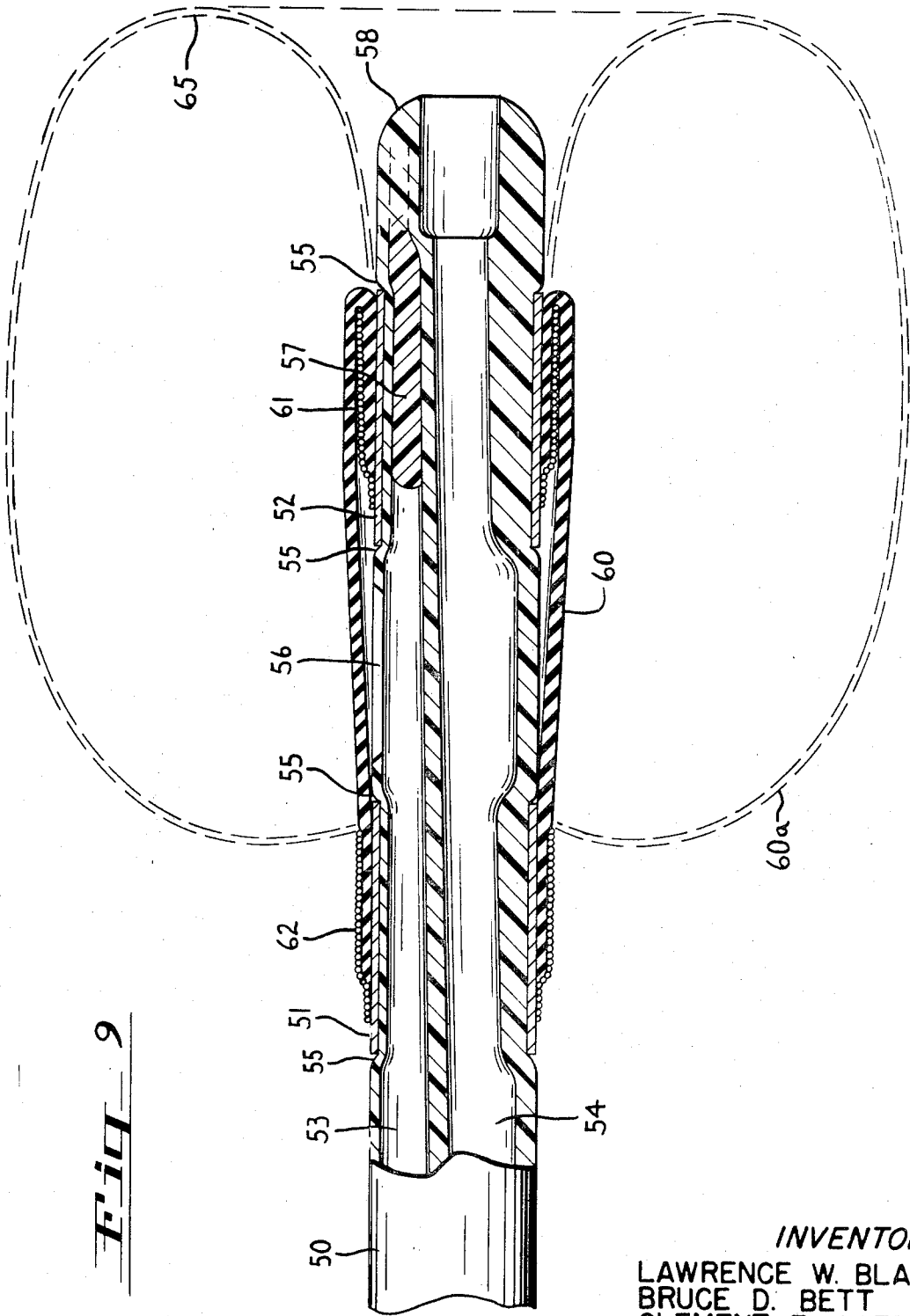


Fig. 9

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METHOD OF MAKING MULTILUMEN BALLOON CATHETER

BACKGROUND OF THE INVENTION

This invention relates to multilumen balloon catheters and is particularly concerned with a new and improved method for making such catheters and with an improved flow-directed catheter.

In catheters which are very small in diameter the balloon cannot be formed by a dipping process as are the balloons on the larger drainage catheters. The most satisfactory balloon construction has proved to be a very thin elastic sleeve secured at its ends to the catheter tube by windings of fine thread. There is a tendency, however for the plastic in the thin wall sections of a small tube to yield and creep under the pressure of the windings, choking off the lumens in the tube. This makes it difficult to construct a multilumen catheter of small enough size to pass freely through small arteries and veins and especially when the catheter tube is soft and limp as in the case of a flow-directed catheter.

Objects of the invention are, therefore, to provide an improved multilumen balloon catheter, to provide an improved and economical method for making such a catheter, to provide improved flow capacity in small multilumen catheters, to provide an improved support for the balloon windings, and to provide an improved flow-directed catheter.

SUMMARY OF THE INVENTION

In the present construction, multilumen catheter tubes are economically produced by extrusion of a thermoplastic material having a memory characteristic. The novel process steps comprise heating an end portion of the tube sufficiently to permit drawing out said portion of the tube to reduced diameter, applying a pair of metal ferrules over the reduced diameter portion of the tube, heating said end portion of the tube sufficiently to reexpand the tube and lock the metal ferrules in place, applying an elastic sleeve-type of balloon and binding end portions of the balloon over the metal ferrules.

The plastic material under the ferrules is thus not subject to the binding pressure and does not yield or creep causing constriction of the lumens. Catheters of very small size may be made in this manner and the method is of particular advantage in making flow-directed catheters having a soft and limp tube.

The invention will be better understood and additional objects and advantages will become apparent from the following description of the preferred embodiments illustrated in the accompanying drawings. Various changes may be made, however, in the details of construction and arrangement of parts and in the details of the method and all such modifications within the scope of the appended claims are included in the invention. The present catheters are not limited to use in veins and arteries but may also be used in the biliary system and elsewhere as will be understood by persons skilled in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic illustration of the first step in the method of the invention;

FIG. 2 illustrates a second step;

FIG. 3 illustrates a third step;

FIG. 4 illustrates a fourth step;

FIG. 5 illustrates the final step;

FIG. 6 is a longitudinal sectional view of the completed catheter tip;

FIG. 7 is a view on the line 7—7 in FIG. 6;

FIG. 8 is a view on the line 8—8 in FIG. 6; and

FIG. 9 is a longitudinal sectional view of a flow-directed catheter embodying the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Tube 10 is formed as an extrusion of a suitable thermoplastic material having a memory characteristic such as polyvinyl chloride. This extrusion contains a large through

lumen 11 of approximately semicircular shape in cross section as shown in FIG. 7 and a small circular balloon inflation lumen 12. The extrusion is cut off to the desired length and the end portion which is to receive the balloon is heated with hot water 13 as shown in FIG. 1. The heated and softened portion of the tube is then drawn by pulling in opposite direction with the fingers as indicated by arrows 14, causing the softened portion 15 to neck down to reduced diameter. This drawing step does not impair the integrity of the lumens 11 and 12.

After the drawing step, end portion 16 is cut off as shown in FIG. 2 and a pair of rigid ferrules 20 and 21 of suitable material such as stainless steel is placed on necked portion 15. These ferrules are placed in appropriate positions for the balloon windings and the necked portion of the tube is reexpanded by heating with heat lamp 22 as shown in FIG. 3. In this reexpansion step, utilizing the memory characteristic of the plastic, necked portion 15 returns to its original diameter forming shoulders 25 which securely lock the ferrules 20 and 21 in place in indentations in the tube. The ferrules preferably have an outside diameter slightly less than the original diameter of the extrusion.

The memory characteristic referred to is the result of crystalline structures set up within some of the polymer chains. When such material is heated under tension, these chains tend to untangle and straighten out. As long as the yield point is not exceeded, i.e., the chains are not broken, the material will return to its original form if reheated and not constrained. One of the advantages of polyvinyl chloride for the present purpose is that it will undergo a great deal of elongation before reaching its yield point.

The reexpansion step in FIG. 3 also restores the lumens 11 and 12 to approximately original size. A cylindrical plug 26 of suitable material such as polyvinyl chloride is secured in lumen 12 by a solvent bonding material. This plug is of sufficient length to extend from the cut end 27 of the tube to a point a short distance on the proximal side of ferrule 21.

Then a round wire 30 is inserted temporarily in lumen 11 as indicated in FIG. 4 and a tapered tip 31 is formed on the end of the tube by a heated die. The heat of the die causes the outer end portion of plug 26 to lose its identity and merge into the material of the tube as indicated by broken lines at 32 in FIG. 6. When the tip-forming operation is completed, wire 30 is removed leaving a round opening 11a at the end of lumen 11. In the tip forming operation wire 30 is held in concentric axial position within the tube so that opening 11a will be in the center of the tube.

A plurality of balloon inflation openings 33 are formed intersecting the lumen 12 and an elastic balloon sleeve 35 is pulled over the tube. The ends of the balloon sleeve are secured by windings 40 of suitable material such as Dacron thread overlying the ferrules 20 and 21 as shown in FIG. 5. These ferrules provide a solid backing for the windings whereby the lumens 11 and 12 are not constricted regardless of the tightness of the windings. Windings 40 may be substantially contained within the indentations in the tube created by the ferrules whereby the balloon portion of the catheter has approximately the same diameter as the rest of tube 10.

In use, the catheter is passed through a vein or artery or other body lumen until the tip reaches the area under investigation. The proximal end of the catheter tube, not shown, is equipped with the usual fittings providing fluid connections with the lumens 11 and 12. The introduction of balloon inflation fluid under pressure into lumen 12 expands the balloon 35 sufficiently to occlude the body lumen. Lumen 11 may be utilized for injection of therapeutic or diagnostic agents, sampling of a body fluid or pressure monitoring.

The extrusion may contain more than two lumens and a second balloon may be applied to the tube in the same manner on the proximal side of balloon 35 if desired.

FIG. 9 shows a highly flexible catheter embodying the invention for introduction percutaneously into a peripheral vein for flow guide catheterization of systemic veins, the right heart and pulmonary vessels. Tube 50 is extruded from a suitable

thermoplastic material having a memory characteristic, such as soft polyvinyl chloride. The method steps essentially as shown in FIGS. 1 to 5 are utilized for application of the two rigid ferrules 51 and 52 of a suitable material such as stainless steel. The catheter tube has a balloon inflation lumen 53 and a through flow lumen 54, the tube being flexible to the extent of being completely limp.

For application of the ferrules, the distal end portion of the tube is heated and drawn out to shrink its diameter as shown in FIG. 1 and the ferrules applied as shown in FIG. 2. The heating step in FIG. 3 utilizes the memory characteristic of the plastic to reexpand the tube, forming shoulders 55 which lock the ferrules in place in indentations in the tube. A longitudinal balloon inflation slit 56 intersecting the lumen 53 is formed by a rotary cutter. The end of lumen 53 is closed by a plug 57 and a contoured tip 58 is die formed on the end of the tube as described in connection with FIG. 4. Ferrule 52 is positioned very close to the end of the tube for a reason which will presently appear.

The distal end of balloon 60 is everted under Dacron winding 61 overlying ferrule 52 and winding 62 overlying ferrule 51 is applied to the proximal end of the balloon as shown. When the balloon is inflated it assumes the shape as shown in broken lines at 60a having a fold forming an annular bulge at 65 which preferably projects beyond and, in any event, forms a guard around the tip end 58 of the catheter tube. Tip 58 is contained in a dimple in the end of the balloon.

A second balloon may also be provided, if desired, spaced a short distance in a proximal direction from the balloon 60 and inflated from lumen 53 or from a second balloon inflation lumen. In such case, four ferrules would be applied as shown in FIG. 2 instead of two ferrules. The tube 50 may also include additional lumens 54. When there are two balloons, there may be an additional lumen having an external port opening between the two balloons. There may also be a still further lumen having an external port opening on the proximal side of the second balloon, if desired.

Balloon 60 acts as a sail to transport appropriate sensor devices in the catheter into the central circulation. The balloon forms a blunt body which is subjected to the drag force of the blood flowing past it, causing the balloon to pull the catheter along with it. For example, with the balloon deflated, the catheter may be inserted into an ante-cubital or other peripheral vein. When the balloon is inflated, it will flow carry the catheter through the right heart chambers and into the smaller radicals of the pulmonary artery so that pulmonary capillary wedge pressure may be measured. If the balloon is deflated at this point, pulmonary arterial pressures are mea-

sured; when the balloon is inflated, wedge pressure is again seen. The catheter is allowed to advance to the desired destination. Thus, the catheter in FIG. 9 may be used for pressure monitoring, blood sampling or infusion without fluoroscopy and with a minimal hazard to the patient. The field of use is in no way limited, however, to the particular example described.

When the balloon 60 is inflated, the annular bulge 65 prevents point contact of the tip of the catheter tube with the heart or artery wall. The presence of the balloon around the tip of the catheter alters the catheter system from one with a point force to one with forces dispersed over a surface. This markedly reduces the incidence and significance of ventricular extra-systoles which are occasioned by the pressure of a catheter tip on the endocardial and the subendocardial tissues. This is of critical importance in the management of seriously ill patients in whom an arrhythmia, even of transient duration, may prove to be fatal.

Having now described our invention and in what manner the same may be used, what we claim as new and desire to protect by Letters Patent is:

1. The method of making a balloon catheter comprising providing a catheter tube of a thermoplastic material having a memory characteristic and containing a balloon inflation lumen, applying heat to an end portion of said tube sufficient to soften said material, drawing out and elongating said softened portion to shrink its diameter, applying a pair of rigid ferrules over said shrunken portion, applying heat to said shrunken portion to reexpand its diameter and lock said ferrules on said tube, forming a balloon inflation opening in said material communicating with said lumen, applying a sleeve of elastic balloon material over said reexpanded portion, and binding said balloon material to said ferrules.

2. The method of claim 1 including the step of forming said tube initially by extrusion.

3. The method of claim 1 including the step of applying a rotary cutter to said tube to form said balloon inflation opening.

4. The method of claim 1 wherein said tube has a through flow lumen in addition to said balloon inflation lumen.

5. The method of claim 1 including the step of plugging the distal end of said balloon inflation lumen.

6. The method of claim 5 including the step of die-forming a contoured tip on said tube.

7. The method of claim 1 wherein said softening heat is applied by hot water.

8. The method of claim 1 wherein said reexpanding heat is applied by radiant energy.

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