

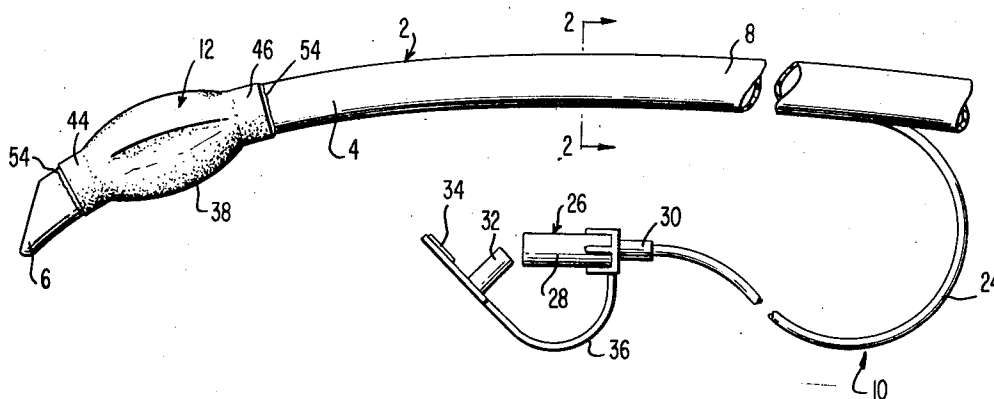
[72] Inventors **David S. Sheridan**
Hook Road, Argyle, N.Y. 12809;
Isaac S. Jackson, Greenwich, N.Y.
 [21] Appl. No. **860,278**
 [22] Filed **Sept. 23, 1969**
 [45] Patented **Dec. 7, 1971**
 [73] Assignee **David S. Sheridan**
Argyle, N.Y.

[56] **References Cited**
UNITED STATES PATENTS
 3,528,869 9/1970 Dereniuk..... 156/294
Primary Examiner—Carl D. Quarforth
Assistant Examiner—Stephen J. Lechert, Jr.
Attorney—Kemon, Palmer & Estabrook

[54] **BALLOON-TYPE CATHETERS AND METHOD OF MANUFACTURE**
9 Claims, 11 Drawing Figs.

[52] U.S. Cl..... **156/229,**
156/244, 156/257, 156/294, 156/296, 128/349
 [51] Int. Cl..... **B32b 31/00**
 [50] Field of Search..... **156/293,**
294, 296, 303.1, 229, 83, 250, 257; 128/349

ABSTRACT: Disposable balloon-type catheters are made from tubes of extruded waterproof plastic having a major lumen and at least one secondary lumen within the tube wall. Such secondary lumens are joined for fluid flow to inflation tubes by a series of cutting and cementing steps and to elastic inflatable balloons which are fitted in special fashion to the distal end of the tube.



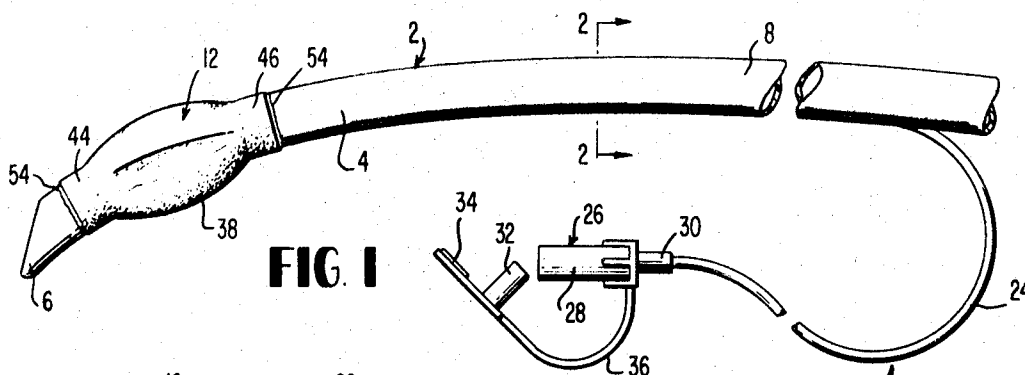


FIG. 1

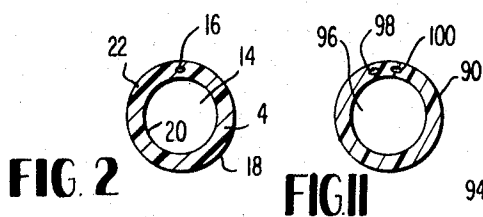


FIG. 2

FIG. 2

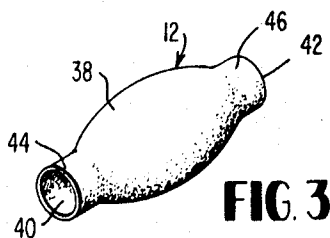


FIG. 3

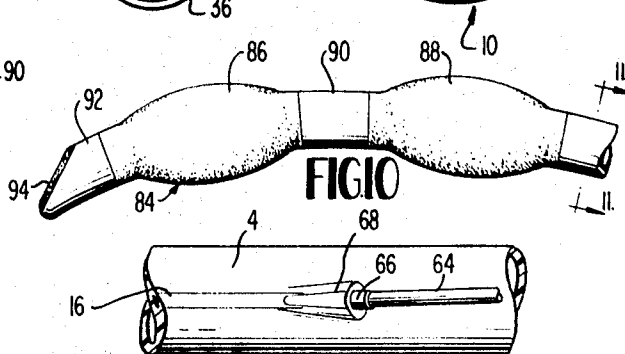


FIG. 4

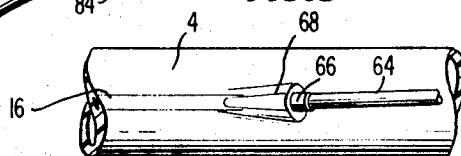


FIG. 5

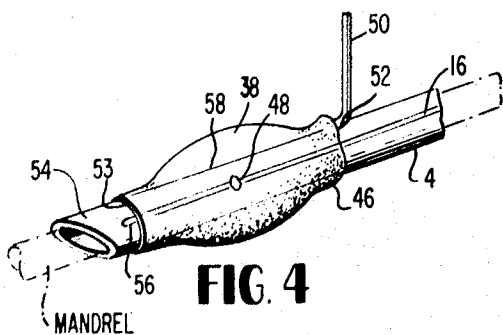


FIG. 6

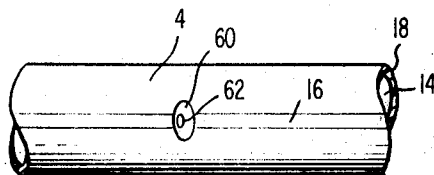


FIG. 7

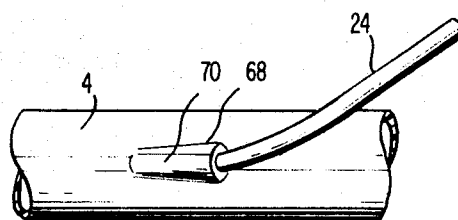


FIG. 8

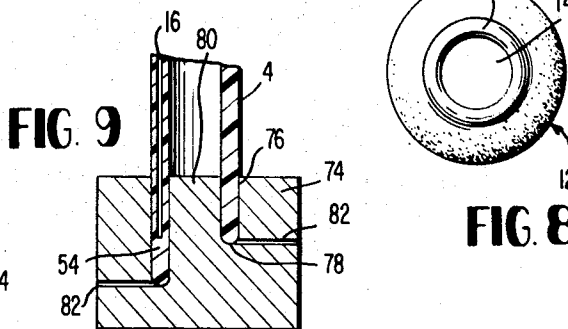


FIG. 9

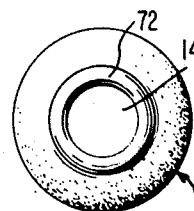


FIG. 10

INVENTORS
DAVID S. SHERIDAN
ISAAC JACKSON

BY *Keman, Palmer & Estabrook*
ATTORNEYS

BALLOON-TYPE CATHETERS AND METHOD OF MANUFACTURE

BACKGROUND OF THE INVENTION

This invention relates to balloon-type catheters, i.e., catheters which are provided at the distal end with an inflatable balloon or cuff which serves, during the medical or surgical procedure performed using the catheter, to retain the catheter in a desired position within the patient, to close a passage in the patient, etc.

Medicosurgical tubes may assume a variety of sizes, shapes and be provided with a variety of fluid openings, couplings, connectors or the like. Terminology applied to such devices by users, e.g., physicians, surgeons, hospitals, etc., frequently refer to them as catheters, e.g., rectal catheters, urethral catheters, hemostatic catheters and the like, but in other cases they are referred to as tubes, e.g., endotracheal tubes, feeding tubes, suction tubes, drain tubes and the like. For the sake of brevity in describing the improved devices of the invention and their method of production, the term "catheter" is employed throughout the specification and accompanying claims to encompass pertinent medicosurgical devices whether they be popularly referred to by the medical profession and other users as "catheters" or "tubes."

The modern trend in medical and surgical practices is toward the use of disposable catheters, i.e., those which may be used a single time on one patient and then discarded. The high cost of labor in sterilizing tubes of the reusable type tends to offset the cost of a single use disposable catheter. Also, the use of a disposable catheter reduces cross-infection cases which constitute a serious problem in hospital operations. Of course, the cost of a disposable catheter must be competitive with the cost of a reusable type over its usable life span plus the cost of sterilizing the reusable catheter. Hence, it is necessary for the acceptance and a practical utilization of disposable-type catheters that they be manufactured at a minimum cost. Reduction in cost of manufacture of simple catheters such as rectal tubes, Foley catheters and the like have been possible so that reusable catheters of this class are rapidly being displaced in the industry by disposable-type catheters. On the other hand, the more complicated construction and manufacturing costs associated with the production of balloon-type catheters has not permitted these catheters heretofore to be in major proportion of the disposable type, i.e., reusable balloon-type catheters are still extensively used because of cost and construction factors.

A balloon-type catheter normally involves a plurality of lumens one being the major lumen which serves to convey urine blood serum, gases and any other fluid which may be introduced into or removed from the body of a patient and at least one secondary lumen which is used as a conduit for air or liquid employed in inflating a balloon which forms a portion of the distal end of the catheter. Such secondary lumen is attached to an inflation tube through which the air or liquid used to inflate the catheter balloon is introduced. The manner of attachment of the inflation tube to the catheter has been a contributing factor in the cost of manufacture of balloon-type catheters heretofore. The principal method of attaining this has been in the past to form the inflation tube integrally with the remainder of the catheter by moulding, casting or dipping operations (see U.S. Pat. No. 2,927,584). To attain high rates of production and low cost of operation, it would be desirable to have available a satisfactory method for producing balloon-type catheters by an extrusion method. This necessitates having available some means by which the inflation tube may be satisfactorily attached to the extruded tube forming the major part of the balloon-type catheter. Of course, such an attachment procedure must provide a reliable connection between the inflation tube and the catheter without substantially increasing the cost of manufacture or the rate at which the units may be produced.

Another feature of balloon-type catheters which creates cost and production problems in their manufacture is the con-

struction of the inflatable balloon and its method of attachment to the catheter. This must be accomplished so that the balloon in the deflated condition will not present protrusions, edges or the like which prevent the smooth insertion or withdrawal of the catheter in the patient thereby avoiding damage to tissues or organs through which the catheter passes during its use upon the patient. One method of attachment of the inflation balloon has involved its inclusion totally inside the wall of the main tubing forming the catheter (see U.S. Pat. No. 2,919,697). Such construction is complicated and involves, however, the problem of an integrally formed inflation tube as discussed above. Other approaches to the problem of attachment of the inflatable balloon have involved the casting or dipping of a plastic balloon on the end of the catheter (see U.S. Pat. No. 3,292,627) or a concentric arrangement of tubes with grooves cut or otherwise formed in the outside walls of a portion only of the inner tube constituting the main body portion of the catheter (see U.S. Pat. No. 2,912,981). While such constructions may be effective in creating a nontraumatic balloon attachment to the catheter, the constructions required and the number of steps involved in production of such catheters serves to undesirably increase the cost of manufacture.

As previously indicated, the balloon-type catheters encompass a wide variety of specific medicosurgical devices used in different operations and medical procedures. They may be urethral catheters (see U.S. Pat. No. 2,919,697), endotracheal tubes, hemostatic catheters (see U.S. Pat. No. 3,045,677) or any other of a number of related devices known to the medical art. In addition, such catheters may involve special units or devices for introducing inflation fluid into the inflatable bag or balloon formed as a part of the distal end of the catheter (see U.S. Pat. Nos. 2,896,629 and 3,409,016). The present invention is contemplated for use in connection with all forms of balloon-type catheters.

Another factor that has contributed to the cost of disposable catheters, particularly endotracheal tubes which have a relatively large distal end opening, is the finishing of the distal tip. In the past this has involved extensive hand work, i.e., grinding, buffing and polishing and required a high degree of skill in the finishing operators even to accomplish a mediocre result. The utilization of balloon type as well as other disposable catheters would be improved if a method of finishing the distal tips with less hard work, need for less skilled workers, or both, could be provided.

OBJECTS

The principal object of the present invention is the provision of new improvements in catheters and their production. Further objects include the provision of:

1. New methods for the production of disposable plastic balloon-type catheters.
2. New forms of extruded plastic catheters having a balloon cuff on the distal end which has been installed in a manner to give a polished, rounded junction between the balloon shoulders and the outside wall of the catheter tube.
3. New methods for affixing inflation tubes to balloon-type catheters permitting the main body portion of the catheter to be formed of extruded waterproof plastic material.
4. Disposable endotracheal tubes having a balloon cuff feature of improved design.
5. New methods for the shaping and polishing of the distal end tip of medicosurgical tubes and particularly balloon-type catheters comprising a major lumen and at least one secondary lumen within the wall of the catheter.
6. Balloon-type catheters of improved design capable of being manufactured at low cost and high rates of production to exact specifications completely competitive on a single use, disposable basis with reusable tubes of the same general type designed for multiple use with sterilization between uses.

7. New methods for the formation of arcuate tubing by extrusion having a secondary lumen in the tubing wall on the inside of the tubing arc for use in producing endotracheal tubes.

SUMMARY OF THE INVENTION

These objects are accomplished according to the present invention by the provision of balloon-type catheters which comprise:

- a. an extruded tube formed of flexible waterproof plastic material having a major lumen with an area equal to at least one-half the cross-sectional area of the tube and at least one secondary lumen of smaller diameter than the wall thickness of the tube, all said lumens extending substantially the entire length of the tube,
- b. a smoothly rounded distal end on the catheter presenting the major lumen in full opening and closing the end of said secondary lumen,
- c. an inflation tube of flexible waterproof plastic material having an outside diameter slightly larger than said secondary lumen fixed through a first opening in said tube with the end of the inflation tube extending into such secondary lumen in the direction of the distal end of the catheter,
- d. a second opening cut through the wall of the catheter adjacent the distal end into communication with said secondary lumen, and
- e. an elastic inflatable balloon fixed about the catheter adjacent its distal end enveloping said second opening.

In the embodiments of the invention where the catheter has a plurality of secondary lumens, there will be a separate balloon element and inflation tube for each secondary lumen.

In a preferred embodiment of the invention, the new balloon-type catheters are endotracheal tubes having an angled distal end tip and a permanent arcuate shape with the secondary lumen being positioned on the inside of the curve of the endotracheal tube. Such endotracheal tubes further are preferably formed of plasticized polyvinyl chloride containing a small amount of white pigment which gives the tube a milky translucency, but retains sufficient transparency to permit the major lumen of the tube to be viewed through the side walls of the catheter.

The objects of the invention are further accomplished by the method for production of balloon-type catheters which comprises:

- a. providing an extruded tube of predetermined length formed of flexible waterproof plastic material, said tube having a major lumen and at least one secondary lumen, said major lumen having an area equal to at least one-half the cross-sectional area of the tube, said secondary lumen being of smaller diameter than the wall thickness of the tube, both said lumens extending the full length of the tube,
- b. cutting a first opening through the wall of said tube adjacent the distal end thereof into communication with said secondary lumen,
- c. closing said secondary lumen at the distal end of said tube while leaving the secondary lumen open for fluid flow proximal of said first opening,
- d. sealing an elastic inflatable balloon to the outside of said tube so as to envelope said first opening,
- e. cutting a second opening through the wall of said tube into communication with said secondary lumen between said first opening and the proximal end of the tube,
- f. providing a section of extruded tubing of predetermined length having an outside diameter slightly larger than said secondary lumen,
- g. inserting a heated tapered mandrel into said second opening to cause said lumen to be expanded in the region of said second opening,
- h. removing said mandrel from said second opening, and promptly inserting one end of said section of extruded tubing into the expanded second opening, and

- i. allowing said second opening to contract about said inserted end of tubing.

The objects of the invention are further accomplished by forming the balloon cuff on the new balloon-type catheters by a procedure which comprises:

- a. providing an elastic inflatable balloon having a pair of opposed circular openings defined by short integral tubular extensions or shoulders, said shoulders having an inside diameter slightly smaller than the outside diameter of said extruded tube,
- b. fitting said balloon about said tube adjacent one end of the tube by passing the tube through said shoulders while stretching the shoulders sufficiently to permit such passage,
- c. forcing a thin layer of liquid cement between the outside wall of said tube and said tubular extensions with the balloon stationary in the fitted position of said step "b", and
- d. allowing said cement to harden while the balloon remains in said fitted position.

The method of closing the secondary lumen distally of the opening which connects the secondary lumen to the balloon cuff of the catheter is accomplished by forcing the distal end of the tube into a mold heated to a temperature sufficient to produce plastic flow of the plastic material of the tube, the mold having a concave contour to create a smooth convex surface upon the end of the tube. This heating and molding step simultaneously polishes the end of the tube and closes the secondary lumen so that any fluid passed into the secondary lumen through the inflation tube will be forced to enter the balloon cuff.

Advantageously, the balloon cuff applied to the catheter is made by dipping a mandrel in polyvinyl chloride plastisol to form a balloon cuff with opposed shouldered openings that are slightly smaller in diameter than the outside diameter of the catheter, i.e., about 0.5 mm. smaller than the outside diameter of the catheter tube.

DESCRIPTION OF THE DRAWINGS

A more complete understanding of the new methods and the devices of the invention may be had by reference to the accompanying drawings in which:

FIG. 1 is a fragmentary plan view of an endotracheal tube formed in accordance with the invention showing for most part the distal end portion of the tube and also illustrating the attached balloon inflation means of the catheter.

FIG. 2 is an enlarged sectional view taken along the line 2—2 of FIG. 1.

FIG. 3 is a perspective view of an elastic inflatable balloon cuff with opposed shouldered openings of the type used in the invention in forming the inflatable balloon feature of the new catheters.

FIG. 4 is a fragmentary perspective view illustrating one step in the method of affixing a balloon cuff of the type shown in FIG. 3 to the distal end of a catheter in accordance with the invention.

FIG. 5 is a fragmentary enlarged side view of the section of a catheter in accordance with the invention in one stage of affixing a section of inflation tube to the secondary lumen of the balloon-type catheter.

FIG. 6 is a fragmentary side view related to FIG. 5 showing the catheter in a further stage of installation of the inflation tube.

FIG. 7 is a fragmentary side view related to FIGS. 5 and 6 showing the inflation tube installed upon the catheter.

FIG. 8 is an enlarged distal end view of the catheter shown in FIG. 1 with the balloon cuff inflated.

FIG. 9 is a fragmentary side view, partially in section, illustrating a step in the heat molding of the distal end portion of catheters in accordance with the invention.

FIG. 10 is a fragmentary side view of a catheter in accordance with the invention which has a pair of inflatable balloons and a pair of secondary lumens.

FIG. 11 is an enlarged, sectional view taken on the line 11—11 of FIG. 10.

Referring in detail to the drawings, the endotracheal tube 2 comprises a nonfibrous tube 4, a distal end 6, a central body portion 8, a proximal and (not shown), inflation means 10 and elastic inflatable balloon means 12. As will be understood by those skilled in the art, devices of this type will vary in size to accommodate different patients and operative conditions, e.g., a typical endotracheal tube would have an inside diameter of 7.0 mm., an outside diameter of 9.3 mm., a length of about 12 inches and will be of arcuate form defining a circle of radius about 5–12 inches.

The cross section of the endotracheal tube of FIG. 1 as shown in FIG. 2 is representative of all of the balloon-type catheters of the invention having a single secondary lumen. The tube 4 defines a major lumen 14 having an area equal to at least one-half the cross-sectional area of the tube 4 and a secondary lumen 16 which is of smaller diameter than the wall thickness of the tube so that the lumen 16 is formed completely within the wall 18 of the tube 4. By this construction, the inside wall 20 and outside wall 22 of the tube 4 may be completely smooth and uninterrupted by protrusions, indentations or the like. As a consequence, the major lumen 14 can have its entire cross section maintained throughout the entire length of the catheter 2 from the distal end 6 through to the proximal end. Similarly, the outside surface 22 of the catheter will present a smooth, uniform circular cross section.

Using standard extrusion apparatus and techniques, the tube 4 will present smooth, highly polished or so-called "plate finish" surfaces 20 and 22. However, the endotracheal tube 2 or any other balloon-type catheter formed in accordance with the invention may be provided with a frosted surface, in whole or in part, for the purposes and using the methods described and claimed in copending application, Ser. No. 772,890, filed Nov. 4, 1968 for "Medicosurgical Tubes Having Frosted Surface."

The inflation means 10 is formed of a section of extruded tubing 24 and closure means 26. This closure means can take any convenient form such as a syringe puncture plug of the type shown in U.S. Pat. No. 2,896,629, but in the preferred embodiment shown in FIG. 1, the closure means 26 comprises a cylindrical portion 28, a nipple 30 into which the tubing section 24 is cemented, a plug 32, a pull-tab 34, and a flexible connector strip 36. The entire closure unit 26 is advantageously formed of flexible plastic material by injection molding, but may be formed in any other suitable fashion from other materials such as semirigid plastics, rubber or the like by compression molding, dip coating or the like.

The balloon means 12 comprises an elastic inflatable balloon cuff 38 having a pair of opposed circular openings 40 and 42 defined by short integral tubular extensions or shoulders 44 and 46, respectively. The shoulders 44 and 46 have an inside diameter slightly smaller than the outside diameter of the tube 4, e.g., about 0.1 to 1.0 mm. and particularly about 0.5 mm. smaller than the tube.

The balloon cuff 12 is assembled to the catheter 2 by fitting the balloon cuff over the distal end 6 of the tube by passing the tube 4 through the shoulders 44 and 46 while stretching them sufficiently to permit such passage. This positioning of the balloon cuff about the tube may be helped by dipping the balloon in a lubricant to provide slippage between the balloon shoulders and the outside surface of the tube. Before such placement of the balloon cuff 12 is made, however, a small hole 48 is cut through the wall of the tube 4 adjacent the distal end 6 so that it is in communication with the secondary lumen 16. The balloon cuff 12 is then positioned during the fitting step just described so that the balloon 38 envelopes the opening hole 48. In this manner, any fluid which is forced through the secondary lumen 16 and the hole 48 will enter the inside of the balloon 38.

The balloon means 12 is permanently fixed in the required position by placing the tube on a mandrel to straighten the tube and hold it for rotation. Then a hypodermic needle or

similar fine diameter hollow tube 50 with a right angle tip 52 is positioned as shown in FIG. 4 with the right angle tip 52 under a shoulder of the balloon. A suitable cement such as vinyl resin adhesive, is forced from a syringe (not shown) into the needle 50 and thence between the right angle tip 52 and the balloon shoulder 46. The tube mounted on the mandrel is then rotated while a necessary small amount of liquid cement is forced under the balloon shoulder. The compressive force of the shoulder 46 when handled in this manner causes a clean smooth joint to be formed between the shoulder 46 and the tube 4 and upon drying or hardening of the cement, a permanent connection between balloon cuff 12 and the tube is obtained. This procedure is repeated for the second shoulder 44 of the balloon cuff. A "Bead" finish 53 can be obtained at the very end junction between the shoulders 44 and 46 and the tube 4 by brushing some of the liquid cement around the tube at this junction.

The sealing 54 at the distal end 56 of the secondary lumen 16 can be accomplished, in the manner described hereinafter, prior to the attachment of the balloon to the catheter as just described or at some suitable subsequent time. Regardless of the particular time for formation of the end sealing 54 of the secondary lumen, this serves to close off the end of the secondary lumen so that fluid introduced into the secondary lumen through the inflation means 10 will be required to pass through the hole 48 into the space between the balloon 38 and the outside wall 58 of the tube 4 for the purpose of inflation of the balloon as required in the operative procedure for which the catheter is employed.

Installation of the inflation means 10 in the catheter is illustrated in FIGS. 5–7. At an appropriate position along the catheter, normally within the first half length of the tube from the proximal end, a cut 60 is made in the wall of the tubing 4 forming an opening 62 communicating with the secondary lumen 16. A small mandrel 64 with a tapered end 66 which has been heated to a suitable temperature, e.g., between 150°–200° F., is forced into the opening 62. As shown in FIG. 6, this produces a conical expansion 68 of the side wall of the tube defining the secondary lumen 16 to occur. A section of tubing 24 having an outside diameter slightly larger than the diameter of the secondary lumen 16 is prepared for insertion into the expanded hole 62 by applying a thin coating of solvent, e.g., dimethyl ketone, to the end 70 of the tubing section 24. The mandrel 64 is then pulled from the expanded opening 68 and the end 70 of the tube section is inserted as shown in FIG. 7. Very promptly the elastic memory of the plastic material of which the tube 4 is formed will cause the expanded wall portion 68 to shrink and make a tight joint with the end 70 of the tube section 24. In the case of endotracheal tubes made in accordance with the invention, the secondary lumen 16 will be on the inside of the arcuate shape of the device and, consequently, the entrance of the inflation tube section 24 into the catheter tube will also be on the inside curve of the device.

An important feature of catheters produced in accordance with the invention is illustrated in FIG. 8. The distal end tip 72 is smoothly rounded in a convex contour. This is important in attaining smooth entry of the catheter into the body of a patient without tendency to tear or injure tissue during the insertion procedure. Of equal importance, however, is the fact that the smooth rounding of the tube end 72 does not result in any reduction in the diameter of the major lumen 14. This is in contrast to any prior tube end polishing procedures which have employed heat or solvent to attain a polishing of the tube end since such prior known methods result in a contraction of the tube end producing a substantial reduction in the diameter of the tube opening at the distal end.

The manner of obtaining the desired smooth rounded finish to the distal end tip 72 without diminution in the lumen 14 and a simultaneous sealing of the end 56 of the secondary lumen 16 is illustrated in FIG. 9. A mold made of metal or any other suitable material which may be heated to a temperature sufficient to soften the plastic material of which the catheter is

made, e.g., between about 170°–450° F., is formed with a cavity 76 shaped with a rounded bottom 78 to the contour desired in the end 72 of the catheter. A central pin or extension 80 having the exact outside diameter corresponding to the diameter of the major lumen 14 is provided in the mold 74. Also, one or more vent holes 82 are provided in the mold to permit air to escape upon the insertion of the distal end 6 of the catheter into the heated mold 74. With the mold heated as indicated, the distal end of the catheter is forced into the mold cavity 76 with sufficient pressure at the temperature of the mold to create plastic flow in the plastic material of the tube 4. This causes the tip 72 of the tube to be contoured into a smoothly rounded tip and at the same time to produce the seal 54 at the end of the secondary lumen 16 for the purpose described hereinbefore.

The formation of the polished tip on catheters in accordance with the invention is particularly important with catheters having an angular distal end, e.g., endotracheal tubes as shown in FIG. 1. Using the procedures of the invention it is possible to convert a square-cut end of a tube into a polished angular tip in a single pressure molding operation. The provision of the small air vent in the base of the shaping mold permits the plastic which is softened by heat exchange with the heated mold, to flow into the bottom of the mold cavity. In doing this, a small amount of molten plastic may exit through the vent, but this can be sheared off easily leaving the catheter with a nicely polished distal tip. All this is accomplished quickly and without reducing the inside diameter or increasing the wall thickness of the catheter at the distal end.

The embodiment of catheter 84 shown in FIGS. 10 and 11, comprises two separate balloon cuffs 86 and 88. Such double balloon catheters are used for example in long-term patients, the separate balloons being alternately inflated and deflated.

In the catheter 84, the tube 90 has the cuffs 86 and 88 positioned adjacent the proximal end 92 of the catheter which is also provided with an X-ray opaque, slanted tip 94. The balloon 86 is inflatable through the secondary lumen 98 while the balloon 88 is inflatable through the secondary lumen 100. The construction of the additional balloon unit will follow the same procedures described above in connection with the catheters having a single secondary lumen and will be apparent to those skilled in the production of catheters from the descriptions herein.

DISCUSSION OF DETAILS

New balloon-type catheters of the invention may be manufactured to professional specifications and may be produced in varying degrees of flexibility or rigidity by varying the formulation of the plastic material from which the tubes are extruded. They may be used interchangeably with similar catheters which do not incorporate the improved features of the new devices of the invention.

The new disposable catheters of the invention should be waterproof, flexible over a relatively wide range of temperatures, resistant to attack by body fluids, capable of being sterilized, such as by exposure to ethylene oxide or gamma radiation, and capable of being produced by extrusion at high speeds and at relatively low costs. There are a variety of plastic materials capable of providing these requirements in the production of disposable, single use catheters. Advantageously, the new catheters will be formed of nonfibrous plastic material and a particularly useful material for this purpose is plasticized polyvinyl chloride. However, other thermoplastic materials which are useful in forming the catheters are available, e.g., nylon, polyethylene or other polyolefins and equivalent materials. A particularly useful material is plasticized polyvinyl chloride formulated to have an extrusion temperature of about 325°–375° F. and especially 350° F. The present invention is contemplated for use in connection with any plastic material known or found to be useful in the formation of disposable catheters.

The plastic material used in forming the new catheters may be unpigmented. However, in some cases, pigments designed to give X-ray opacity may be incorporated in the plastic material. In a preferred embodiment of the invention, a small amount of very finely divided white pigment, e.g., about 0.01 to 1 percent by weight of titanium dioxide pigment, is incorporated in the otherwise transparent plastic material used in forming the catheter to give the final extruded tube a milky translucency, but still retaining sufficient transparency to permit the major lumen to be viewed through the sidewall of the catheter. It has been found that this milky translucency creates a clean appearance but retains a "see through" quality which emphasizes the presence within the major lumen of obstruction materials such as articles of body tissue, blood clots and the like.

The new catheters may include special features which are known in the construction of medicosurgical tubes and which may be required for particular procedures in which the new catheters are to be employed. These may include a nonsparking feature (see U.S. Pat. No. 3,070,132), X-ray line feature (see U.S. Pat. No. 2,857,915) or a tapered section feature (see U.S. Pat. No. 2,940,126).

In accordance with known practice, markings may be applied to the catheters to designate the distance from the distal end to aid the physician or surgeon in the use of the tube. As will be understood by those skilled in the art, these distance markings will vary with the tube size, e.g., with a 5.5 mm. I.D. tube, the marks will generally designate 12, 13.5 and 15 cm. distance from the distal end and with a 7.0 mm., I.D. tube, the markings will designate 18, 20 and 22 cm. from the distal end for endotracheal tubes which constitute one of the important forms of catheters which can be made by the invention.

FIG. 1 of the drawings shows the new catheter device to have a slanted or sloped end. However, any other form of end or openings as have been established by practice for a particular catheter or which may be found necessary hereinafter by new design may be utilized in production of catheters in accordance with the invention. This can include catheters which have a closed tip and side entering eyes or openings (see U.S. Pat. No. 2,927,584).

Since the new catheters are designed particularly for disposable, single use purpose, they are advantageously packaged as single units each in its own individual envelope, tube or other suitable container. A variety of film or other packaging material is available for this purpose in which the catheter may be contained for extended period of time in sterile condition immediately available to the physician, nurse or other user of the catheter at the location where the catheter will be used with the patient. As previously indicated, ethylene oxide, gamma radiation or equivalent methods may be used to sterilize the catheter and the package in the production of such packaged units.

Commercially available extrusion equipment may be used in conjunction with suitable extrusion dies to produce the multiple lumen tubing required in the creation of balloon-type catheters of the invention. However, in accordance with the invention, a special technique is employed in producing the multiple lumen tubing for endotracheal tubes of arcuate form with the secondary lumen on the inside of the tube curvature. When plastic tubing is normally extruded into drums as it is withdrawn from the extrusion die, it will develop a twist in it. If a multiple lumen tube is produced in such known manner and cut into lengths for making endotracheal tubes, the secondary lumen can, and usually will, be in a twisted or spiralled position. This requires added steps for the formation of final catheters, e.g., placement on curved mandrels, baking and cooling, with properly arranged secondary lumens.

In accordance with the present invention, the multiple lumen tubing as it is extruded, is conveyed away from the extrusion die and directly coiled onto a drum, being restrained in the conveying to the drum so that the secondary lumen faces directly toward the drum. The drum is of a diameter corresponding the radius of curvature desired in the arcuate

catheter. The tubing is extruded continuously and coiled as indicated on the drum. As soon as one drum is full, it is replaced with another and this operation continues until the required amount of tubing is produced. The drums with the carefully positioned tubing thereon are baked, e.g., at 150° to 350° F. 10 to 20 minutes and then cooled. When the cooled tubing is removed from the drums, it has the right degree of curvature and the secondary lumen is in the right position, i.e., on the inside of the curvature. The tubing is cut in required lengths and formed into catheters as previously described and the final catheters have the correct curvature and lumen position.

CONCLUSION

The invention as described herein provides balloon-type catheters having noteworthy improvements while permitting such catheters to be made at substantial savings in costs. The new methods for producing balloon catheters. Hence, the invention makes a reality of single-use, disposable balloon-type catheters.

The embodiments of the invention in which an exclusive property or right is claimed are defined in the accompanying claims:

1. Method for the production of balloon-type catheters which comprises:

- a. providing an extruded tube of predetermined length formed of flexible waterproof plastic material, said tube comprising a major lumen and a secondary lumen, said major lumen having an area equal to at least one-half the cross-sectional area of the tube, said secondary lumen being of smaller diameter than the wall thickness of the tube, both said lumens extending the full length of the tube,
- b. providing an elastic inflatable balloon having a pair of opposed circular openings defined by short integral tubular extensions of said balloon, said extensions having an inside diameter slightly smaller than the outside diameter of said extruded tube,
- c. fitting said balloon about said tube adjacent one end of the tube by passing the tube through the entire length of said balloon while stretching said tubular extensions thereof sufficiently to permit such passage,
- d. with the balloon stationary in the fitted position of said step "c," inserting a fine diameter hollow tube between the outside wall of said tube and said tubular extensions and forcing liquid cement through said tube to form a thin layer between said outside wall of the tube and the inside of the tubular extensions, and
- e. allowing said cement to harden while the balloon remains in said fitted position.

2. A method as claimed in claim 1 wherein liquid cement is applied at the ends of said tubular extensions around the walls of said tube to form beaded joints between the tube and the balloon.

3. Method for the production of balloon-type catheters which comprises:

- a. providing an extruded tube of predetermined length formed of flexible waterproof plastic material, said tube comprising a major lumen and a secondary lumen, said major lumen having an area equal to at least one-half the cross-sectional area of the tube, said secondary lumen being of smaller diameter than the wall thickness of the tube, both said lumens extending the full length of the tube,
- b. cutting a first opening through the wall of said tube adjacent the distal end thereof into communication with said secondary lumen,
- c. closing said secondary lumen at the distal tip of said tube while leaving the secondary lumen open for fluid flow proximal of said first opening,
- d. sealing an elastic inflatable balloon to the outside of said tube so as to envelope said first opening,
- e. cutting a second opening through the wall of said tube into communication with said secondary lumen between said first opening and the proximal end of the tube,
- f. providing a section of extruded tubing of predetermined length having an outside diameter larger than said secondary lumen,
- g. inserting a heated tapered mandrel into said second opening to cause said lumen to be expanded in the region of said second opening,
- h. removing said mandrel from said second opening, inserting promptly one end of said section of extruded tubing into the expanded said second opening, and
- i. allowing said second opening to contract about said inserted end of tubing.

4. A method as claimed in claim 3 wherein a layer of liquid cement is applied to said one end of tubing section before inserting said tubing into said second opening in step "i."

5. A method as claimed in claim 3 wherein said closing of the secondary lumen in step "c" is accomplished by forcing the end of the tube into a mold heated to a temperature sufficient to produce plastic flow of the plastic material of the tube, said mold having a concave contour to create a smooth convex surface upon the tube end in the step of closing of the secondary lumen.

6. A method as claimed in claim 5 wherein the distal tip of said tube is cut at an angle to the longitudinal axis of the tube and said mold is complementarily contoured to create a smoothly rounded tapered distal end tip on the balloon-type catheter.

7. A method as claimed in claim 6 wherein said catheter is an endotracheal tube and the tube provided in step "a" has a permanent arcuate shape.

8. A method as claimed in claim 6 wherein air within said mold is allowed to escape therefrom through an air bleed hole that extends through a wall of said mold.

9. A method as claimed in claim 4 wherein said tube is made of plasticized polyvinyl chloride having an extrusion temperature about 300°-350° F. and said tapered mandrel is heated to a temperature about 160°-200° F.

* * * * *

Disclaimer

3,625,793.—*David S. Sheridan*, Argyle, and *Isaac S. Jackson*, Greenwich, N.Y.
BALLOON-TYPE CATHETERS AND METHOD OF MANU-
FACTURE. Patent dated Dec. 7, 1971. Disclaimer filed Apr. 14, 1977,
by the assignee, *Mallinckrodt, Inc.*

Hereby enters this disclaimer to claims 1 and 2 of said patent.

[*Official Gazette July 26, 1977.*]