Aug. 28, 1973 D. S. SHERIDAN ET AL 3,755,525

METHOD OF MAKING MULTIPLE LUMEN TUBING FOR MEDICO-SURGICAL TUBES

Original Filed July 12, 1971

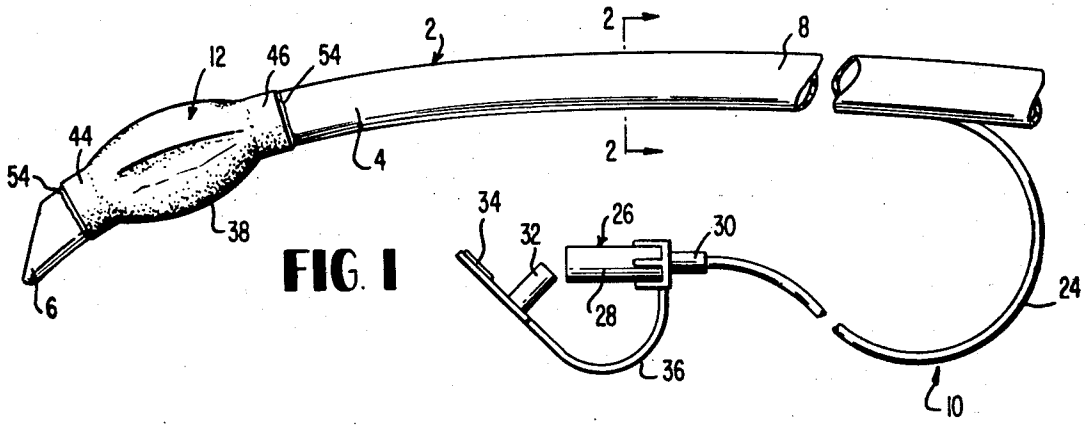


FIG. 1

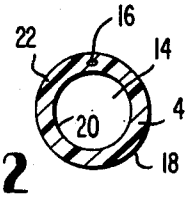


FIG. 2

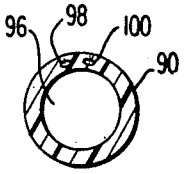


FIG. 4

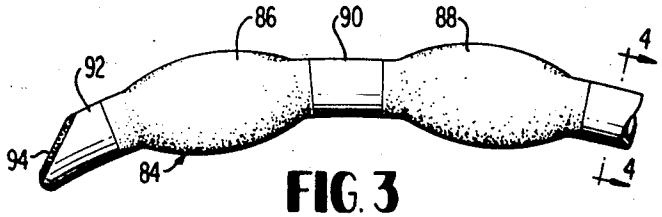


FIG. 3

United States Patent Office 3,755,525 Patented Aug. 28, 1973

3,755,525

METHOD OF MAKING MULTIPLE LUMEN TUBING FOR MEDICO-SURGICAL TUBES

David S. Sheridan, Hook Road, Argyle, N.Y. 12809, and Isaac S. Jackson, Greenwick, N.Y., said Jackson assignor to said Sheridan

Original application July 12, 1971, Ser. No. 860,278, now Patent No. 3,625,793. Divided and this application July 12, 1971, Ser. No. 161,877

Int. Cl. B29d *23/04;* B29c *17/00*

U.S. Cl. 264—167 1 Claim

ABSTRACT OF THE DISCLOSURE

Multiple lumen tubing for use in medico-surgical tubes that have an arcuate shape, e.g., endotrachael tubes, are formed by extrusion and then wound on a drum with the secondary lumen facing the drum. The tubing and drum are then stored for at least 10 minutes at an elevated temperature, after which the tubing is cooled while still wound on the drum. Finally, the cooled tubing is removed from the drum and cut into desired lengths to make the medico-surgical tubes.

This application is a division of Ser. No. 860,278, now U.S. Pat. No. 3,625,793.

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.

Medico-surgical 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, etc., rectal catheters, urethral catheters, hemostatic catheters and the like, but in other cases they are referred to as tubes, e.g., endotrachael 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 or 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. 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 as 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 construction 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. 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. 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. 2,912,981). While such constructions may be effective in creating a non-traumatic 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 medico-surgical devices used in different operations and medical procedures. They may be urethral catheters (see U.S. 2,919,697), endotrachael tubes, hemostatic catheters (see U.S. 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. 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 endotrachael 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 re-

quired 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.

SUMMARY OF THE INVENTION

The present invention provides a new method for the production of multiple lumen tubing having a permanent arcuate shape for use in the manufacture of endotrachael tubes or other medico-surgical tubes requiring such a configuration. The method basically involves:

(a) extruding a tube from flexible waterproof plastic material to comprise a major lumen and a secondary lumen, the major lumen having an area equal to at least one-half the cross-sectional area of the tube and the secondary lumen being of smaller diameter than the wall thickness of the tube, both lumens extending the full length of the tube,

(b) winding said tubing as it is extruded onto a drum so that the secondary lumen of the tubing always faces the drum,

(c) storing the drum with the tubing so wound upon it at an elevated temperature below the melting point of said plastic material for at least 10 minutes,

(d) cooling the tubing while still wound on the drum, and

(e) removing the cooled tubing from the drum.

The resulting tubing possesses a permanent bend in it with the secondary lumen on the inside. The tubing can be then cut into desired lengths and made into endotrachael tubes as disclosed and claimed in U.S. Pat. 3,625,793.

DESCRIPTION OF THE DRAWING

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 endotrachael 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 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. 4 is an enlarged, sectional view taken on the line **11—11** of FIG. 10.

Referring in detail to the drawings, the endotrachael tube **2** comprises a non-fibrous 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 endotrachael 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 endotrachael 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 endotrachael 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 U.S. Pat. 3,508,554.

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. 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 semi-rigid 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 or 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 embodiment of catheter **84** shown in FIGS. 3 and 4, 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 water-proof, 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 disc catheters. Advantageously, the new catheters will be formed of non-fibrous 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 materal. In a preferred embodiment of the invention, a small amount of very finely divided white pigment, e.g., about 0.01 to 1% 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 side wall 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 medico-surgical tubes and which may be required for particular procedures in which the new catheters are to be employed. These may include a non-sparking feature (see U.S. 3,070,132), X-ray line feature (see U.S. 2,857,915) or a tapered section feature (see U.S. 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 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 endotrachael 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. 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 conjuinction 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 endotrachael 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 endotrachael 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 with 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 claim:

1. A method of making multiple lumen tubing for use in forming catheters which comprises extruding a tube from flexible water-proof thermoplastic plasticized polyvinyl chloride resin to comprise 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 and any secondary lumen being of smaller diameter than the wall thickness of the tube, all lumens extending the full length of the tube, winding said tubing as it is extruded onto a drum so that any secondary lumen of the tubing is always positioned between said drum and said major lumen, baking the tubing while still wound on the drum at about 150° to 350° F. for at least 10 minutes, cooling the tubing while still wound on the drum and finally removing the cooled tubing from the drum.

References Cited

UNITED STATES PATENTS

2,551,710	5/1951	Slaughter	264—209
3,423,491	1/1969	McLain et al.	264—177 F
3,493,459	2/1970	McIntosh et al.	264—177 F X
2,268,321	12/1941	Flynn	264—209 X
2,230,151	1/1941	Winder	264—264 X
3,454,695	7/1969	Holmgren	264—281 X

ROBERT F. WHITE, Primary Examiner

W. E. HOAG, Assistant Examiner

U.S. Cl. X.R.

264—209, 210, 295

Disclaimer

3,755,525.—*David S. Sheridan*, Argyle, and *Isaac S. Jackson*, Greenwich, N.Y. METHOD OF MAKING MULTIPLE LUMEN TUBING FOR MEDICO-SURGICAL TUBES. Patent dated Aug. 28, 1973. Disclaimer filed Apr. 14, 1977, by the assignee, *Mallinckrodt, Inc.*

Hereby enters this disclaimer to claim 1 of said patent.

[*Official Gazette July 12, 1977.*]