ABSTRACT OF THE DISCLOSURE

Catheters of the disposable, seamless, extruded plastic type are made with distal end ports that are X-ray opaque by fusing a plastic annulus containing X-ray opaque pigment onto the preformed tube. The catheter may have one or more of such X-ray opaque outlined openings in the distal end portion and where a plurality are provided, their spacing may be proportioned to the size and type of the catheter. Such X-ray outline portions permit the position of the distal end portion of the catheter within a patient to be determined by X-ray methods.

BACKGROUND OF THE INVENTION

In order to reduce the possibility of cross-infections and eliminate the expense of sterilization of reusable type catheters and other medico-surgical tubes, extensive use is being made of disposable-type catheters designed for single patient and single use. Such disposable catheters are almost exclusively produced by extrusion of water-proof plastic material which is non-toxic, non-absorptive and resistant to attack or deterioration by fluids of body tissue into which the catheter or other medico-surgical tube may be inserted in the course of a surgical or clinical operation (see U.S. 2,940,126).

In many surgical or clinical procedures, it is important to be able to determine the location or position of the catheter within the body of the patient into which it has been inserted. X-ray observations, e.g., photographic or fluoroscopic, is a convenient method of making this position determination, but the usual plastic material from which the disposable catheters are formed is not X-ray opaque. Accordingly, several catheter constructions have been devised in order to permit the body position of catheters to be determined by X-ray observation. One known construction makes the entire tube opaque to both visible light and X-rays by incorporation of pigment through the tube. Another has been to form on catheters disconnected lines of X-ray opaque material (see U.S. 2,212,334). A further method has been to extrude plastic material into tubular form with a continuous X-ray opaque strip extending longitudinally along the entire length (see U.S. 2,857,915).

In many surgical or clinical operations, it is the location of the distal end portion of the catheter which is most important to know. The requirement may be for knowledge of the position of the distal tip of the catheter, or, for the position of the most proximal eye in the distal end portion which extends through the side wall of the catheter a short distance back from the distal tip. Such distal end portion opening determination has been accomplished by interrupting a continuous X-ray line formed integrally in a catheter by an opening in the distal end portion of the catheter (see U.S. 3,190,290).

The variety of medical and surgical procedures for which catheters are employed require a variety of inlet opening configurations in the distal end portions of catheters, e.g., gastro-intestinal catheters. In some catheters, a single opening is employed which contains the distal tip of the catheter. In others, the catheter distal tip is closed while the inlet opening constitutes an eye through the side wall of the catheter (see U.S. 2,857,915). In other cases, both a tip opening and one or more side wall holes may be required (see U.S. 3,190,290). These openings may be formed by punching, cutting, abrading or the like. In any event, creation of holes or openings which are smooth and which will not create irritation or injury to delicate tissues into which the catheters may be inserted are essential if the catheters are to be acceptable to hospital administrators, surgeons or other parties involved with purchase and use of these products. Various techniques are employed to create acceptably smooth surfaces in holes or like openings required in catheters (see U.S. 2,972,779). Any procedure of this type which is used must not adversely affect the strength, non-toxic or other essential characteristics of the catheter and should not materially increase the costs of manufacture.

OBJECTS

The principal object of this invention is the provision of new forms of catheters of the single use disposable type made from waterproof, non-fibrous plastic material which permit the position of the distal end portion of the catheter within living tissue into which the catheter may be inserted to be determined by X-ray observation.

Further objects include the provision of:

1. New methods of making plastic catheters which simultaneously create smooth rounded surface inlet openings in the distal end portion of catheters and provides an X-ray observable marking upon the distal end portion of the catheter.

2. New catheter constructions which enable X-ray observation to determine where the tip of a catheter is within living tissue into which the catheter is inserted and the angle of the tip within the tissue, an accomplishment which cannot be attained through the use of X-ray line catheters known heretofore.

3. New catheter constructions which provide greater X-ray opacity contrast than has been possible with related X-ray marked medico-surgical tubes known heretofore.

4. Catheters having smoothly rounded inlet openings in the distal end portion which are defined by an integral X-ray opaque annulus and which can be manufactured and sold at costs competitive with related plastic disposable catheters available heretofore which do not include such improved features.

5. Such catheters in which tendency of the catheter to bend or buckle, causing an eye during use is mitigated.

Other objects and further scope of applicability of the present invention will become apparent from the detailed description given hereinafter; it should be understood, however, that the detailed description, while indicating preferred embodiments of the invention, is given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description. It should also be understood that the foregoing abstract of the disclosure is for the purpose of providing a non-legal brief statement to serve as a searching-scanning tool for scientists, engineers and researchers and is not intended to limit the scope of the invention as disclosed herein nor is it intended it should be used in interpreting or in any way limiting the scope or fair meaning of the appended claims.

SUMMARY OF THE INVENTION

These objects are accomplished according to the present invention by forming catheters of transparent, non-fibrous, waterproof plastic material, that is non-absorptive to body fluids, with a distal end portion of the catheter having a plastic member fused to the tube, the member containing X-ray opaque pigment uniformly dispersed therein in
sufficient quantity to permit it to be observed by X-rays within living tissue into which the catheter may be inserted. The objects are further accomplished according to the invention by a method of making such new plastic catheters with the X-ray observation outlined portion which comprises:

(a) Forming non-fibrous, transparent tubing of waterproof plastic material by extrusion,

(b) Cutting the tubing into a length required of a catheter,

(c) Forming at least one inlet opening in the distal end portion of said length of tubing,

(d) Providing an annulus wafer or like member of plastic material containing X-ray opaque pigment uniformly dispersed therein of desired configuration, and

(e) Fusing said member to said tube by heat and pressure to render the member integral with said tubing and form a smooth surface on the tube.

The determination of the location of a distal end portion of catheters is most important in endotracheal tubes, suction catheters, stomach tubes, gastro-intestinal catheters, thoracic catheters, abdominal sump drains, heart catheters, ureteral catheters, and feeding tubes and the new structures and methods of the invention are most advantageously applied to such catheters. Actually, the term "catheter" as used in this specification and the accompanying claims is intended to mean any medico-surgical tube which includes a proximal end, a distal end portion and a longitudinal bore extending therebetween, with the distal end portion having one or more inlet openings therein and which are designed for insertion into some tissue, organ, cavity, e.g., vascular or arterial branch, or the like in a patient to serve as a channel for removing fluids from or introducing fluids into the tissue, organ or the like within the patient. As just stated in connection with the types of products to which the invention is most advantageously applied, these devices are sometimes referred to as tubes and other times as catheters. For the sake of brevity and consistency, the term "catheter" is used as a general designation for any medico-surgical devices of this type, including those having a single lumen or those of a multiple lumen type. It will be further understood by those skilled in the art that these catheters may be further combined with syringes, valves, fluid traps or other units in creating assemblies required for the particular medical or clinical procedure being applied to the patient.

In one preferred embodiment of catheters of the invention, only a single inlet opening is provided in the distal end portion and this constitutes the tip or extreme end of the catheter. In another embodiment, the catheter has one or more internal X-ray opaque inlet openings in the distal end portion and, preferably, one of such openings defines the distal tip or distal extreme end of the catheter and another defines the most proximal inlet opening extending through the side wall thereof. Advantageously, the side wall opening is of a measured predetermined length from the distal tip and this length is related to the type of the catheter and its nominal size. As is well known to the medical profession, catheter sizes may be designated in terms of actual diameters of the tube lumen, e.g., 5.5 mm. I.D. or in terms of some arbitrary O.D. size designation, e.g., 5 French.

Although the new methods and resulting catheters of the invention may be used with any suitable thermoplastic material known to be useful in the manufacture of medico-surgical tubing, the invention is advantageously utilized in the production of catheters by extrusion from plasticized vinyl chloride polymers.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Further understanding of the structure of the new catheters of the invention and their method of production may be had by reference to the accompanying drawings in which:

FIG. 1 is a perspective view of a catheter prepared in accordance with the invention.

FIG. 2 is an enlarged fragmentary view of the distal end portion of the catheter of FIG. 1.

FIG. 3 is an end view of the catheter of FIG. 1.

FIG. 4 is a diagrammatic fragmentary view partially in section illustrating a step in the manufacture of the new catheters.

FIG. 5 is a fragmentary side view partially in section illustrating the completion of the manufacturing operation as shown in FIG. 4.

FIG. 6 is a perspective, fragmentary view of another form of catheter in accordance with the invention.

FIG. 7 is a perspective, fragmentary view of an open end form of catheter according to the invention.

FIG. 8 is a fragmentary, side view of the catheter distal end portion of FIG. 7.

FIG. 9 is a perspective, fragmentary view of a closed end form of catheter according to the invention.

FIG. 10 is a fragmentary, side view of the catheter distal end portion of FIG. 9.

FIG. 11 is a perspective, fragmentary view of the distal end portion of a catheter haxing X-ray outlined open end, side-eye and indicator dot in accordance with the invention.

FIG. 12 is a perspective, fragmentary view of another embodiment of catheter similar to FIG. 11, but with an X-ray band indicator instead of a dot.

FIG. 13 is a perspective fragmentary view of yet another form of catheter in accordance with the invention.

FIG. 14 is an exploded, perspective, fragmentary view illustrating a step in the production of the catheter of FIG. 13.

FIG. 15 is a perspective, fragmentary view of a further embodiment of a catheter in accordance with the invention.

FIG. 16 is an exploded, perspective, fragmentary view illustrating a step in the production of the catheter of FIG. 15.

**DESCRIPTION OF PREFERRED EMBODIMENTS**

Referring in detail to the drawing, the catheter 2 constitutes an endotracheal tube having a proximal end 4, a distal end portion 6 and a longitudinal bore 8 extending therebetween. The catheter 2 is formed of transparent, nonfibrous, waterproof plastic material and in the central body portion 10 designations 12, such as ink embossed markings, are provided to indicate the distance along the catheter from the inlet tip, e.g., 12, 13, 15 cm. for a 5.5 mm. I.D. size endotracheal tube.

FIG. 2 illustrates in more detail the construction of the distal end portion of the catheter 2 which has a single inlet opening 14, the locus of which is a plane running at an acute angle to the axis of the longitudinal bore 8 of the catheter. Accordingly, the periphery 16 of the openings 14 is elliptical in shape when viewed from the side as in FIG. 2. However, when viewed end on as in FIG. 3, the inlet opening appears circular since it defines the tip or extreme end of the catheter and presents in section the full lumen of the catheter. The periphery 16 of the X-ray opaque plastic section is of limited longitudinal extent relative to the length of the tube and of varied displacement relative to the longitudinal axis of the tube.

The periphery 16 of the opening 14 has smoothly rounded edges 18 and the opening is defined by an integral plastic annulus containing X-ray opaque pigment uniformly dispersed therein.

In contrast to X-ray marked catheters known heretofore, it is possible with X-ray tip catheters of this invention to determine the angle of the tip relative to tissue within which the catheter may be inserted. Further, since the X-ray tip when radiated from the side of the tube, such as in the plane of the drawing of FIG. 5, will give a screening to the X-rays by more than double the thickness of the wall of the catheter. Accordingly, the opacity contrast which
can be attained is critically improved as compared to the single thickness screening which can be obtained with continuous line X-ray marking such as known hereto-
fore.

Construction of peripheral outline X-ray openings in catheters according to the invention can be obtained by the methods diagrammatically illustrated in FIGS. 4 and 5. This is started by provision of a suitably sized tube which can be created in any suitable fashion. Advantageously, a section of plastic tubing 20 is formed of non-fibrous transparent waterproof plastic material by extrusion. This tubing is then cut into a required length for a catheter and one or more inlet openings are cut in its distal end portion. In the tubing 20 of FIG. 4, this is done by slicing the end 22 on the tubing 20 at an acute angle to the longitudinal bore 24 which extends through the tubing. In a separate operation, a plastic washer or annulus 26 containing X-ray opaque pigment uniformly dispersed therein is created, such as by extruding tubing of plastic material with the opaque pigment and then slicing washers, such as the washer 26, from it. This combi-
nation is then inserted into a suitably shaped die and while heat is used to soften the tubing end and washer 26, pressure is applied to force the assembly together and form an integral unit from the tube 20 and the plastic annulus 26 as shown in FIG. 5. Such heated pressing of the annulus will use the annulus to the tube and at the same time create the rounded edge 28 on the inlet opening.

As shown in FIG. 6, other forms of catheters in accordance with the invention may have a plurality of inlet openings in the distal end portion each presenting the X-ray detection feature. Thus, the catheter 30 has a square end tip 32 defined by the integral X-ray opaque pigment containing annulus and a second inlet opening 34 extending through the side wall of the tube 30 defined by another integral plastic annulus 36 containing uniformly dispersed X-ray opaque powder.

Another form of open end catheter 40 is shown in FIGS. 7 and 8. The X-ray opaque distal tip 42 is slightly restricted in cross-section as compared with the lumen of the tube. Most open end catheters are of this reduced tip area type.

A closed end form of catheter 44 is shown in FIGS. 9 and 10. The X-ray opaque tip 46 is produced by fusing a flat wafer of X-ray opaque plastic to the open end of the tube 38 and at the same time molding the heat softened wafer into the rounded shape of the tip 46.

The catheter 50 shown in FIG. 11 comprises an X-ray opaque outlined open tip 52. X-ray eye 54 and X-ray dot 56. The eye 54 and dot 56 are formed by fusing and molding suitably sized X-ray opaque plastic rings to the periphery of holes in the tube 58. The dot 56 is formed by fusing an X-ray opaque plastic wafer to a hole in the side wall of the tube 58, at the same time molding the wafer so as to form a smooth butt joint between the tube and the wafer.

The formation of the eye 54 as described can provide, in addition to the X-ray outline feature, another advantage, i.e., a stiffening of the tube wall surrounding the eye. As is well known by users of plastic catheters, they have a tendency to bend or buckle at the inlet eyes when being inserted in a patient or otherwise handled. This buckling can cause injury to the patient or present other problems to the correct insertion or use of the catheter. By using an X-ray opaque plastic annulus which is formed of stiffer or more rigid plastic material than the tube 58 to which it is fused, the resulting integral X-ray outlined eye structure 54 exhibits appreciably less tendency to bend or buckle.

The formation of catheter 60 seen in FIG. 12 comprises the X-ray tip 62, X-ray eye 64 and X-ray band 66. The band 66 is made of X-ray opaque plastic material and may be fused into the tube 68, either inside or on one side. Alternatively, the band can be butted welded to a separate tube front portion 70 and main tube portion 68, thereby making a catheter with uniform cross-section in the region of the band 66.

FIGS. 13 and 14 illustrate a catheter 72 having an X-ray band 74 at the catheter tip. Such a structure is useful where a greater X-ray opaque area is required than with the catheter 40 of FIG. 7. The catheter 72 can be made by pushing a tubular X-ray opaque plastic section 76 into the bore of the tube 78 and welding the section 76 to the tube by any suitable method.

The form of catheter 80 shown in FIG. 15 comprises X-ray markings 82-88 formed from plastic filaments of X-ray material. A catheter of this type may be made by extrusion of a plastic tube 90 having a main lumen 92 and a small wall bore 94. A section of X-ray opaque filament or rod 96 is inserted into the may be made X-ray opaque filament or rod 96 may be fused in the bore 94 at a desired location by solvent action or by heat. Alternatively, the filament section may be held in position merely by a snug fit between it and the small lumen. After positioning of the X-ray opaque rod or filament, the exposed ends of the lumen 94 may be fused or otherwise sealed to close off the minor bore 94 from subsequent entrance of fluids. In this manner, a variety of X-ray markings may be created, e.g., the tip marking 82, the eye location marking formed by the interruption between filament portions 84 and 86, and a reference marker 88 to designate a given distance along the catheter from the tip 98.

In the use of catheters of the new type as described, special handling procedures are not required. Thus, the new catheters can be sterilized, handled, packaged, manipulated or stored under the same conditions and handling procedures familiar to physicians, surgeons and other personnel accustomed to working with the disposable plastic type catheters. Moreover, the catheters can be formed to include bubbles, tapered sections, O-ring additions or any other auxiliary elements with which catheters are now produced or may be required to be formed in the future. Similarly, the catheters may be made to have a substantially uniform wall thickness throughout their length or, where special application or professional preference dictates, tapered portions or wall sections of varied thickness may be provided in the catheters by air blowing, vacuum drawing or other techniques known to the plastics art.

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

1. A catheter formed of transparent, non-fibrous, waterproof plastic material that is non-absorbive to body fluids, having a proximal end, a distal end, and at least one longitudinal bore extending therebetween, said distal end portion comprising at least one inlet opening, the periphery of said opening being smoothly rounded and being defined by an integral plastic annulus containing X-ray opaque pigment uniformly dispersed therein in sufficient quantity to permit the position of the distal end of the catheter within living tissue into which the catheter may be inserted to be determined by X-ray observation.

2. A catheter as claimed in claim 1 having a single inlet opening in the distal end portion, said opening defining the extreme end and presenting the full lumen of the catheter.

3. A catheter as claimed in claim 2 wherein the locus of said opening is a plane which is at an acute angle to the axis of the longitudinal bore of the catheter, said opening being elliptical in shape.

4. A medico-surgical tube as claimed in claim 1 where in said annulus is made of plastic material which is more rigid than the plastic material of which said catheter is formed.

5. A catheter as claimed in claim 1 wherein said inlet opening extends through the side wall of said distal end portion.

6. A catheter as claimed in claim 1 wherein there are a plurality of said integral X-ray opaque inlet openings in the distal end portion of the catheter, one of said
openings defining the tip of the catheter and another defining the most proximal opening extending through the side wall thereof.

7. A catheter as claimed in claim 5 wherein the distance between said distal tip opening and said side wall opening is of measured, predetermined length related to the type and size of the catheter.

8. A catheter formed of transparent non-fibrous, waterproof plastic material having a proximal end, a major longitudinal bore, a minor longitudinal bore, and a distal end portion having a plurality of inlet openings therein, one of said openings defining the tip of the catheter and a second opening extending through the side wall of said distal end portion, said minor bore being of a diameter less than the wall thickness of the catheter and positioned within the wall of the catheter with the catheter presenting substantially smooth inner and outer walls, said second opening interrupting said minor bore in said distal end portion, a section of X-ray opaque filament or rod being fixed in said minor bore on each side of said second opening marking the distal and proximal extremities of said second opening, said minor bore being closed at the ends against entrance of fluids.

9. A catheter of claim 8 wherein a section of X-ray opaque filament or rod extends to the tip of the catheter, the periphery of said opening in the catheter tip is smoothly rounded and the distal extremity of section that extends to said tip is included in a portion of said periphery.

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DALTON L. TRULUCK, Primary Examiner

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