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Wallace

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[54] **BALLOON TRACHEAL CATHETER WITH INFLATION VALVE AND INDICATOR**

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[52] **U.S. Cl.** ..... **128/351;** 128/349 BV; 128/274; 251/342

[51] **Int. Cl.**[2] **A61M 25/00**

[58] **Field of Search** ..... 128/348, 349 B, 349 BV, 128/350 R, 351, 246, 344, 274; 251/341, 4, 342, 349; 137/223; 273/65 C, 65 D

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[57] **ABSTRACT**

A disposable balloon type catheter or endotracheal tube is provided in which an improved valve is utilized and which is operable by the insertion of a syringe to the valve inlet passage to open the valve and allow gas to be forced from the syringe into the main and pilot balloons for inflation thereof. The valve itself is of a resilient plastic material having a main passageway with a plug normally blocking the flow of gas through the passageway. At least one radially inwardly directed projection is formed on the interior surface of the passageway and which is engaged by the inserted syringe to distend the passageway internal surface outwardly to allow gas from the syringe to bypass around the periphery of the plug. The disposable catheter also includes a novel design of pilot balloon having a molded plastic tubular extension extending throughout the length of the pilot balloon. The thin balloon material surrounds the tubular extension and is prestretched along the extension so that the pilot balloon configuration takes on a shriveled appearance in its non-inflated state.

11 Claims, 3 Drawing Figures

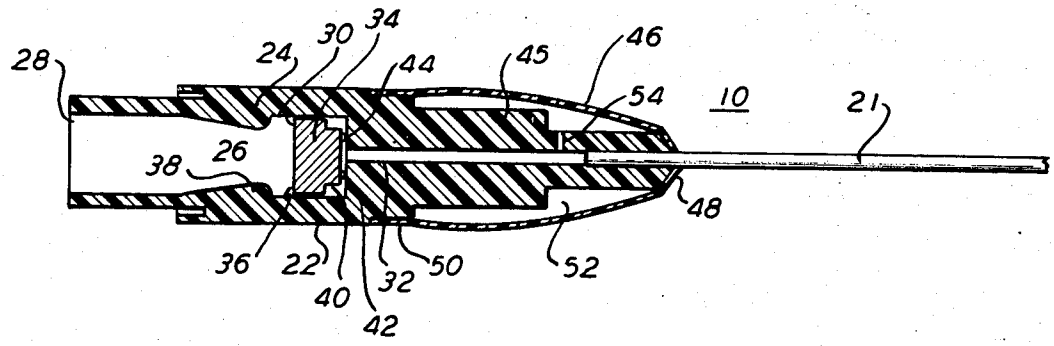


FIG. 1

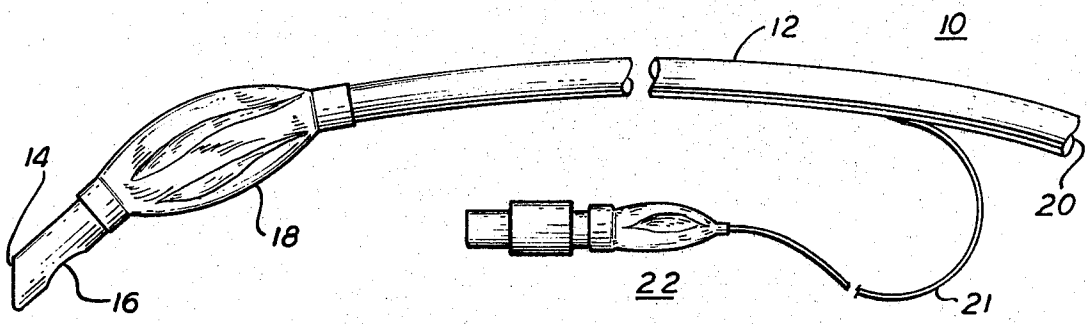


FIG. 2

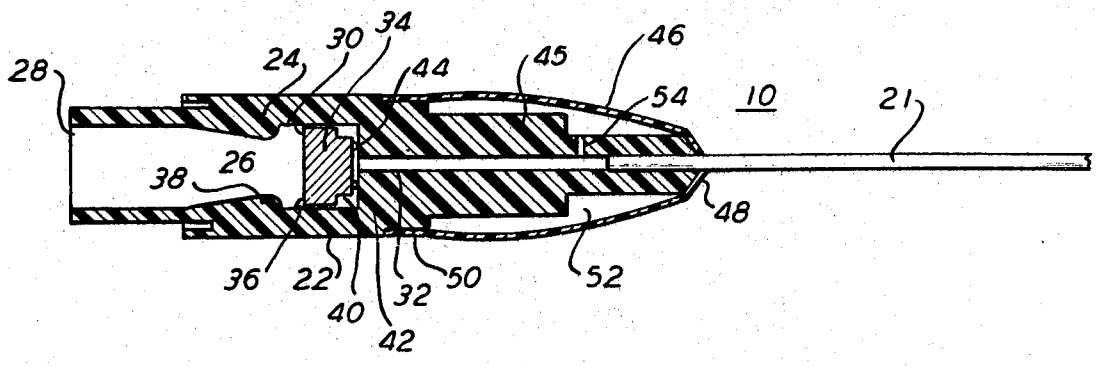
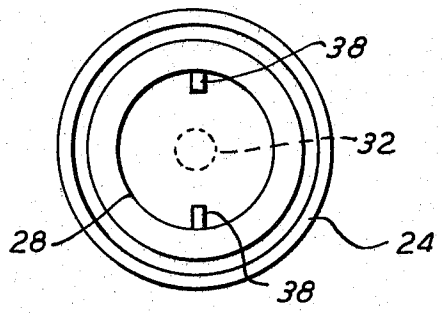


FIG. 3



BALLOON TRACHEAL CATHETER WITH INFLATION VALVE AND INDICATOR

BACKGROUND OF INVENTION

This invention relates to balloon-type catheters or endotracheal tubes designed for insertion into a patient for introduction of gases to the patient. Such catheters are commonly inserted into a patient's trachea, or windpipe, and include an inflatable balloon or cuff at the distal end which, when inflated, retains the catheter in position and seals the catheter against the internal wall of the trachea.

At the present time, it is common commercial practice to provide disposable catheters of the type herein described. Such tubes can be used only once and then disposed of, thus eliminating the cost of sterilizing to prevent cross-infection. The practical value of disposability, of course, depends greatly upon the cost of producing and marketing the disposable tubes. Such tubes, therefore, should be capable of rapid mass production manufacturing techniques, yet the resultant catheter must, of course, be of fool-proof design so that mass production cannot give rise to the possibility of a failure or defect in the catheter.

In the balloon-type catheters of the present type, the catheter includes a pilot balloon which is generally joined to the main cuff by a small passageway or lumen and is in series thereto so that the pilot balloon and main cuff inflate and deflate simultaneously. A valve means is provided to control the gas which may be forced into the pilot balloon, and thus, via the lumen, to the main cuff or balloon. The pilot balloon remains exterior of the patient and thus is used as a continuous visual indication as to the inflated or deflated state of the main cuff. This visual indication must be as clear as possible so that there is no doubt to any viewer as to the condition of the main cuff at any time. Present pilot balloons generally are formed in the same overall shape and configuration of the main cuff, however, as such, many do not deflate sufficiently, even when the gas pressure within the main cuff is released, so that a false indication may be gained, i.e. the pilot balloon appears inflated even when the main cuff is not pressurized. The false indication is attributable to the shape of the pilot balloon or its wall thickness, or both factors.

A further problem in present disposable balloon-type catheters is in the valve itself. The cuff and pilot balloons are preferably inflated by means of a syringe which is inserted into or adjacent the valve and gas is forced from the syringe into the pilot balloon, thence, through the lumen to the main cuff. Various valves are commercially available to serve this purpose. Some are relatively expensive to mass produce in that they include a plurality of separately manufactured and assembled components while others are not operable by the syringe itself. The disadvantage of the former drawback is economics, while the disadvantage of the latter drawback is that the valves may not operate instantaneous, so that some gas is lost in trying to close off the passageway to the lumen or are cumbersome in actual operation.

SUMMARY OF THE INVENTION

In the present invention, there is thus provided a disposable balloon-type catheter having an inflatable main cuff and pilot balloon and wherein an improved valve is employed to control gas for inflation and deflation of the cuff and the pilot balloon. The valve has a minimum of parts and is principally of unitary molded plastic material susceptible of rapid, inexpensive manufacturing procedures. The valve includes an inlet opening which is adapted to receive a syringe for introducing gas to the main valve passageway. The main valve passageway is of a molded flexible material and has at least one radially inwardly directed projection. A blocking plug is retained within the main valve passageway adjacent the projection and normally serves to prevent the passage of gas through the passageway by an interference fit between the periphery of the plug and the interior surface of the main passageway. As a suitable syringe is inserted into the inlet opening, the distal end of the syringe engages the projection and distorts the passageway interior surface radially outward, thus breaking its seal against the periphery of the blocking plug to allow gas forced from the syringe through a bypass then formed about the blocking plug. The gas then can pass by the valve and into the pilot balloon and cuff for inflation thereof. As the syringe is thereafter removed, the flexible main valve passageway returns to its normal position and again seals about the periphery of the plug to again close the main passageway.

The pilot balloon is designed to assume a shriveled appearance in its deflated state to assure that the condition of the cuff is readily apparent. The pilot balloon surrounds a tubular molded plastic extension and forms a chamber about the extension for inflating the pilot balloon. The molded tubular extension may be molded integral with the valve housing as one piece and it extends entirely through the interior of the pilot balloon so that, during manufacture, the pilot balloon can be stretched before having its ends adhered to the extension. Thus, the finished pilot balloon is pre-stretched, which gives a shriveled appearance to the extremely thin plastic balloon material in its deflated condition. The pilot balloon can be inflated in normal fashion and its inflated condition is apparent in contrast to its deflated or even semi-inflated condition which is discernible to the eye without any doubt as to its condition.

Since the condition of the pilot balloon assumes the same condition as the cuff within the patient, the precise amount of inflation of the cuff can be easily determined.

The overall valve and pilot balloon unit is very inexpensive to produce due to its unique design. The valve body and tubular extension can be of a single, molded plastic piece and the valve is completed in assembly by the simple insertion of a valve plug into the valve main passageway in an interference fit. Once the plug is inserted it is retained in position and will not dislodge under normal conditions. Thus, the valve can be quickly, efficiently, and inexpensively produced by mass production techniques. The pilot balloon also can be easily added to the tubular extension by prestretching the thin flexible pre-molded balloon material and adhering the ends to the extension while retaining the pre-stretched condition.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of an endotracheal tube or catheter of the present invention showing the main cuff at the distal end of the tube and the pilot balloon and valve means.

FIG. 2 is a cross-sectional view of the molded valve means and pilot balloon of FIG. 1.

FIG. 3 is an enlarged end view of the inlet end of the valve means shown in FIG. 2.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring particularly to FIG. 1, there is shown a disposable balloon-type catheter, or endotracheal tube 10, in accordance with the present invention. The endotracheal tube 10 includes, generally, a plastic tube 12 which is preferably of polyvinyl chloride or other plastic, and has a distal end 14 having an opening 16 for introducing gas to the patient and a proximal end (not shown). The main balloon or cuff 18 surrounds tube 12 near the distal end in a gas tight relationship. Such cuff 18 may be easily made by separately forming the cuff of a thin urethane or vinyl plastic material and sealing its ends, such as by an adhesive, to the desired location along tube 12. The tube 12 is normally formed in an arcuate configuration for convenience in inserting into the patient's trachea. The main tracheal tube passageway 20 receives gas at its proximal end for induction to the patient through opening 16.

A secondary passageway (not shown) extends along the length of the tube 12 within the wall thereof and may be formed when the tube 12 itself is formed by extrusion. As an alternate, a separate passageway or lumen may be provided exterior of tube 12. The secondary passageway communicates with the interior of the cuff 18 for inflation of the same. In the preferred form, when the passageway is formed during extrusion within the tube wall, the tube 12 may be slit at any point within the cuff 18 prior to its affixing in position so that the secondary passageway communicates with the interior of cuff 18 for inflation and deflation thereof. The remaining portion of the integral passageway toward the distal end 14 may be sealed during formation of the distal end 14 by heat sealing.

In the preferred embodiment, as shown, a small capillary tube 21 joins the integral passageway to the inflating means shown generally at 22 and which will be later described in detail.

Turning now to FIG. 2, the inflating means 22 comprises a plastic valve housing 24 which is easily molded in one operation of relatively flexible vinyl plastic material. The housing 24 has a main passageway 26 through which gas introduced at the housing inlet 28 can pass, as will be explained. As shown, the main passageway 26 has a relatively large diameter internal surface 30 but is reduced to a small diameter passage 32 within the housing 24.

A plug means 34 is positioned within the informal surface 30 and has its outer periphery inserted in an interference fit within the passageway 26 in sealing engagement with internal surface 30 to normally prevent the passage of gas in the main passageway 26 past the plug means 34. The plug means 34 is preferably a metal cylinder which is held in position, as shown, by a small circular bead 36 molded within the internal surface 30.

A radially inwardly projection 38 is molded to the internal surface 30 adjacent the plug means 34.

The projection 38 has a generally inwardly sloping surface to receive the external tip of a syringe which is inserted within inlet 28 when it is desired to either inflate or deflate the main cuff 18. As the top of the syringe is forced against projection 38, the resilient wall surrounding the plug means 34 is forced outwardly and a bypass passageway is created to allow gas to freely pass around the plug means 34 into or from the small diameter passage 32. As may be easily seen, when the syringe tip is removed from projection 38, the resilient wall will again close into sealing engagement with the plug means 34 and thus close main passageway 26. In the preferred form, a plurality of projections 38 may be formed on the internal surface 30.

Also, in order to assure unimpeded flow of gas by the plug means 34 when the syringe is in operative position, a portion of the plug means 34 may be recessed, as at 40. A means is provided to prevent the plug from sealing against the end 42 of the main passageway 26 and may include a plurality of molded tips 44, or in the alternate, a plurality of recesses may be formed in the plug means 34 adjacent the passageway end 42.

The plastic valve housing 24, in its preferred form has a tubular plastic extension 45 which is molded in one unitary piece. The pilot balloon 46 surrounds the tubular extension 45 and is sealed at its ends 48 and 50 to the extension 45, creating a gas-tight chamber 52 therewithin. A stub passageway 54 provides gas communication between the small diameter passageway 32 and the chamber 52. At the end of the extension 45 the capillary tube 21 communicates with and is joined to the small diameter passage 32 so that the gas within chamber 52 is generally at the same pressure as within the main cuff 18. As the cuff 18 is inflated therefore, the pilot balloon 46 will also inflate and in similar manner deflation of both balloons is simultaneous. The balloon 46 is of a plastic material, preferably urethane or vinyl, and has a thickness of about .002 to .010. In securing the balloon 46 to the extension 45, the balloon is stretched longitudinally and the ends are secured to extension 45 in the stretched condition. It is therefore essential that the extension 45 be solid or unbroken through the entire length of balloon 46 to maintain the pre-stretch and provide support. Due to the pre-stretch introduced into a balloon of this thinness, the balloon assumes a shriveled state and its deflated condition is readily apparent. The shriveled effect is also believed to be enhanced by providing a balloon which is secured at its ends to the extension 45 having different diameters, that is, one end of the balloon 46 is secured to a relatively large diameter surface of extension 45 while the other end is secured to a smaller diameter surface of the extension 45. The resulting pilot balloon 46 is extremely sensitive to internal gas pressure and the condition of the cuff 18 can be determined easily by visual indication of the pilot balloon 46.

I claim:

1. A tracheal tube for insertion into the trachea of a patient for introducing and removing gas, said tube having an inflatable chamber surrounding the distal end thereof, a gas passageway having one end communicating with the interior of said inflatable chamber and having its other end adapted to receive gas for inflation of said chamber, said gas passageway including a valve means, said valve means comprising a molded flexible housing having a gas passage therethrough, a plug means positioned in an interference fit within said gas passage whereby said plug normally prevents the flow of gas through said gas passage, said housing including at least one inwardly directed projection facing into said gas passage, said projection being moveable outwardly to distort said housing from said plug means to break the interference fit to allow gas to bypass said plug means.

2. A tracheal tube adapted for insertion into the trachea of a patient for introducing and removing gas, said tube having a main inflatable chamber surrounding the distal end thereof, a gas passageway having one end communicating with the interior of said main inflatable chamber and having the other end adapted to receive an inflating means for delivering gas to inflate said main inflatable chamber, said gas passageway including a valve means for selectively introducing gas through said passageway to said inflatable chamber and a pilot balloon means comprising a tubular extension, a flexible oval-shaped balloon having its outer open ends secured to said tubular extension, thereby forming an enclosed pilot chamber, said pilot chamber being in gas communication with said main inflatable chamber, said flexible balloon secured to said tubular extension in a prestretched condition along its length whereby said balloon appears shriveled in the non-inflated conditions; and said valve means, tubular extension and pilot balloon means forming substantially a unitary structure at the inflating means-receiving end of said gas passageway.

3. A tracheal tube as defined in claim 2 wherein said flexible oval-shaped balloon has outer open ends of different diameters secured to said tubular extension.

4. A tracheal tube adapted for insertion into the trachea of a patient for introducing gas to the patient, said tube having a main inflatable chamber surrounding the distal end thereof, a gas passageway for inflating said main chamber, said gas passageway including a valve means for receiving an inflating means for introducing gas into said passageway, said valve means comprising a molded flexible housing having a gas passage therethrough, said housing having one end adapted to receive said inflating means and the other end having an integrally molded tubular extension, a plug means within said flexible housing normally blocking the flow of gas through said passage, said housing adapted to be distorted outwardly from said plug means by said inflating means to allow gas to bypass around said plug means, and an oval inflatable pilot balloon having open ends secured to said tubular extension and having its interior communicating with said gas passage, said pilot balloon being secured to said flexible extension in a pre-stretched condition whereby said balloon appears shriveled in its noninflated state.

5. A tracheal tube as defined in claim 4 wherein said plug means is cylindrical and its periphery is in an interference fit within said passage.

6. A tracheal tube as defined in claim 4 wherein said housing further includes at least one inwardly directed projection and said inflating means contacts said projection to force said projection radially outward, thereby distorting said housing to allow gas to bypass said plug means.

7. A tracheal tube as defined in claim 6 wherein said pilot balloon is a plastic material having a thickness of about .002 to .010 inches, and said open ends secured to said extension are of dissimilar diameters.

8. In a tracheal tube for insertion into the trachea of a patient having an inflatable cuff surrounding the distal end thereof for inflation by an inflating syringe, a gas passageway having one end communicating with the interior of said cuff for inflating said cuff and a valve means for controlling the introduction of gas to the passageway by the inflating syringe, the improvement wherein said valve means comprises a flexible housing having an opening at one end thereof for receiving said inflating syringe and having the other end thereof communicating with said gas passageway, said housing having a passage therethrough, a plug means within said passage normally preventing the passage of gas through said passage, said housing including at least one inwardly directed projection adapted to be engaged by the insertion of the inflating syringe into said opening to distort said housing to allow gas to bypass said plug means.

9. In a tracheal tube as defined in claim 8 the improvement wherein said housing includes an annular inner bead adapted to retain said plug means within said passage.

10. In a tracheal tube as defined in claim 9, the improvement wherein said housing, said at least one inwardly directed projection and said annular inner bead are of one piece molded plastic.

11. In a tracheal tube as defined in claim 10 the improvement wherein said housing has a molded plastic extension, an expandable pilot balloon secured to said extension and an opening formed in said extension to allow gas communication between said passage and said expandable pilot balloon.

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