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INTRODUCERS AND ASSEMBLIES

BACKGROUND OF THE INVENTION

This invention relates to introducers and assemblies including introducers.

The invention is more particularly concerned with introducers of the kind used to assist intubation of medical tubes, such as endotracheal tubes.

Where the insertion route for a tracheal tube cannot be clearly seen, it is often necessary to use an introducer to help ensure correct intubation. The introducer takes the form of a rod that can be bent to a desired shape. The introducer can be inserted more easily than the tube because it can be bent to a desired shape and it has a smaller diameter. The smaller diameter of the introducer also enables a better view of the trachea. Once correctly inserted, a tube can be slid along the introducer into the correct location. A similar device can also be used as a stylet to assist introduction, by inserting it in the tube before the tube is inserted in the patient. The tube and introducer are bent to a shape that facilitates insertion, and the tube and introducer are then inserted together. Preferably, the introducer only takes the desired shape temporarily and returns close to its original shape after insertion, so that the introducer can be removed easily from the tube without disturbing it. Also, the introducer is softened by the heat of body, thereby making removal easier.

Introducers are also used as guides when a tube needs to be changed, if the original intubation was difficult. An introducer with a plain end is inserted into the tube before removal and the tube is then slid out along the introducer, while this remains in place. A new tube is then slid in along the introducer.

One example of a conventional tracheal tube introducer is sold by Eschmann Healthcare of Hythe, Kent, England under catalogue number 14-504-17. This introducer is made by braiding a sleeve from polyester filament on a mandrel, which is then repeatedly coated with a resin and dried in an oven. The mandrel is removed after a few coats and the coating and drying stage is repeated over twenty times to give the introducer the desired handling properties. This is a labour-intensive and expensive process.

BRIEF SUMMARY OF THE INVENTION

It is an object of the present invention to provide an introducer that can be made more easily.

According to one aspect of the present invention there is provided a medical tube introducer comprising an elongate member substantially of an aliphatic polyurethane material, the material being selected such that the introducer is resilient within a range of deformation and beyond this range it is bendable into a set shape that only resumes its original shape at a slower rate.

The introducer is preferably a solid rod, and the material may have a hardness between about 50 Shore A to 80 Shore D, preferably about 60 Shore D. The material may contain barium sulphate, such as at about 20%. The introducer may have a braided outer sleeve covered by a coating. The introducer may have a bend at its patient end.

Alternatively, the introducer may be a hollow rod.

According to another aspect of the present invention there is provided an assembly of a medical tube and an introducer according to the above one aspect of the invention. The tube may be an endotracheal tube.

An introducer and an assembly including an introducer, according to the present invention, will now be described, by way of example, with reference to the accompanying drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross sectional side elevation view of the introducer and an endotracheal tube, with the introducer inserted in the patient and the tube not yet inserted;

FIG. 2 is a cross sectional side elevation view of the introducer and tube, with the tube also inserted; and

FIG. 3 is a partly sectional side elevation showing the tube after removal of the introducer.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to FIG. 1, there is shown an endotracheal tube 1 and an introducer 2, with one end 20 of the introducer inserted in the patient and with the tube threaded on the other end of the introducer, externally of the patient.

The endotracheal tube 1 is of conventional form, having an extruded, tubular shaft 10 of a plastics material, such as PVC, and curved along its length to a circular arc. An inflatable cuff 12 embraces the shaft 10 close to the patient end and can be inflated by means of air supplied via an inflation lumen 13 extruded within the wall of the shaft. The tube 1 is bendable but, in its natural state, takes up a curved form that follows approximately the shape of the patient's anatomy. The material of the shaft 10 softens slightly at body temperature to enable the tube to bend more readily when in location. In use, the patient end 11 of the tube 1 is inserted through the patient's mouth so that it extends through the vocal folds and is located in the trachea, with the machine end 14 of the tube projecting from the patient's mouth.

The introducer 2 is a rod of circular section about 720 mm long and about 5 mm in diameter, although other sizes could be used. The ends 20 and 21 of the introducer 2 are smoothly rounded to make them atraumatic. In its natural state, the introducer is straight and the patient end 20 may be preformed, as shown, during manufacture with an optional Coude tip, that is, a short length bent at an angle of about 40°. The introducer is made of an aliphatic polyurethane loaded with 20% by weight barium sulphate and has a hardness of 60 Shore D. This material is available from Thermedics Inc of Woburn, Mass., USA under the trade mark TECOFLEX, code number EG60D B20. The introducer 2 is made by extruding and then heat forming the tips 20 and 21, although it could be made by other techniques, such as injection moulding.

The introducer 2 has a relatively hard feel and is resiliently flexible when bent to a certain extent, resuming its initial shape rapidly when released, behaving like a conventional resilient element. If, however, the introducer is bent beyond this resilient limit, such as, to a radius of less than about 10 cm, it behaves differently. When first released, the introducer behaves resiliently, moving rapidly to a certain extent, and then it returns considerably more slowly, having, in effect taken a set or memory of the shape to which it was deformed. The mechanical performance of the introducer could be equated to a series connection of two springs, one of which is heavily damped.

The introducer 2 is used mainly in cases of difficult intubation, where the route for the tracheal tube 1 cannot be easily seen. The patient end 20 of the introducer 2 is first bent to the desired shape, which will usually be a shape having a smaller radius of curvature, as shown in FIG. 1, so that the patient end of the introducer enters the trachea instead of the oesophagus during insertion. The user bends the introducer 2 to shape immediately before introducing it into the trachea and bends it initially beyond the desired