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A61M 16/04 25/092

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A5R RGBB

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US 4906230 A US 4838859 A

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INT CL^6 A61M 16/00 16/01 16/04 25/00 25/01
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(54) Controlled bending of an endotracheal tube

(57) Bending of an endotracheal tube 1 to aid insertion is effected by control of fluid pressure in one or more distally placed passageways 20 extending partially around the circumference of the tube 1. Said passageways 20 may be integral with or attached to the tube wall. Fluid (e.g. saline) pressure is controlled by a proximally located sack or bulb (not shown) connected to passage 24 which extends along the length of the tube 1 and is in fluid communication with said distal passageways 20. Manual pressure to the sack or bulb causes changes in fluid pressure within the passageways 20 causing them to expand or contract leading to bending of the distal end of the tube 1.

Also disclosed are endotracheal tubes where bending is effected by a cord or flexible rod connecting the distal and proximal ends of the tube. A series of grooves cut into the wall of the tube provide a region of increased flexibility to allow localised bending to take place.

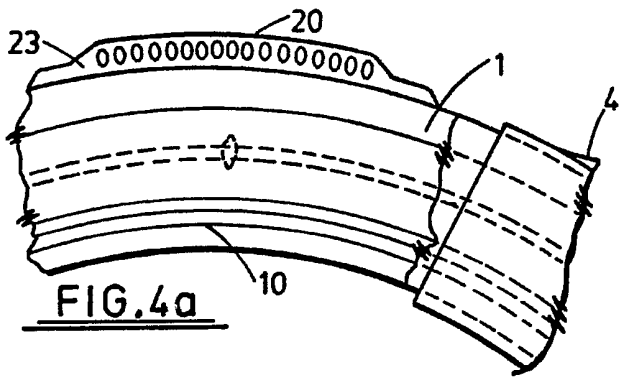

FIG.4a

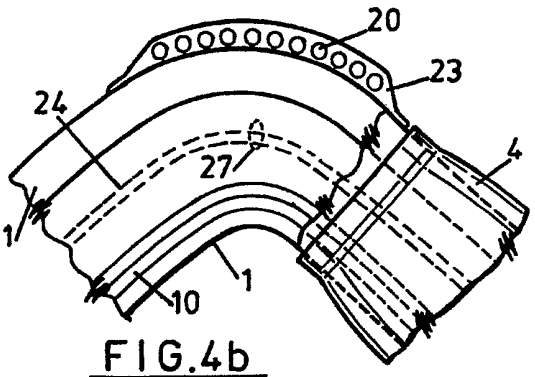

FIG.4b

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

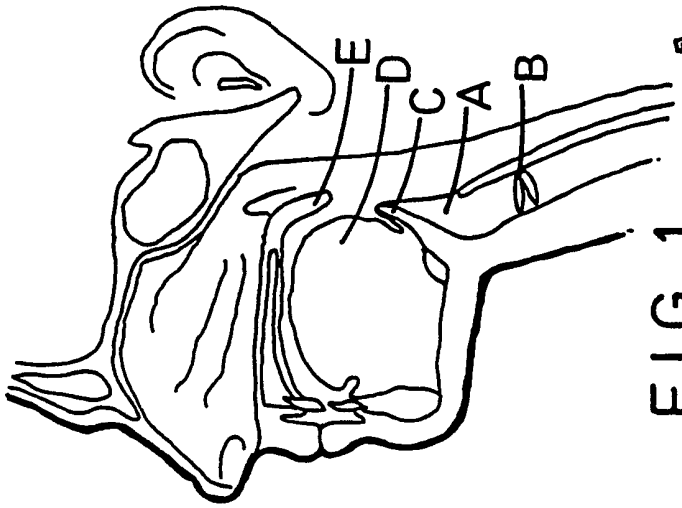

FIG. 1

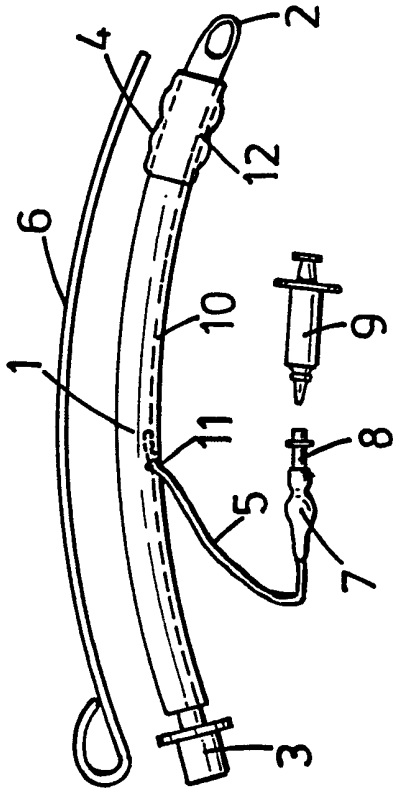

FIG. 2 (Prior Art)

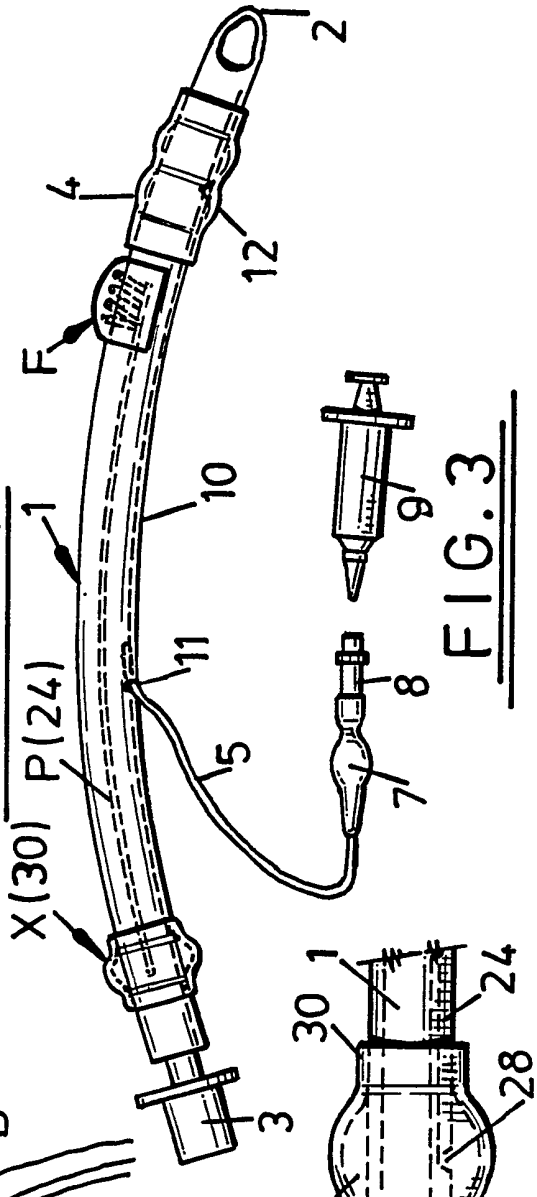

FIG. 3

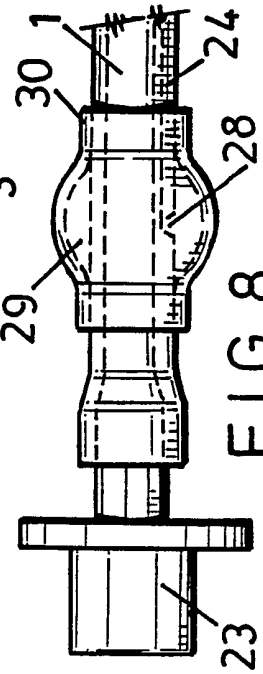

FIG. 8

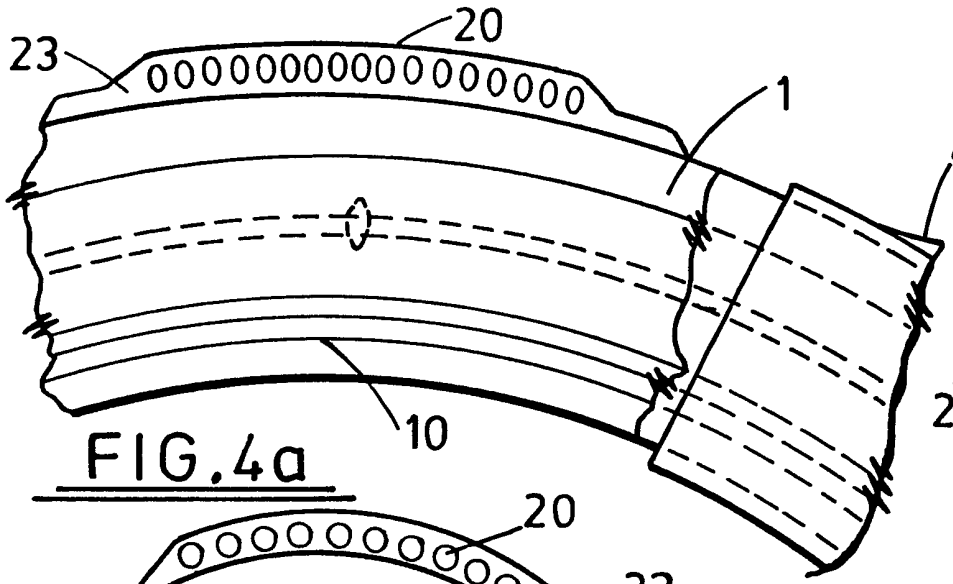

FIG.4a

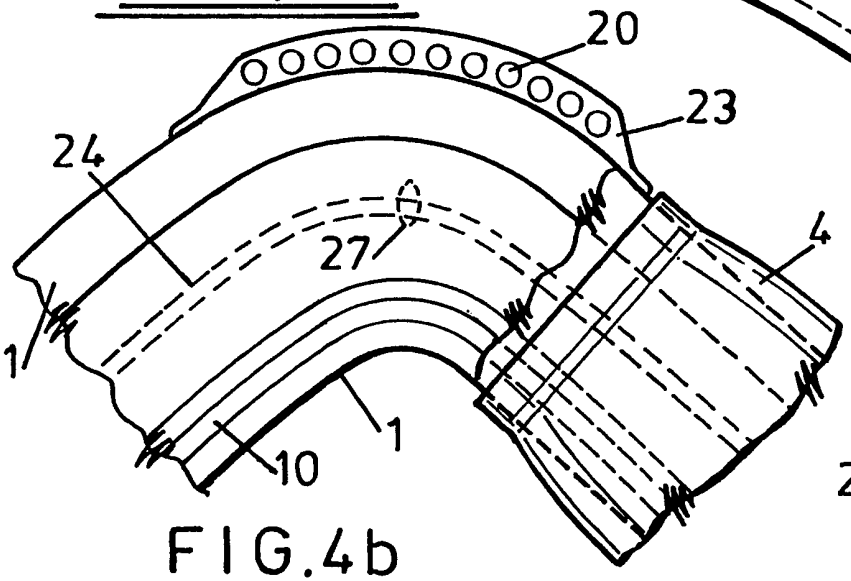

FIG.4b

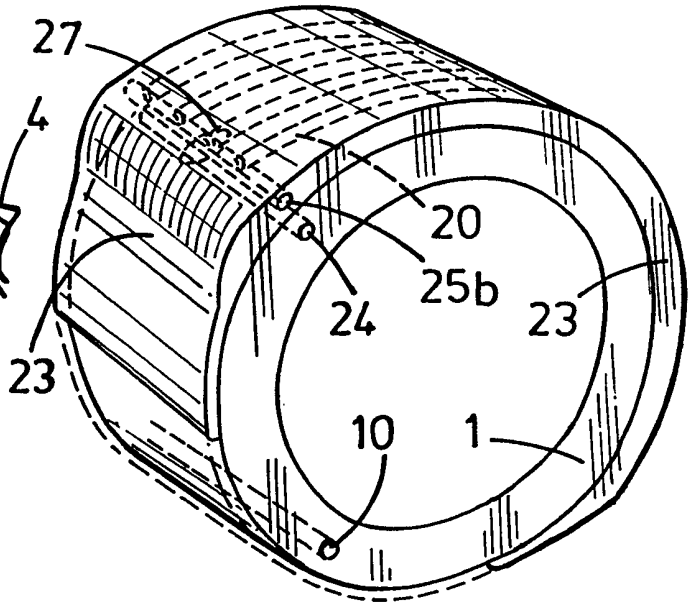

FIG.3a

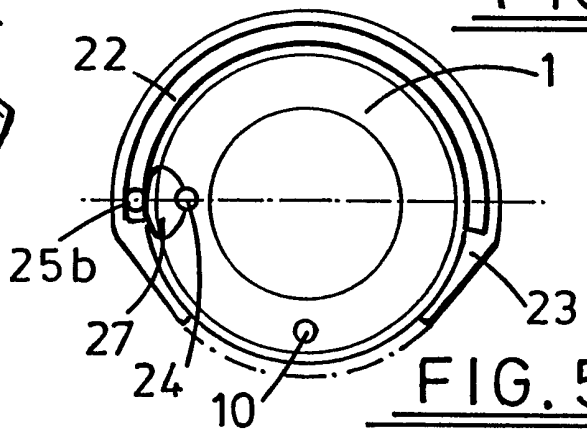

FIG.5

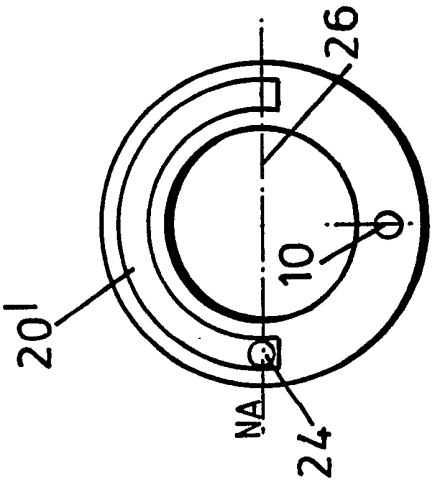

FIG.6

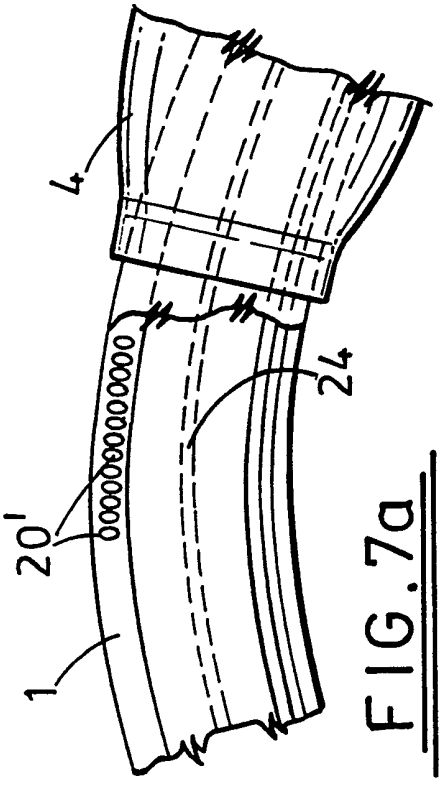

FIG.7a

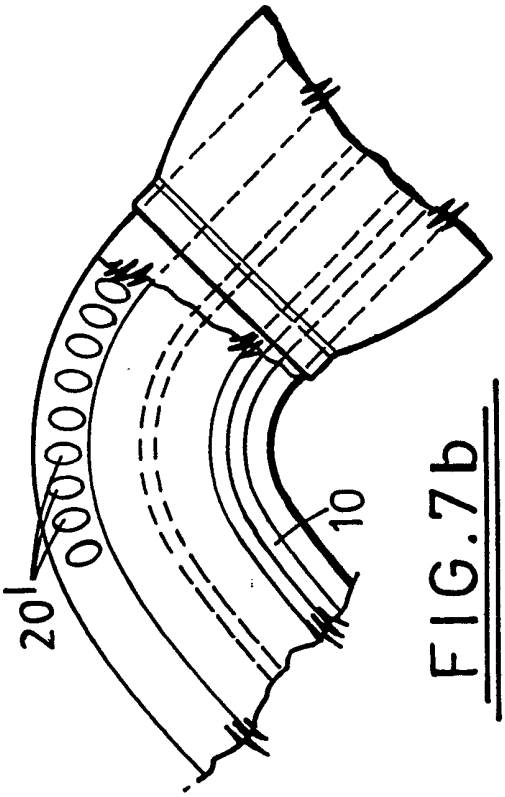

FIG.7b

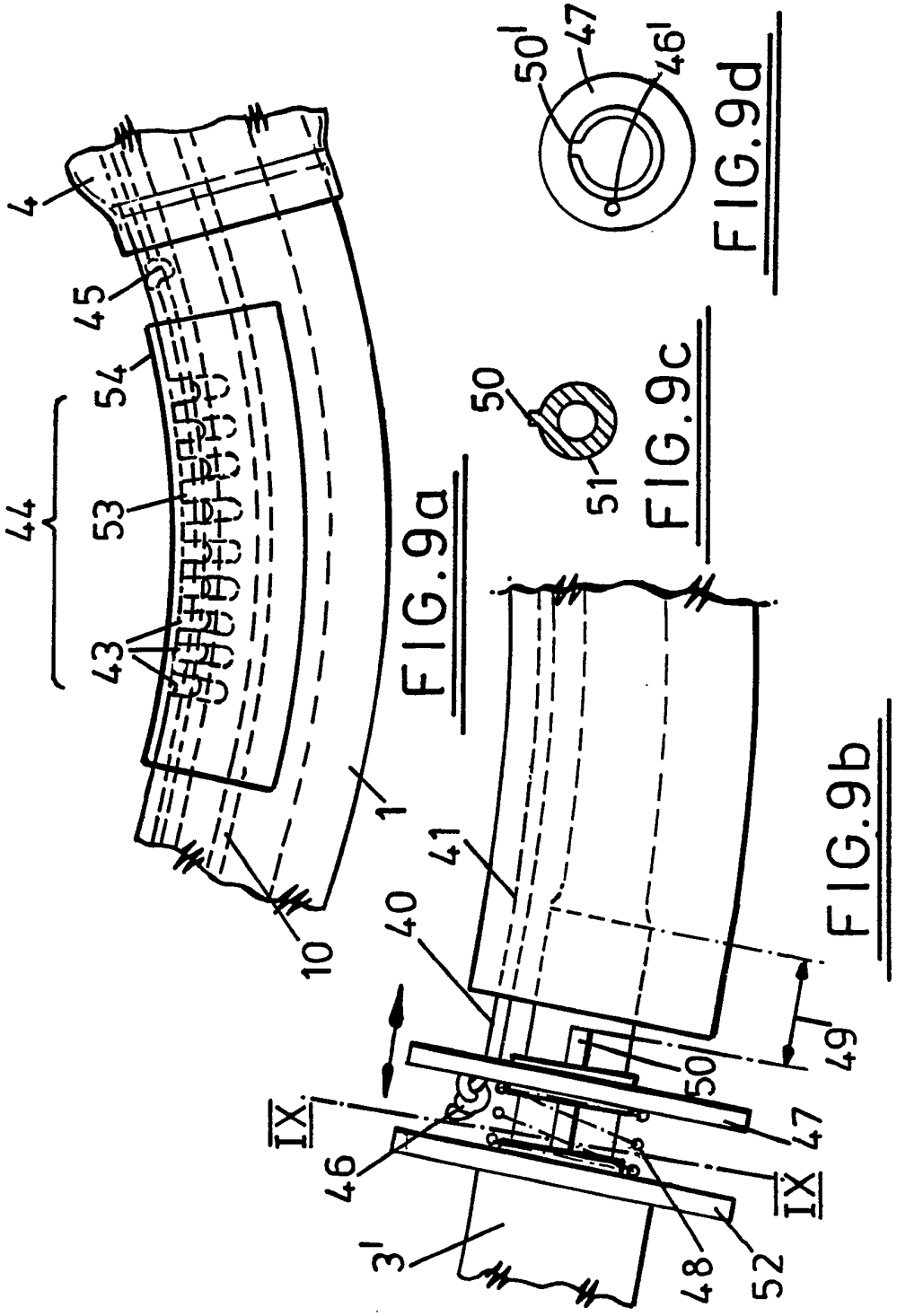

FIG.9a

FIG.9b

FIG.9c

FIG.9d

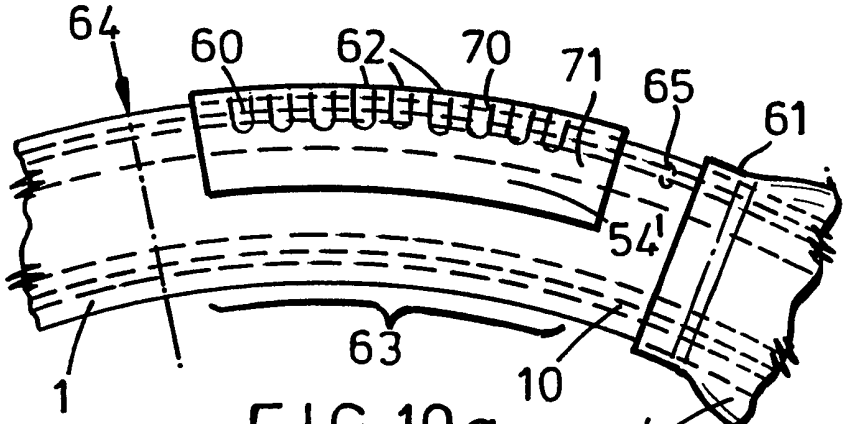

FIG.10a

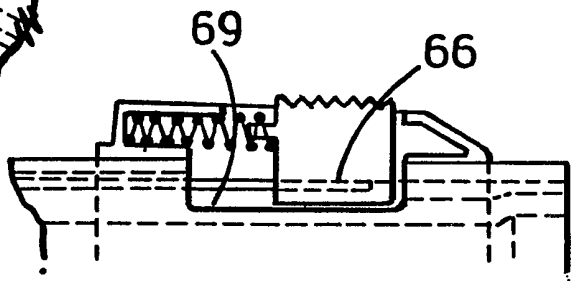

FIG.10c

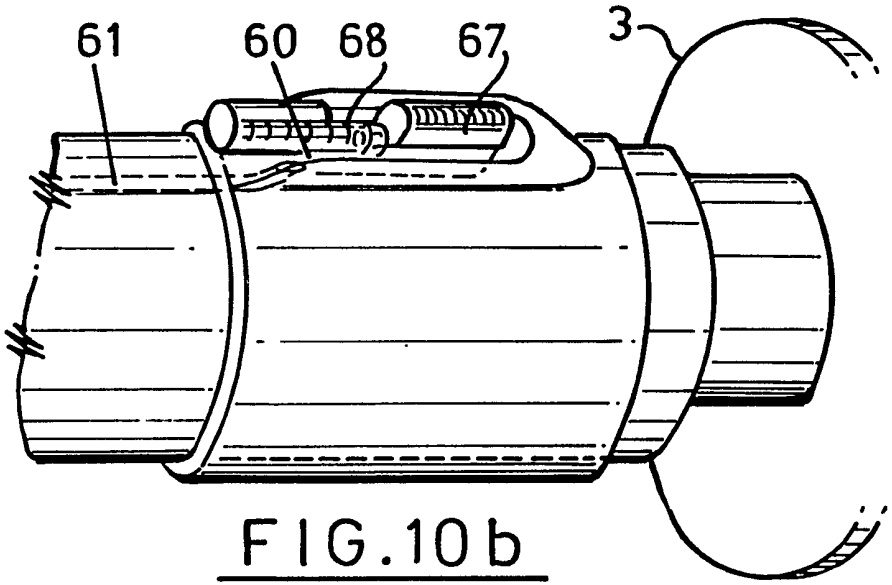

FIG.10b

Title: Controlled Bending of an Endo-Tracheal Tube

DESCRIPTION

The present invention relates to controlled bending of a endo-tracheal tube.

In administering an anaesthetic, ventilation of the unconscious and relaxed patient requires a means of obtaining secure access to the trachea, while preventing inhalation of reflux stomach contents. Commonly, a flexible plastic tube is used, having a connector to the anaesthetic machine at one end and an inflatable cuff for sealing the airway at the end which enters the trachea. The tube has a natural curve to facilitate insertion past the vallecula into the trachea. In perhaps 10-20% of patients the curvature near the inserted end needs to be increased by another device in order to be guided around anatomy producing a more acutely angled pathway. This increased bend is achieved by inserting a malleable metal rod down the lumen of the anaesthetic tube, then bending the assembly so that the appropriate tube shape is held by the rod, then inserting the tube and withdrawing the rod. This solution can often cause discomfort to the patient and cause damage to the delicate tissues.

It is an aim of the present invention to provide

a solution.

Accordingly, the present invention provides an endo-tracheal tube comprising means to effect controlled bending of the tube at a prescribed position along its length, and wherein said means is actuable from a remote location. Conveniently bending occurs adjacent but spaced from the inner end of the endo-tracheal tube. By remote location, we mean at a location remote from the position where bending occurs and usually adjacent the externally accessible end.

The means to effect bending conveniently comprises one or more discrete formations to a wall of the tube which are subject to an actuating force to effect bending of the tube by expansion or contraction (as the case may be) of part of the tube wall. More particularly still the bending means can be relaxed after insertion of the tube and indeed bending itself can be controlled during insertion. Thus, the present invention incorporates into the tube design a bending mechanism which allows remote bending by means controllable from the end which is held. Such a facility is advantageous in saving time at a critical point in introducing the tube and it is believed it will reduce the chance of tissue damage since the relative rigidity of the inserted rod of the prior art device is avoided. An advantageous feature of the present

invention is that the bending means is made entirely of flexible materials. A preferred construction is such that by squeezing the held end of the tube the person inserting the tube, usually the anaesthetist, can deflect the leading end to a greater or lesser degree as it approaches the entrance to the trachea and should be able to feel the tube moving through the entrance and into the trachea. Thus, there should be little or no delay to the completion of the insertion process.

According to one embodiment, the formations are formed by passageways in the wall of the endo-tracheal tube (or as a separate member securely attached thereto) and located at a distance from the inner end where bending is desired. Advantageously the passageways are axially spaced thereby weakening the wall. By constructing the passageways to occupy only part of the circumference of the tube, contraction and expansion of the passageways gives rise to bending about the neutral axis of the tube. According to one embodiment fluid pressure is used to distort the passageways. For example the passageway as made are non-circular (for example elliptical) in cross section which when subject to fluid pressure will attempt to become circular thereby changing the shape of the tube wall. For an elliptical cross-section the major axis is disposed generally in a radial plane and the minor axis is

disposed generally axially. By constructing a passageway leading from the inner end to the outer end of the endo-tracheal tube, means of remote communication to the said formations is possible. A syringe may be connected to said passageway at the outer end to control expansion and contraction of the formations. A preferred alternative utilises a fluid filled bulb or sack fitted and sealed onto the surface of the endo-tracheal tube and containing, for example, a saline solution, thus the anaesthetist can squeeze the bulb thereby urging fluid down the tube to pressurise the afore-mentioned passageways and change the shape of the tube. Once inserted the anaesthetist can release the pressure on the bulb thus relaxing the tube in the patient.

The tube may be purpose-designed with the afore-mentioned passageways or these may be constructed as an add-on to the existing endo-tracheal tube.

Alternative methods of achieving the remote controlled bending are possible. For example, the afore-described passageways may comprise radial ribs and the connecting passageway may incorporate a flexible line connected to the tube at a position adjacent the inner end whereby a tension force applied to the line at the outer end generates a compressive force acting on the tube beyond the formations thereby causing it to

adopt an enhanced degree of curvature. In such an embodiment the formations would be on the inner side of the bend rather than on the outer side as in the previously described embodiment.

A yet further embodiment utilises a rod-like transmission mechanism which will resist collapsing but can itself accommodate bending. Such a construction can have its end fixed to the tube beyond the ribbed formation whereby exerting an axial compressive force to the rod serves to extend the wall over the length of the formations thereby generate bending about the neutral axis.

The present invention will now be described further, by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 is an anatomy of the nasal cavity,

Figure 2 is a side view of a prior art endo-tracheal tube,

Figure 3 is a side view of an endo-tracheal tube embodying the present invention,

Figure 3a is a fragmentary perspective view showing in further detail the formations at the inner end of an endo-tracheal tube according to one embodiment of the invention,

Figures 4a and 4b are fragmentary sectional views showing the tube of Figure 3, 3a in a relaxed and a bent

condition respectively,

Figures 5 is a cross sectional view of the construction of Figure 3,

Figure 6 is a cross-section adjacent the inner end of another embodiment,

Figures 7a and 7b are fragmentary sectional views of the embodiment of Figure 6 showing the relaxed and bent condition respectively,

Figure 8 is an elevation of the other end of the tube for the embodiments illustrated in Figures 3 through 7,

Figures 9a and 9b show the respective inner and outer ends of an endo-tracheal tube according to a further embodiment,

Figure 9c is a sectional view on IX-IX of Figure 9b,

Figure 9d is an end view of the actuating collar shown in Figure 9b,

Figures 10a and 10b are views of the inner and outer ends of an endo-tracheal tube according to a still further embodiment, and

Figure 10c is a fragmentary detail of the embodiment of Figure 10b.

Referring firstly to Figure 1, the entrance to the trachea is shown at A, the larynx at B which is one obstruction in the trachea which has to be passed by

the end of the endo-tracheal tube, the vallecula at C and the base of the tongue at D and the soft palate at E. Referring now to Figure 2, a prior art endo-tracheal tube comprises a hollow, flexible plastic tube 1, which has a fine secondary bore moulded or extruded along its length into the wall of the tube as illustrated by the dotted line 10. A notch 11 is cut into the wall of the tube and into item 10 into which a fine plastic tube 5 is inserted. This runs into the secondary bore for a short distance effectively sealing off the bore above the notch and creating an external path into the secondary bore for administering air under pressure to inflate a cuff 4 surrounding the tube adjacent the leading end 2 of the tube. A notch 12 is also cut into the fine secondary bore to connect it to the cuff 4. The leading end of the tube is chamfered. The chamfering process also serves to seal the end of the secondary bore. A hard plastic adapter 3 is fitted into the external end of the tube to which the external ventilation apparatus is attached in use. A small inflatable bladder 7 is used to give an outwardly visible sign of the state of inflation of the cuff and a one-way valve 8 allows a syringe 9 to be detached after it has been used to administer a discrete amount of air to ensure correct inflation of the cuff. If necessary a malleable metal rod 6 may be inserted into the main bore

of the endo-tracheal tube to give the tube a preformed set shape. Thus, the process of inserting the endo-tracheal tube follows the following steps. Before the endo-tracheal tube is inserted it is necessary to prevent the tongue from falling back and obstructing the airway. This is achieved with a laryngoscope which hooks around the back of the tongue and pulls it forward and down. This in turn opens up the airway and in most cases it makes it possible to see the vallecula C and the entrance A to the trachea. However, in some patients the vallecula hangs back down and obscures the entrance to the trachea, thus making it difficult for the anaesthetist to see whether the leading end of the endo-tracheal tube is going down the correct passage. For most anaesthetics the patient's head is tilted back to straighten the airway and further assist the anaesthetist to see what he is doing. For some patients with neck problems this is not always possible again making it difficult to find the entrance to the trachea. In some 10%-20% of patients the curvature near the leading end of the endo-tracheal tube needs to be increased. On encountering this difficulty the anaesthetist obtains and lubricates the malleable metal rod 6 and inserts it down the lumen of the endo-tracheal tube 1. He then bends the end of the tube so that the appropriate shape is held by the rod, then inserts the

tube and withdraws the rod. In all cases where this problem arises there is a delay at a critical stage of the anaesthetic and an increased chance of tissue damage from the relatively rigidity of an inserted rod. Having successfully inserted the tube the inflatable cuff 4 is inflated to ensure only anaesthetic gases enter the trachea and reflux stomach contents are kept out. This is why it is necessary to ensure that the tube is properly inserted into the trachea, far enough to ensure that the cuff is far enough into the trachea to seal it.

Referring now to Figure 3, there is illustrated an endo-tracheal tube according to one embodiment of the invention. It has all the features of the prior art device which are denoted by like reference numerals and not described further in detail. The malleable rod is not illustrated as this is dispensed with by the provision of integral means for effecting controlled bending of the tube according to the various embodiments disclosed further hereinafter. In general terms it includes:- formations F located adjacent the cuff 4 at which bending takes place; actuating means X disposed towards the externally accessible end of the tube; and a connecting passageway P between the actuating means and the formations.

Reference is now made to Figures 3a through 5 which describes one embodiment of formations F. In this

embodiment a series of parallel tubes 20 of generally elliptical cross section are arranged in arc-fashion around part of the circumference of the endo-tracheal tube and above but adjacent the cuff 4. Interconnecting with these parallel tubes is a connecting passageway 25b which runs generally axially.

In one embodiment the passageways 20, 25b are formed in a separate component part 23, which may be a tube-like member, which is secured to the external wall of the endo-tracheal tube 1 in the desired location where bending is to be generated. The endo-tracheal tube has a passageway 24 which runs along the length of the endo-tracheal tube and is conveniently formed in the wall of the endo-tracheal tube in the same way as passageway 10 which is used for inflating the cuff. Conveniently this additional passageway lies adjacent to the neutral axis of the endo-tracheal tube. The passageway 24 is connected by a notch 27 to passageway 25b. To provide a simple means of expanding the arc-fashion parallel tubes, a flexible bulb 30 (see Figure 8) is provided to the outer end of the endo-tracheal tube. Conveniently this is sealed onto the outer surface of the endo-tracheal tube and a notch 28 made in the wall of the tube to enter the connecting passageway. The bulb and connecting passageways (24, 25b, 20) are filled with fluid, typically a saline solution.

Squeezing of the bulb at the appropriate point during insertion of the endo-tracheal tube into the trachea, forces saline down the passageway 24 and into the arc-fashion parallel tubes expanding them. Because these are elliptical in shape in their rest condition the pressure now exerted on their internal walls will cause them to change to a roughly circular cross sectional shape thus increasing the longitudinal length of this section of the endo-tracheal tube wall and resulting in an increasing curvature of the tube (see Figure 4b) and so obtaining a desired deflection of the end of the endo-tracheal tube towards the entrance to the trachea. The anaesthetist would then be able to complete insertion and then release pressure on the bulb thus relaxing the tube in the patient. The wall of the endo-tracheal tube and the component 23 is sufficiently flexible (also elastic) to permit axial extension under the force so applied. The bulb may be provided with a hard plastic inner wall to protect the bore of the tube from being constricted as the bulb is squeezed - thus ensuring an uninterrupted air supply to the patient.

The embodiment of Figures 6, 7a, 7b also utilises a fluid filled bulb 30 communicating with passageways of elliptical cross-section, but in this embodiment the passageways 20' are formed directly in the wall of the endo-tracheal tube and extend over one half of the

circumference to terminate in the plane of the neutral axis 26. The passageways are interconnected and supplied directly by passageway 24 which passages through them.

A second way of obtaining the deflection of the inserted end of the endo-tracheal tube is outlined with reference to Figures 9a, b, c and d. The basic feature of the endo-tracheal tube is as described previously. Bending is controlled by means of a fine chord 40 running down a passageway 41 moulded or extruded into the endo-tracheal tube. A series of grooves 43 intersecting this passageway are cut arc-fashion into the outer wall of the endo-tracheal tube in the inside bend region 44 of least radius. One end of the chord 45 is anchored to the tube below this bend region, the other end 46 is led out of the tube at the external end and fastened to a collar 47 slidably movable as a modified hard plastic adaptor 3′ that is used to connect the endo-tracheal tube to the anaesthetic machine. A spring 48 a flange 52 of the adapter and the collar 47 ensures the tube can return to its natural state after the purpose of bending has been achieved. A raised key 50 is moulded into 3′ to prevent the collar 47 from rotating. The key is machined away over the lower part 49 to provide a clean airtight fit of the adapter in the tube 1. Figure 9c shows a section through 3′ and its

key 50 while Figure 9d shows an end view of the collar 47 and its corresponding keyway 50' and hole 46 to receive the line 46.

Because this device needs to go on the side of least curvature - where the normal passageway 10 goes, this passageway will need to be moved around onto the neutral axis say as shown in Figure 9a. What was 10 now becomes 41. Thus the cuff 4 may still be inflated by the usual means.

It is envisaged that these arc-fashion grooves will stop short of the neutral axis to avoid penetrating the airway 10. It may also be necessary to cover the ribs 53 with a thin cover 54. This may be constructed with fibres running circumferentially to limit stretching radially while allowing maximum freedom to move longitudinally.

A third way of obtaining the deflection of the inserted end of the endo-tracheal tube is outlined with reference to Figures 10a, b and c. This embodiment uses a fine rod 60 running in a passageway 61 moulded or extruded into the endo-tracheal tube. A series of grooves 62 are cut arc-fashion into the outer wall of the tube intersecting this passageway in the bend region 63 and on the side of greatest radius 64. A thin cover 54' is applied over the tube to cover the slots as in the embodiment of Figure 9. One end of the rod 65 is

fixed to the tube below this region, the other end 66 is secured to an operating tab 67 constructed for axial movement. A spring 68 acts on the tab 62 to return the tube to the relaxed state. This slider is mounted on the external end of the tube near the hard plastic adapter 3 that is used to connect the endo-tracheal tube to the anaesthetic machine.

If this fine rod if sufficiently resistant to buckling it can be led out of the tube to an external slide. Otherwise a clearance groove 69 will need to be cut in the wall of the tube so that the fine rod can be fastened onto the tab in a direct line with it, the tab in this case being made deeper to protrude into this longitudinal groove.

It may be possible to design this slider device to be integral with the adapter 3 to minimise components and ease assembly.

To prevent the rod stretching the fine ribs 70 in the wall of the tube, a slotted 'low-stretch' cover 71 could be stuck over the ribs as shown. If this also extends to roughly the neutral axis of the tube, this will provide least resistance to bending and maximum resistance to stretching. This cover could also be manufactured using fibres arranged to allow longitudinal movement but limiting circumferential stretching.

CLAIMS

1. An endo-tracheal tube comprising means to effect controlled bending of the tube at a prescribed position along its length, and wherein said means is actuable from a remote location, which bending occurs generally in the vicinity of an inner end of the endo-tracheal tube, said remote location being remote from the position where bending occurs and adjacent an externally accessible end of the tube in use, the means to effect bending comprises one or more discrete formations to a wall of the tube which are subject to an actuating force to effect bending of the tube by expansion or contraction (as the case may be) of part of the tube wall, said formations being formed by one or more passageways in the wall of the endo-tracheal tube or as a separate member securely attached thereto and located at a distance from the inner end to effect bending where desired, the passageways occupy only part of the circumference of the tube, so that contraction and expansion of the passageways gives rise to bending of the tube, and wherein fluid pressure is used to distort the or each passageway, and further comprising a passage leading from the outer end of the endo-tracheal tube to the inner end for passage of the fluid to said formations to control bending.

2. An endo-tracheal tube as claimed in claim 1 in which the or each passageway as made are non-circular (for example elliptical) in cross section such that subjecting to fluid pressure will distort them thereby changing the shape of the tube wall.

3. An endo-tracheal tube as claimed in claim 2 in which for an elliptical cross-section of passageway the major axis is disposed generally in a radial plane and the minor axis is disposed generally axially.

4. An endo-tracheal tube as claimed in any one of claims 1, 2 or 3 in which where more than one passageway is provided they are axially spaced, but in fluid communication one with the other.

5. An endo-tracheal tube as claimed in any one of claims 1 to 4 in which a syringe is connected to said passage at the outer end to control expansion and contraction of the formations.

6. An endo-tracheal tube as claimed in any one of claims 1 to 4 further comprising a fluid filled bulb or sack fitted and sealed onto the surface of the endo-tracheal tube and containing a fluid, for example a saline solution, in fluid communication with said passage and whereby squeezing the bulb thereby urges fluid down the tube to pressurise the afore-mentioned passageways and change the shape of the tube.

7. An endo-tracheal tube as claimed in claim 6 in

which releasing the pressure on the bulb relaxes the tube.

8. An endo-tracheal tube as claimed in any one of the preceding claims in which the aforesaid passage and/or passageways are an integral part of the tube.

9. An endo-tracheal tube constructed and arranged substantially as hereinbefore described with reference to and as illustrated in any one of the accompanying drawings of Figures 3, 3a, 4a, 4b, 5, 6, 7a, 7b or 8, and any combination thereof.

10. An endo-tracheal tube comprising means to effect controlled bending of the tube at a prescribed position along its length, and wherein said means is actuable from a remote location, which bending occurs generally in the vicinity of an inner end of the endo-tracheal tube, said remote location being remote from the position where bending occurs and adjacent an externally accessible end of the tube in use, the means to effect bending comprises one or more partially extending circumferential recesses which when the tube is subject to an actuating force allows bending of the tube.

11. An endo-tracheal tube as claimed in claim 10 in which there are a plurality of said recesses which are axially spaced.

12. An endo-tracheal tube as claimed in claim 10 or 11 in which the means to effect bending further

comprises a flexible rod, line or cord actuated from the externally accessible end of the tube and connecting with the tube below the recesses.

13. An endo-tracheal tube constructed and arranged substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings of Figures 9 or 10.

Patents Act 1977
Examiner's report to the Comptroller under Section 17
(The Search report)

Application number
GB 9500341.4

Relevant Technical Fields

(i) UK Cl (Ed.N) A5R; RGEX, RGBB, RGED

(ii) Int Cl (Ed.6) A61M 16/00, 16/01, 16/04, 25/00, 25/01

Search Examiner
MR S J PILLING

Date of completion of Search
10 APRIL 1995

Databases (see below)
(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

(ii) ONLINE: WPI

Documents considered relevant following a search in respect of Claims :-
1 TO 9

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
Y	GB 1513495	(MALLINCKRODT INC) page 1 lines 72 to 92 and Figure 2	1, 2 and 4 to 8
Y	EP 0488322 A1	(HAOJUN) page 3 lines 12 to 53, page 7 lines 13 to 36 and Figures 5 to 12	1, 2 and 5 to 8
Y	US 4983165	(LOITERMAN) column 2 lines 49 to 68, column 3 line 29 to column 4 line 65 and Figures 1 to 6	1, 2 and 5 to 8
Y	US 4906230	(MALONEY) column 1 lines 8 to 30, column 2 line 61 to column 3 line 6, column 4 line 57 to column 5 line 10 and Figures 1 to 4	1, 2, and 4 to 8
Y	US 4838859	(STRASSMAN) column 2 lines 3 to 5 and 27 to 54, column 4 line 65 to column 5 line 34 and Figures 2a and 2d	1, 2 and 5 to 8

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).