

[54] TUBING

[75] Inventor: David Edward Cross, Folkestone,
Kent, England

[73] Assignee: Smiths Industries Limited, London,
England

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[58] Field of Search 128/348-351

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Primary Examiner—Lawrence W. Trapp
Attorney, Agent, or Firm—Elliott I. Pollock

[57]

ABSTRACT

An endotracheal tube has an inflatable cuff of undulatory bellows-like configuration to provide spaced circumferential convolutions, whereby cuff contact in establishing a labyrinth seal with the intubated patient's trachea is restricted to narrow bands so as to reduce the extent, and consequential healing-time, of any pressure-induced necrosis. A cuff convoluted over only part of its length is provided on a tracheostomy tube, and alternative configurations of cuff of partially-convoluted form and involving cylindrical shoulders of different lengths, are used for endotracheal and tracheostomy tubes. The cuff in each case is inflated from an air-line that includes a pilot balloon and is coupled into a passageway which is incorporated in the tube wall and which opens through the wall into the cuff.

9 Claims, 6 Drawing Figures

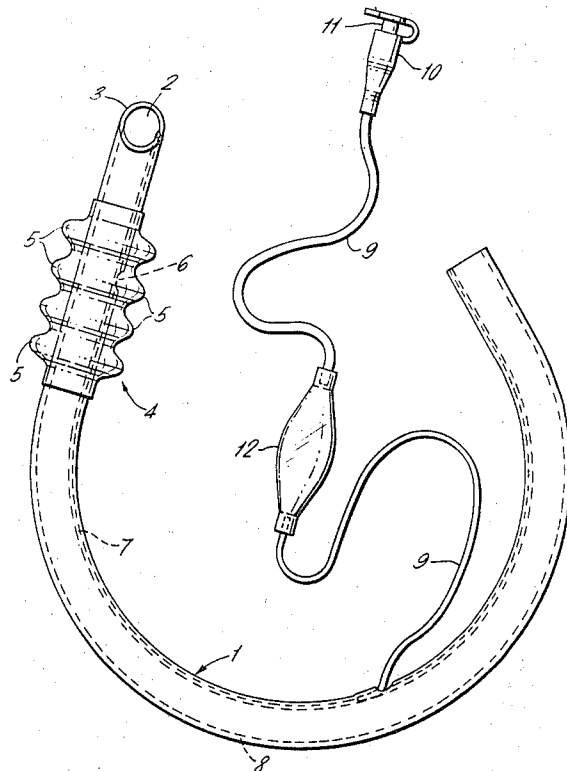
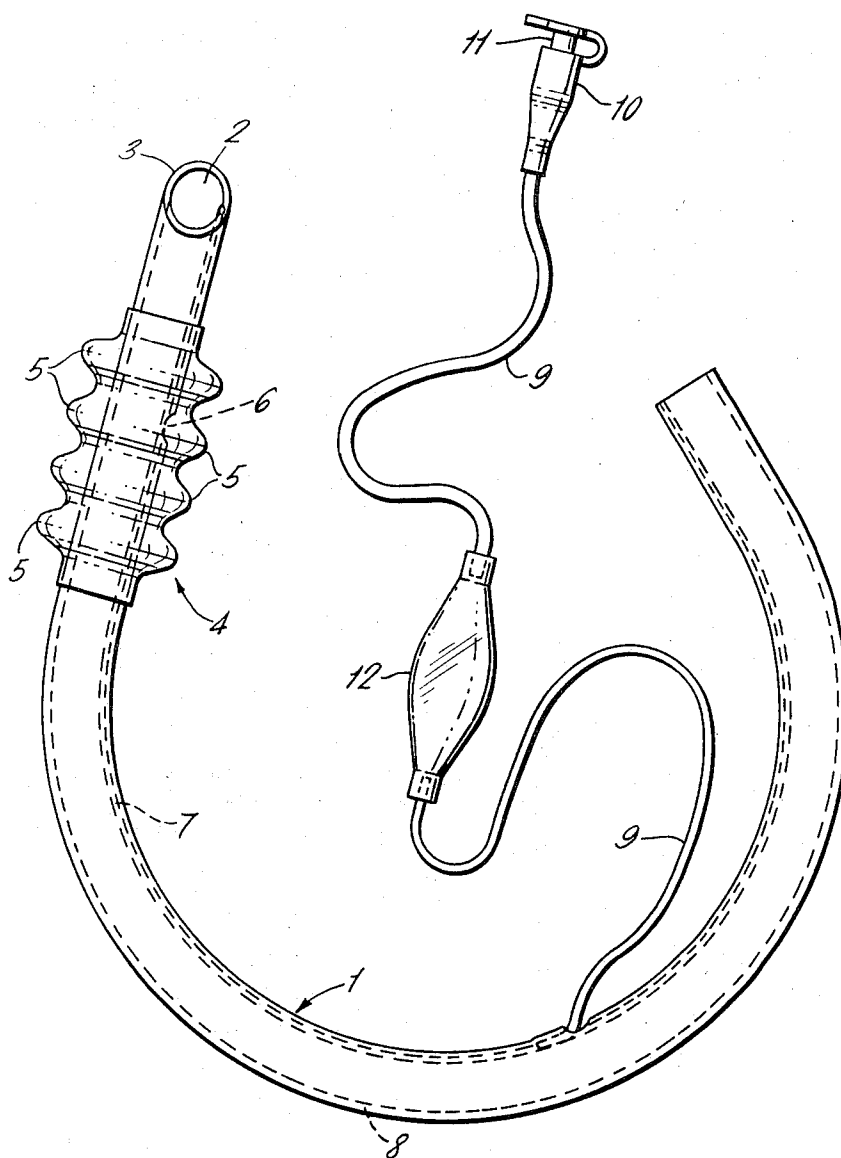


FIG. 1.



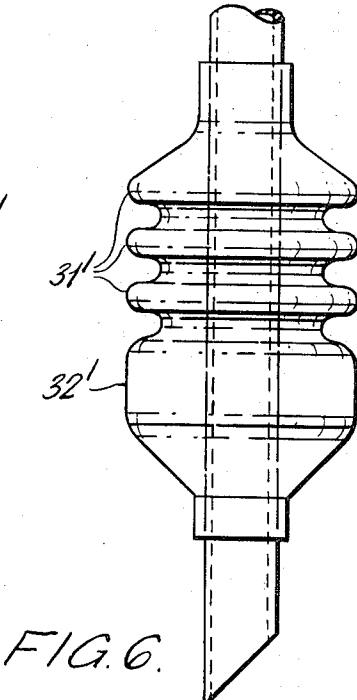
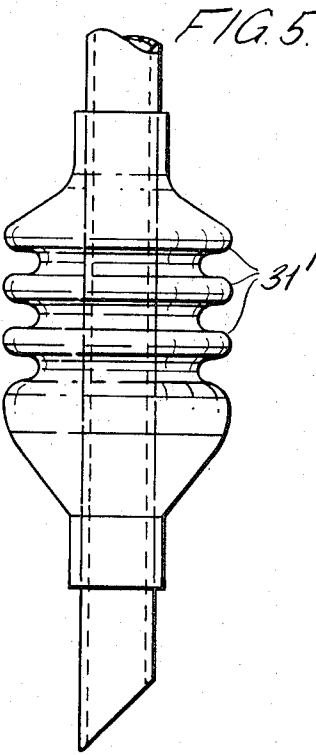
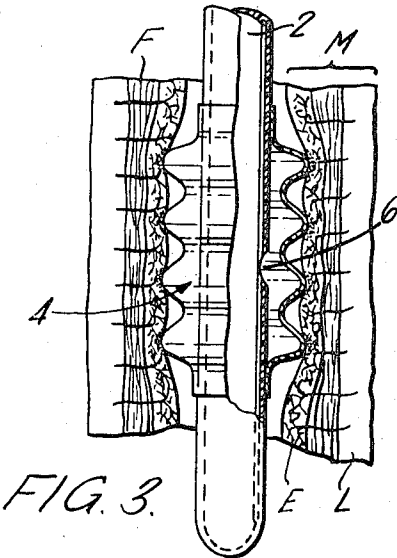
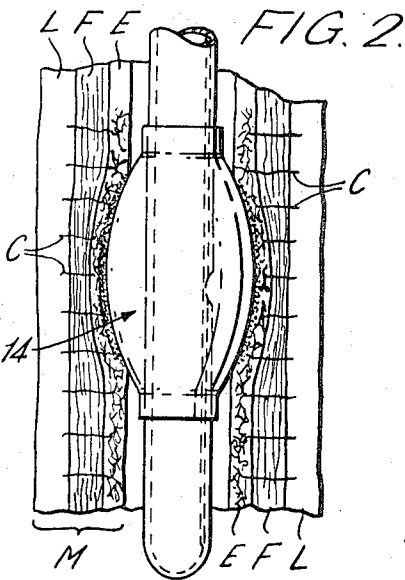
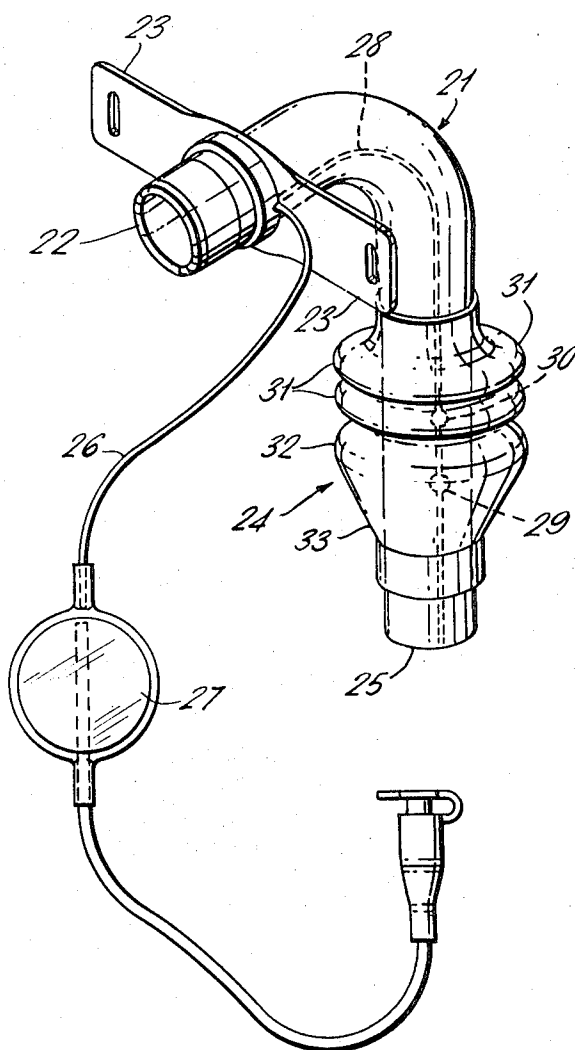


FIG. 4.



1 TUBING

BACKGROUND OF THE INVENTION

This invention relates to medical or surgical devices, and in particular to such devices of the kind having an inflatable balloon or cuff for introduction into the body to effect a seal therein.

Medical or surgical devices of this kind are known in the treatment of humans and also animals, and commonly take the form of a tube that is provided with an inflatable cuff encompassing a portion of its length. Examples of such tubes are to be found in the various forms of cuffed endotracheal tube that are commonly used in anaesthesia. The tube in this case is for introduction into a patient's trachea through the mouth or nose, and carries a cuff near the distal end so that inflation causes the cuff to distend into contact with the tracheal wall and thereby effect sealing of the tube in the trachea. Similar practice applies in tracheostomy, but the cuffed tube used in this case is specially adapted for insertion into the trachea through a surgical opening in the patient's neck.

The purpose of the seal provided with both the cuffed endotracheal and tracheostomy tubes is to ensure that all air or other gas administered to the patient is routed through the tube, and also to prevent mucous, vomit or other material from the upper respiratory tract, entering the lungs. However, there is the risk of injury resulting from the inflation pressure exerted by the cuff on the tracheal wall, in that blood-carrying capillaries in the wall may become occluded and this may lead to necrosis of the tracheal tissue. The cuff used is generally of a uniform-cylindrical or barrel-shape configuration and contacts the tracheal wall over an area of such an extent that healing of the necrosis, by natural growth from adjacent undamaged areas and restoration of blood supply, is usually very slow. The injury may, however, take the more serious form of stenosis, resulting from an invasion of the affected area by fibrous tissue, and relief of consequential tracheal-restriction may necessitate surgery.

A proposal (Dr. P. D. Salpekar, British Medical Journal, 29th Jan. 1966, page 296) for reducing the risk of tracheal-wall injury in tracheostomy, involves the use of two axially-spaced and independently-inflatable cuffs. With this arrangement the two cuffs are inflated alternately with one another, so that each is in use to provide the desired seal for only half the period of intubation. Although this reduces the time of capillary occlusion at any position on the tracheal wall, it does not fully avoid the fundamental possibility of there being extensive areas of necrosis that are slow to heal and rejuvenate.

The risks and difficulties of necrosis and possible stenosis referred to above in connection with cuffed endotracheal and tracheostomy tubes, apply correspondingly to other cuffed devices (such as for example catheters) used elsewhere in the body, and it is an object of the present invention to provide a cuffed device for medical or surgical use that will enable such risks and difficulties to be reduced.

SUMMARY OF THE INVENTION

According to the present invention there is provided a medical or surgical device having an inflatable balloon or cuff for introduction into the body to effect a seal therein, wherein the cuff presents a convoluted ex-

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ternal surface when inflated so as to contact the body at discrete positions therein.

With the cuffed device of the present invention contact with the body is made only at the discrete positions so that the possibility of extended and unbroken areas of necrosis with the long recovery time required, is substantially reduced.

The balloon or cuff may have a wall of undulatory configuration, and may encompass a portion of a length of tubing, for example the tubing of an endotracheal or tracheostomy tube of plastics or rubber. In these latter circumstances the cuff may have convolutions which each encircle the tubing and which are spaced from one another axially of it. The cuff may be convoluted along the whole, or only a part, of its length.

BRIEF DESCRIPTION OF THE DRAWINGS

Cuffed medical and surgical devices in accordance with the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

FIG. 1 shows an endotracheal tube provided with a convoluted cuff, in accordance with the present invention;

FIGS. 2 and 3 illustrate respectively and for comparison purposes, the circumstances applicable to tracheal intubation of an endotracheal tube of the prior art and the endotracheal tube of FIG. 1;

FIG. 4 shows a cuffed tracheostomy tube according to the present invention; and

FIGS. 5 and 6 illustrate two alternative configurations of cuff that are applicable to the endotracheal and tracheostomy tubes of FIGS. 1 and 4.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, the endotracheal tube includes tubing 1 that is of constant bore or lumen 2 throughout its length and has a bevelled, distal, tip 3. An elongate cuff 4 encompasses a portion of the tubing 1 near the bevelled tip 3, being formed by a short length of convoluted sleeving of uniform wall thickness that is bonded or otherwise sealed at both ends to the tubing 1. The cuff 4, of regularly undulating external surface with circumferential crests 5 space axially from one another by the valley recesses, provides a balloon of bellows-like configuration enclosing a portion of the tubing wall 8 around an opening 6 from a passageway 7. The passageway 7, which runs lengthwise of the tube within the wall 8, is closed at the tip 3, and at some two-thirds of the length of the tubing 1 along from the tip 3 is in airtight communication with an external air-line 9 sealed into the wall 8.

Air to inflate the cuff 4 through the opening 6 from the passageway 7, is supplied to the air-line 9 via a standard coupling 10. Supply of air to the air-line 9 in this way distends the convoluted cuff 4 to urge the smoothly-curved crests 5 into contact with the internal wall of the intubated patient's trachea. This contact establishes an effective labyrinth seal with occluded recesses intervening the crests 5, that withstands efficiently the ventilation pressure administered to the patient via the lumen 2, and blocks aspiration of pharyngeal secretions and any other material from his upper respiratory tract. The cuff-inflation pressure is maintained using a stopper plug 11 inserted in the coupling 10 as shown, and

can be checked by reference to the distension of a pilot balloon 12 included in the air-line 9.

The convoluted cuff 4 of the endotracheal tube described above with reference to FIG. 1, contacts the wall or mucous membrane of the trachea in discrete bands rather than throughout the extended area characteristic of the known form of cuff with its uniform-cylindrical or barrel-shape configuration. The circumstances applicable to intubation using the barrel-shape configuration of cuff for example, are illustrated in FIG. 2, whereas those applicable to intubation using the convoluted cuff 4 of the present invention are illustrated in FIG. 3.

As illustrated in FIG. 2, the smooth barrel-shaped cuff 14 contacts the ciliated columnar epithelium E of the mucous membrane M of the trachea over a substantial unbroken area. The pressure applied tends to occlude the mucosal capillaries C which pass from the submucous layer L through the longitudinally-extending elastic fibres F, and which serve to supply blood to the epithelium E at a pressure of between 12 and 30 millimetres of mercury. The pressure of inflation for efficient sealing of the cuff 14 in the trachea, exceeds the ventilation pressure which is commonly set at between 14 and 15 millimetres of mercury, but which may occasionally reach as high as 60 millimetres of mercury. Occlusion of the capillaries C with consequent necrosis, and possible stenosis, is therefore quite likely.

Similar considerations apply to the circumstances of the convoluted cuff 4 illustrated in FIG. 3, but here the greater efficiency of the labyrinth seal provided along the length of the cuff 4 by the successive bands of contact of the crests 5 and their intervening recesses occluded from one another, tends to enable use of a lower inflation pressure. The likelihood of necrosis, and possible stenosis, is therefore reduced, and is in any case confined to spaced bands as distinct from an extended unbroken area. The repair by healing or rejuvenation of any necrotic region is achieved by natural growth of cells adjacent that region together with restoration of capillary blood-supply to it. Accordingly if there is necrosis with the convoluted cuff, the fact of confinement of the damage to spaced bands is the more conducive to speedy natural healing and rejuvenation.

Although the advantages of the convoluted cuff 4 have been referred to above more particularly in connection with an endotracheal tube, they are equally applicable to a cuffed tracheostomy tube. The advantages, however, do not necessarily require the use of a cuff, such as the cuff 4, that is convoluted along its whole length, but may be realised with only partial convolution. A form of tracheostomy tube incorporating a partially-convoluted cuff is illustrated in FIG. 4.

Referring to FIG. 4, the curved tubing 21 of the tracheostomy tube is terminated proximally by a conventional chimney 22 and fixing-strap 23. The cuff 24 encompasses a portion of the tubing 21 near the distal end 25 and is inflatable from an air-line 26 that includes a pilot balloon 27. The air-line 26 is coupled at the chimney 22 into a passageway 28 that extends the length of the tubing 21 and is closed at the distal end 25. The passageway 28 communicates with the interior of the cuff 24 via two openings 29 and 30 through the tubing wall.

The cuff 24 has two distinct proximal crests 31 and a narrow distal crest or rounded shoulder 32 that is of the same diameter as the two crests 31 and is smoothly contoured into a distal section 33 of conical form. Contact with the trachea upon inflation of the cuff 24 is made at the shoulder 32 and the crests 31 so that any necrosis is consequently confined to just three spaced and narrow bands. In this respect also, however, the likelihood of necrosis is reduced by the fact that the cuff 24 is formed of strong, but very thin, plastics material so as to have a normally floppy nature and enable full erection and efficient sealing to be achieved with a low inflation-pressure.

Two modified configurations of 'floppy' cuff that may alternatively be used in place of the cuff 24 of FIG. 4, or the cuff 4 of FIG. 1, are illustrated in FIGS. 5 and 6. As compared with the cuff 24 of FIG. 4 each of these alternative cuffs has three proximal convolution-crests 31' of equal diameter to one another and that of FIG. 6 incorporates an extended, cylindrical crest or shoulder 32' (of the same diameter) at its distal end.

The various convoluted cuffs illustrated in FIGS. 1 and 4 to 6 may be formed of plasticized polyvinyl chloride (or possibly polyurethane) by blow moulding. Alternatively, a dipping process in which a suitably-shaped mandrel pre-heated to approximately 210°C, is dipped into a paste of polyvinyl chloride, may be used. The mandrel when coated with the paste, in the latter process, is inserted in an oven at a temperature of some 280°C for approximately 1½ to 2½ minutes (depending on the cuff size), and is then allowed to cool to some lower temperature at which the completed cuff can be rolled off ready for sealing to the main tubing. This latter tubing may also be of polyvinyl chloride, and may be extruded to include radio-opaque material (conveniently confined to a longitudinal strip integral with the tubing wall) and an appropriate plasticizer to provide for slight softening at body temperature.

I claim:

1. In a medico-surgical device having an inflatable balloon cuff for introduction into the body to effect a seal therein, the improvement wherein the cuff includes means for providing a convoluted external surface to the inflated cuff to restrict cuff contact with the body throughout said seal to discrete bands, the convolution of said external surface in said inflated cuff comprising a series of at least three mutually-spaced crest portions with intervening recess portions to provide said bands of contact occluding the intervening recesses from one another in the seal.

2. A device according to claim 1 wherein the cuff has a wall of regularly configuration.

3. A device according to claim 1 including a length of tubing, and wherein the cuff encompasses a portion of the tubing and has said crest portions spaced axially of the tubing from one another with each crest portion encircling the tubing.

4. A device according to claim 3 wherein the said crests portions occupy only part of the cuff length.

5. A device according to claim 3 wherein the tubing wall incorporates a passageway communicating with the interior of the cuff for inflation purposes.

6. An endotracheal tube comprising a length of tubing, a convoluted sleeve surrounding a portion of the tubing coaxially near one end of said tubing, said sleeve being sealed at both of its ends to said tubing to provide

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a balloon cuff encompassing said portion of the tubing with axially-spaced circumferential convolutions, and means coupled to the interior of the cuff for conveying fluid to inflate the cuff, said cuff at least when inflated having by virtue of said convolutions a series of at least three circumferential outwardly-directed crest portions spaced axially from one another for contacting the tracheal wall in discrete bands.

7. An endotracheal tube according to claim 6 wherein one of said crest portions of said cuff comprises a cylindrical shoulder portion located beyond the others of said circumferential crest portions towards said one end of the tubing, and wherein the shoulder portion and the said others of said crest portions have substantially the same diameter as one another.

8. A tracheostomy tube comprising a curved length of tubing having a distal end for insertion into a patient's trachea through the neck, attachment means coupled to the other, proximal end of the tubing for use

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in securing the tube externally at the patient's neck, an inflatable cuff encompassing a portion of the tubing near the said distal end, and means coupled to the interior of the cuff for conveying air to inflate the cuff, said cuff having a convoluted wall surrounding said portion of the tubing and including a series of at least three axially-spaced circumferential crest portions for contacting the patient's trachea at discrete positions to provide a labyrinth seal therewith when the cuff is inflated.

9. A tracheostomy tube according to claim 8 wherein the cuff wall includes a cylindrical shoulder portion and a plurality of narrow circumferential crests, said shoulder portion being located distally of the said narrow circumferential crests, and wherein the shoulder portion and the said narrow crests have substantially the same diameter as one another.

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