A61M 16/04 (2006.01)

Tubular body (2) comprises a proximate inflatable cuff (3) and a second cuff (4), with consequent coupling thereto of the tubular body (2). The invention comprises a tubular body (2) comprising a proximate inflatable cuff (3) and a second cuff (4), with consequent coupling thereto, to a ventilatory tube for procedures such as tracheotomy.


The invention is directed to a ventilatory tube (1) comprising a tubular body (2) adapted to assume the anatomical curvature of the upper respiratory pathways (A) and provided, at a substantially distal portion, with an inflatable cuff (3) for the hermetic occlusion of the respiratory pathways (A); the ventilatory tube (1) comprises an inflatable second cuff (4), arranged upstream of the first cuff (3) and proximate thereto, the distance in an axial direction with respect to the tubular body (2) between the first cuff (3) and the second cuff (4) being substantially similar to the thickness of the glottis (C), in the configuration for use the glottis (C) being interposed and clamped between the first cuff (3) and the second cuff (4), with consequent coupling thereto of the tubular body (2).

Abstract: A ventilatory tube (1) for procedures such as tracheotomy, which comprises a tubular body (2) adapted to assume the anatomical curvature of the upper respiratory pathways (A) and provided, at a substantially distal portion, with an inflatable cuff (3) for the hermetic occlusion of the respiratory pathways (A); the ventilatory tube (1) comprises an inflatable second cuff (4), arranged upstream of the first cuff (3) and proximate thereto, the distance in an axial direction with respect to the tubular body (2) between the first cuff (3) and the second cuff (4) being substantially similar to the thickness of the glottis (C), in the configuration for use the glottis (C) being interposed and clamped between the first cuff (3) and the second cuff (4), with consequent coupling thereto of the tubular body (2).
VENTILATORY TUBE FOR PROCEDURES SUCH AS TRACHEOTOMY

The present invention relates to a ventilatory tube for procedures such as percutaneous tracheotomy.

Tracheotomy is a procedure that consists in opening an air pathway in the trachea as an alternative to the natural air pathway. This procedure is routinely carried out on patients who require endotracheal intubation for periods, in general, longer than one week (e.g. in a prolonged coma), or at the start of surgical procedures to the head and to the neck which make intubation impossible.

Usually a tracheotomy is carried out on patients who are already intubated in order to avoid prolonging the intubation proper for too long: in fact ventilatory tubes can cause lesions or inflammation of those parts of the larynx or of the pharynx or of the trachea with which they come into contact.

Carrying out a percutaneous tracheotomy on patients who are intubated and subjected to mechanical ventilation is fraught with difficulty.

Patients who are to be subjected to tracheotomy are usually intubated and the tracheal tube is inserted about half-way between the larynx and the carina bifurcation.

The tracheal tube allocated in its correct position obstructs the execution of the percutaneous tracheotomy, which conversely needs free access to the trachea.

The anesthetized patient must compulsorily be ventilated mechanically and, in order to free the trachea, different procedures are adopted:

a) Retraction in the cranial direction of the endotracheal tube until the tracheal portion that is the target of the tracheotomy is freed.

This method, which is commonly adopted, has a high risk of extubation of the patient owing to excessive retraction of the tube; moreover, such retraction must be done until the tracheal cuff is positioned
so as to straddle the vocal cords (i.e. superimposed on the glottis C), effectively making it very precarious to hold the tracheal tube in position and maintain the proper pneumatic seal necessary for correct ventilation.

However, such maneuver requires the presence of a nurse to keep the tube in position during the procedure.

Moreover, a percutaneous tracheotomy, for reasons of procedural safety, is carried out viewed through a fiberscope (a fiberscope is a tube of diameter usually comprised between 6 mm and 10 mm and of variable length from 1 m up to over 20 m, constituted by a bundle of optical fibers. Thanks to the properties of fiber optics, the images are transmitted from one end to the other of the bundle), not least in order to control the risk of perforation of the rear tracheal wall owing to an incorrect maneuver.

Fiberscopes access the trachea through the internal lumen of the entrotracheal tube.

The reduction of the internal tracheal lumen obstructs the correct ventilation of the patient and therefore influences the clinical parameters of the patient.

b) Extubating the patient and positioning a laryngeal mask or other tube.

A laryngeal mask does not ensure protection of the air pathways from the inhalation of gastric juices or saliva and it does not make it possible to ventilate the patient at high pressures in the event of acute respiratory insufficiency.

Conventional tubes have considerable difficulties in their correct positioning in an area that does not interfere with the tracheotomy; the modest space available for executing the dilation, and for arranging the tracheostomy cannula, makes the procedure difficult, especially in the presence of size restrictions dictated by the anatomic morphology of the patient.

The aim of the present invention is to solve the above mentioned
drawbacks, by providing a ventilatory tube for procedures such as tracheotomy which allow the patient to ventilate correctly in conditions of the utmost safety.

Within this aim, an object of the invention is to provide a ventilatory tube for procedures such as tracheotomy which protects the air pathways from inhalation (for example of saliva, blood etc.).

Another object of the invention is to provide a ventilatory tube for procedures such as tracheotomy which can be correctly and easily arranged so as to leave free the tracheal space where the tracheotomy is to be performed.

Another object of the invention is to provide a ventilatory tube for procedures such as tracheotomy which is easy to hold in the correct arrangement without risks of accidental extubation.

Another object of the invention is to provide a ventilatory tube for procedures such as tracheotomy which can allow easy access of the fiberscope or other means of control and verification of the correct positioning and/or of the procedure being carried out.

Another object of the invention is to provide a ventilatory tube for procedures such as tracheotomy which protects the rear tracheal wall.

Another object of the invention is to provide a ventilatory tube for procedures such as tracheotomy which can be used to intubate a patient instead of a conventional entrotracheal tube, thus avoiding the maneuver of extubation and re-intubation, therefore resolving the limitations listed previously.

Another object of the invention is to provide a ventilatory tube for procedures such as tracheotomy which does not obstruct the insertion of the tracheostomy cannula into the trachea of the patient.

Another object of the invention is to provide a ventilatory tube for procedures such as tracheotomy which cannot be damaged by the surgical instruments used to make and widen the stoma into which the tracheostomy
cannula will be inserted.

Another object of the present invention is to provide a ventilatory tube for procedures such as tracheotomies which is low cost, easily and practically implemented, and safe in use.

This aim and these and other objects are achieved by a ventilatory tube for procedures such as tracheotomies, which comprises a tubular body adapted to assume the anatomical curvature of the upper respiratory pathways and provided, at a substantially distal portion, with an inflatable cuff for the hermetic occlusion of the respiratory pathways, characterized in that it comprises a second cuff, arranged upstream of said first cuff and proximate thereto, the distance in an axial direction with respect to said tubular body between said first cuff and said second cuff being substantially similar to the thickness of the glottis, in the configuration for use the glottis being interposed and clamped between said first cuff and said second cuff, with consequent coupling thereto of said tubular body.

Further characteristics and advantages of the invention will become better apparent from the detailed description that follows of a preferred, but not exclusive, embodiment of the ventilatory tube for procedures such as tracheotomies according to the invention, which is illustrated by way of non-limiting example in the accompanying drawings, in which:

Figure 1 is a schematic side view of a ventilatory tube for procedures such as tracheotomies according to the invention, in the configuration for use;

Figure 2 is a perspective view from above of a ventilatory tube for procedures such as tracheotomies according to the invention;

Figure 3 is a view from above of a ventilatory tube for procedures such as tracheotomies according to the invention;

Figure 4 is a perspective side view of a ventilatory tube for procedures such as tracheotomies according to the invention;

Figure 5 is a perspective side view of a particular embodiment of a ventilatory tube for procedures such as tracheotomies according to the
invention, provided with a shield appendage;

Figure 6 is a perspective side view of a particular embodiment of a ventilatory tube for procedures such as tracheotomy according to the invention, provided with a shield appendage that is also adapted for ventilation.

With reference to the figures, the reference numeral 1 generally designates a ventilatory tube for procedures such as tracheotomy.

The ventilatory tube 1 comprises a tubular body 2 adapted to assume the anatomical curvature of the upper respiratory pathways A of a patient B.

In particular the tubular body 2 can have a radius of curvature comprised between 90 mm and 160 mm, although the embodiments that conform closest to the scopes of application are those defined by intermediate radii of curvature with respect to such interval/range (values comprised between 105 mm and 135 mm are therefore preferred).

It should be noted that a specific embodiment of a tubular body 2 according to the invention has a radius of curvature of 120 mm.

The possibility is not ruled out of an embodiment in which the tubular body 2 is straight (in the inactive configuration), but can easily be subjected to bending (for example, elastic): therefore a material must be chosen that is adapted to be easily bent and which therefore has scant mechanical rigidity (therefore ease of deformability) in order to allow adaptation to the anatomical curvature of the upper respiratory pathways A of the patient B.

The tubular body 2 is provided, at a substantially distal portion (sub-glottis portion), with an inflatable first cuff 3 for the hermetic occlusion of the respiratory/air pathways A (it should be noted that in the present description the terms respiratory pathways A and air pathways A will be used interchangeably to define the area affected by the ventilatory tube 1, which is defined by the mouth, pharynx, larynx and trachea of the patient B).

Substantially, when the ventilatory tube 1 is correctly inserted in the
air pathways A of the patient B, the inflation of the first cuff 3 causes its expansion with total hermetic occlusion of the section of trachea in which it is arranged, ensuring that the flow of air can occur only through the tubular body 2.

The ventilatory tube 1 further comprises a second cuff 4, arranged in the supra-glottic area upstream of the first cuff 3 and proximate thereto.

The second cuff 4 can also be inflatable or it can be made of a material with high elastic deformability (for example an expanded foam or the like).

For the purposes of defining the anatomical area where they are intended to be arranged, it should be noted that the first cuff 3 can be correctly defined as the distal sub-glottis cuff, while the second cuff 4 can be correctly defined as the proximal supra-glottis cuff.

The distance, in the axial direction with respect to the tubular body 2, between the first cuff 3 and the second cuff 4 must be substantially similar to the thickness of the glottis C: in the configuration for use, the glottis C will be interposed and clamped between the first cuff 3 and the second cuff 4, with consequent coupling to the glottis C of the tubular body 2 which will therefore be unable to translate (with consequent extraction or further insertion). Thus the glottis C is clamped.

The glottis C is the intermediate segment of the larynx at the vocal cords.

The glottis is located at the height of the larynx, which is the organ for phonation. It is constituted for the most part by a cartilage skeleton divided into three sections: the cricoid, the arytenoid and the thyroid.

The tubular body 2 comprises at least one first internal longitudinal lumen 5 in which the proximal end 6 is suitable for coupling to a connector 7 of a ventilation duct and the distal end 8 protrudes with respect to the first cuff 3.

Similarly, the tubular body 2, in conformance with an embodiment of
undoubted applicative interest, comprises at least one second internal longitudinal lumen 9, in which the proximal end 10 and the distal end 11 are open in order to allow the insertion in such second lumen 9, through the opening of the proximal end 10, of a substantially wire-like instrument. Once insertion has occurred the head of such substantially wire-like instrument will be substantially facing the opening of the second (distal) end 11 of the second lumen 9.

The wire-like instrument can be selected from a plurality of instruments designed to carry out different functions: it should be noted that an optical instrument will be used which makes it possible to analyze and monitor all the steps of the subsequent tracheotomy that has to be carried out on the patient. The possibility is not ruled out that the optical instrument can comprise specific light sources in order to allow a clearer and fuller view for the medical personnel.

With particular reference to an embodiment of undoubted practical interest, the first cuff 3 (which, as mentioned previously, can also be defined as the distal sub-glottis cuff, i.e. distal with respect to the position it assumes in the configuration for use) can have an outside diameter, in the fully inflated configuration, comprised between 20 mm and 32 mm.

The indicated interval of diameters is rather wide, as a function of the variability of the anatomical size parameters of the patients B who might need the ventilation tube 1; it should be noted that, preferably, the diameter of the first cuff 3 will be selected from the sub-range comprised between 27 mm and 29 mm (a diameter of 28 mm identifying the intermediate condition of greatest applicative interest).

Similarly the second cuff 4 (which, as mentioned previously, can also be defined as the proximal supra-glottis cuff, i.e. proximal with respect to the position that it assumes in the configuration for use) will have an outside diameter, in the fully inflated configuration (or fully expanded configuration if it is made of a soft and elastically deformable material, with high
compressibility), comprised between 15 mm and 30 mm.

Also in this case, the indicated interval of diameters is rather wide, as a function of the variability of the anatomical size parameters of the patients who might need the ventilation tube 1: it should be noted that, preferably, the diameter of the second cuff 4 will be selected from the sub-range comprised between 21 mm and 23 mm (a diameter of 22 mm identifying the intermediate condition of greatest applicative interest).

The second cuff 4 will usually have a smaller diameter than that of the first cuff 3 since it is not intended to occlude the trachea but is only there to constitute an abutment shoulder, a locator, that prevents the medical operators from inserting the tubular body 2 beyond a condition of ideal alignment of the ventilatory tube 1 (the condition for ideal alignment corresponds to the interposition of the glottis C between the first cuff 3 and the second cuff 4).

The second cuff 4, in fact, in the insertion step, will collide (delicately, as is obvious, given the type of insertion operation carried out by medical personnel) with the glottis C: the medical personnel will therefore perceive an arrest of the insertion of the ventilation tube 1 and will desist from further pushing since the second cuff 4 will have already assumed its ideal arrangement, resting on the upper wall of the glottis C.

With regard to the correct clamping of the glottis C between the first cuff 3 and the second cuff 4, it should be noted that the distance between the first cuff 3 and the second cuff 4 is comprised between 4 mm and 20 mm.

The indicated interval of distances is rather wide, as a function of the variability of the anatomical size parameters of the patients who might need the ventilation tube 1: it should be noted that, preferably, the distance between the first cuff 3 and the second cuff 4 will be selected from the sub-range comprised between 8 mm and 12 mm (a distance of 10 mm identifying the intermediate condition of greatest applicative interest).

It should also be noted that the thickness of the first cuff 3 (i.e. its
space occupation in the axial direction with respect to the axis of the tubular body 2) is comprised between 12 mm and 35 mm.

The indicated interval of thicknesses is rather wide, as a function of the variability of the anatomical size parameters of the patients who might need the ventilation tube 1: it should be noted that, preferably, the thickness of the first cuff 3 will be selected from the sub-range comprised between 15 mm and 21 mm (a thickness of 18 mm identifying the intermediate condition of greatest applicative interest), in order to avoid invading the anatomical area targeted for the subsequent tracheotomy, while still ensuring the necessary pneumatic seal.

Within such size parameters, it should be noted that the thickness of the second cuff 4 (i.e. its space occupation in the axial direction with respect to the axis of the tubular body 2) must also be conveniently selected from a respective range comprised between 5 mm and 35 mm.

The indicated interval of thicknesses is rather wide, as a function of the variability of the anatomical size parameters of the patients who might need the ventilation tube 1: it should be noted that, preferably, the thickness of the second cuff 4 will be selected from the sub-range comprised between 7 mm and 13 mm (a thickness of 10 mm identifying the intermediate condition of greatest applicative interest).

If both cuffs 3 and 4 are inflatable, it should be noted that the walls of the tubular body 2 comprise at least one first channel 12 which leads to the first cuff 3 and at least one second channel 13 which leads to the second cuff 4: the first channel 12 and the second channel 13 comprising, at their proximal portions, respective connectors (respectively 14 and 15) for connection to inflation apparatuses.

If the second cuff 4 is made of deformable material (and therefore easily deformable following the compression generated in the intubation step), then only the first cuff 3 (the only one that is inflatable, therefore) will have a respective channel 12 for inflation which is associated with a
respective connector 14.

According to an embodiment which is particularly advantageous in that it is adapted to facilitate the successive steps of the tracheotomy, the distal front 16 of the tubular body 2 has an oblique end face (i.e. shaped substantially like the mouthpiece of a recorder), in order to prevent trauma in the step of insertion of the ventilatory tube 1 (intubation) and in order to minimize encumbrances with respect to conventional tubes.

In any case the maximum overall protrusion of the distal front 16 with respect to the first cuff 3 will be preferably comprised between 1 mm and 15 mm.

The indicated interval of protrusions is rather wide, as a function of the variability of the anatomical size parameters of the patients who might need the ventilation tube 1: it should be noted that, preferably, the protrusion of the distal front 16 from the first cuff 3 will be selected from the sub-range comprised between 8 mm and 12 mm (a protrusion of 10 mm identifying the intermediate condition of greatest applicative interest).

The protrusion of the distal front 16 from the first cuff 3 is defined as the distance between its end tip and the distal face of the first cuff 3.

A minimal protrusion implies that the distal front 16 cannot interfere with the subsequent percutaneous tracheotomy.

It should further be noted that the distal front 16 of the tubular body 2 can conveniently accommodate a light source powered by means of an electrical cable associated with the side walls of the tubular body 2.

The electric cable, in turn, can be connected, at its proximal portion, to an electric power supply unit (for example the mains electricity supply or an accumulator battery).

Such light source can preferably be constituted by an LED (which, since it does not produce heat, cannot cause any harm to the patient B): the purpose of the light source is that it can be used as a transilluminator that allows the medical operators to view (transparently with respect to the
tissues of the patient B) the blood vessels (in order to execute the tracheotomy in conditions of the utmost safety, and also to have confirmation of the correct positioning).

The use of an LED light source is preferable in that such devices do not generate heat and they can produce light beams of particular intensity which can be variously oriented and/or concentrated.

It should be noted that the second lumen 9, which is intended to accommodate instruments such as video cameras or other image acquisition devices, could also comprise respective (and optionally further) light sources.

According to a particular embodiment that is specifically designed to safeguard the inner wall of the trachea of the patient from accidental contact with the instruments used to carry out the tracheotomy, the distal front 16 of the tubular body 2 can preferably comprise a protruding flattened lower portion 17.

The maximum overall protrusion of the flattened lower portion 17 with respect to the first cuff 3 is comprised between 5 mm and 100 mm.

The flattened portion 17 constitutes a protective shield for the inner surface of the trachea, in order to avoid accidental contact with the instruments used during tracheotomy.

In essence the flattened portion 17 is shaped substantially like a spoon (with shape and dimensions complementary to those of the interior of the trachea) so as to be arranged parallel to the inner surface of the trachea, proximate thereto, thus defining a form of protective shield.

With particular reference to the embodiment described previously, it should be noted that the flattened portion 17 can also be hollow and the corresponding internal cavity will be connected to the distal end 8 of the first internal longitudinal lumen 5.

In this manner the flattened portion 17, in addition to acting as a protective screen or shield, will also constitute the end part of the at least
one first internal longitudinal lumen 5 and therefore it will be designed for the ventilation of the patient B.

According to a specific embodiment, the flattened portion 17 can be made of a deformable material, such as for example an elastomer, a silicone or the like.

The appendage 17 will therefore usually be bent inside the internal lumen 5 in order to facilitate the intubation operations.

Once the patient B has been correctly intubated, the surgeon proceeds with the extraction (eversion) of the appendage using a wire-like instrument (for example a mandrel) which, inserted into the lumen 5, will push the appendage 17 outside.

The appendage 17 can thus carry out the intended function of protecting the wall of the trachea.

The method of using the ventilation tube 1 according to the invention is as follows.

Firstly, if it is already present, it will be necessary to remove the endotracheal tube already present inside the air pathways A of the patient B.

The medical operator then proceeds to partially insert the ventilation tube 1 with the cuffs 3 and 4 (in the configuration in which they are both deflated or in the configuration in which the cuff 3 alone is deflated since the cuff 4 is made of easily deformable material), until the first cuff 3 has traveled past the tongue.

The medical operator proceeds to inflate the second cuff 4 or, if it is made of easily deformable material, will see the expansion thereof until it at least partially occludes the trachea upstream of the glottis C.

At this point it will be possible to proceed to insert the ventilation tube 1 further until a resistance to insertion is perceived, corresponding to the abutment of the second cuff 4 against the upper surface of the glottis C.

At this point the medical operator has to inflate the first cuff 3, clamping the glottis C of the patient B between it and the second cuff 4.
Optionally, it is possible to carry out each single step of the operations described previously and/or of the subsequent tracheotony using an optical sensor; or a laryngoscope provided with image acquisition means (still cameras, video cameras, optical sensors and the like).

Advantageously the ventilatory tube 1 allows the patient B to ventilate correctly in conditions of the utmost safety.

Profitably the ventilatory tube 1 protects the air pathways from inhalations (for example of saliva, blood etc.).

Positively the ventilatory tube 1 can be correctly and easily positioned so as to leave free the tracheal space where the tracheotomy is to be performed.

Profitably the ventilatory tube 1 is easy to hold in the correct arrangement without risks of accidental extubation.

It is not of secondary importance to note that the ventilatory tube 1 can allow easy access of a fiberscope or other means of control and verification of the correct positioning and/or of the procedure being carried out.

It is worthy of note that the ventilatory tube 1 protects the rear tracheal wall.

It is also of considerable interest that the ventilatory tube 1 can be used to intubate a patient instead of a conventional entrotracheal tube, thus avoiding the maneuver of extubation and re-intubation, therefore resolving the limitations listed previously.

It is also emphasized that the ventilatory tube 1 does not obstruct the insertion of the tracheostomy cannula into the trachea of the patient.

Conveniently the present invention solves the above mentioned drawbacks, by providing a ventilatory tube 1 for procedures such as tracheotomy which does not obstruct the insertion of the tracheostomy cannula into the trachea of the patient B.

In fact the trachea of the patient B is almost completely free since the
ventilation tube 1 ends substantially at the glottis C.

It is therefore possible for the medical personnel to carry out a tracheotomy even at the space defined between the first and second tracheal rings, without risking (or in any case minimizing such risk) that the ventilation tube 1 could interfere with or obstruct such activity.

Advantageously the ventilatory tube 1 cannot be damaged by the surgical instruments used to make and widen the stoma into which the tracheostomy cannula will be inserted.

In fact the tracheotomy will be carried out downstream of the distal front 16 of the tubular body 2 and therefore it is not possible for the instruments used in such operation to damage the ventilation tube 1 proper (for example by perforating or cutting the cuff as can happen with the ventilation tubes of the conventional type).

Positively the ventilatory tube 1 is particularly safe and cannot be subjected to involuntary extubation.

In fact the clamping of the glottis C performed by the two cuffs 3 and 4 makes it possible to stably immobilize the ventilation tube in the operating configuration on the patient B.

Positively the ventilatory tube 1 according to the invention can be easily produced at low cost, ensuring that it will certainly find application on the market.

The invention, thus conceived, is susceptible of numerous modifications and variations, all of which are within the scope of the appended claims. Moreover, all the details may be substituted by other, technically equivalent elements.

For example the second lumen 9 can stably accommodate an optical instrument, of the type of a sensor, a still camera, a video camera, a wire-like element made of optical fiber for transferring images to an external unit and the like.

In this manner the ventilatory tube 1 could constitute a complete,
disposable aid that would not necessitate other instruments in order to be capable of being used as an aid during a tracheotomy.

At the same time such optical instrument can also be used to supply electric power to the light source (preferably constituted by an LED) arranged on any portion of the distal front 16 or of the flattened portion 17. The possibility is not ruled out that the light source can be directly embedded in the optical sensor (and/or associated therewith).

In the embodiments illustrated, individual characteristics shown in relation to specific examples may in reality be interchanged with other, different characteristics, existing in other embodiments.

In practice, the materials employed, as well as the dimensions, may be any according to requirements and to the state of the art.

The disclosures in Italian Patent Application No. BO2014A000723 (1020149023 18767) from which this application claims priority are incorporated herein by reference.

Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly, such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.
CLAIMS

1. A ventilatory tube for procedures such as tracheotomy, which comprises a tubular body (2) adapted to assume the anatomical curvature of the upper respiratory pathways (A) and provided, at a substantially distal portion, with an inflatable cuff (3) for the hermetic occlusion of the respiratory pathways (A), characterized in that it comprises a second cuff (4), arranged upstream of said first cuff (3) and proximate thereto, the distance in an axial direction with respect to said tubular body (2) between said first cuff (3) and said second cuff (4) being substantially similar to the thickness of the glottis (C), in the configuration for use the glottis (C) being interposed and clamped between said first cuff (3) and said second cuff (4), with consequent coupling thereto of said tubular body (2).

2. The ventilatory tube according to claim 1, characterized in that said tubular body (2) comprises at least one first internal longitudinal lumen (5) in which the proximal end (6) is suitable for coupling to a connector (7) of a ventilation duct and the distal end (8) protrudes substantially with respect to said first cuff (4).

3. The ventilatory tube according to claim 2, characterized in that said tubular body (2) comprises at least one second internal longitudinal lumen (9), in which the proximal end and the distal end are open for the insertion in said second lumen (9), through the opening (10) of the proximal end, of a substantially wire-like instrument, once insertion has occurred the head of said substantially wire-like instrument substantially facing the opening (11) of said distal end of said second lumen (9).

4. The ventilatory tube according to claim 1, characterized in that said first cuff (3) has a maximum outside diameter, in the fully inflated configuration, comprised between 20 mm and 32 mm, preferably between 27 mm and 29 mm.

5. The ventilatory tube according to claim 1, characterized in that said second cuff (4) has a maximum outside diameter, in the fully expanded
configuration, comprised between 15 mm and 30 mm, preferably between 21 mm and 23 mm.

6. The ventilatory tube according to claim 1, characterized in that the distance between said first cuff (3) and said second cuff (4) is comprised between 4 mm and 20 mm, preferably comprised between 8 mm and 12 mm.

7. The ventilatory tube according to claim 1, characterized in that the thickness of said first cuff (3) is comprised between 12 mm and 35 mm, preferably comprised between 15 mm and 21 mm.

8. The ventilatory tube according to claim 1, characterized in that the thickness of said second cuff (4) is comprised between 5 mm and 35 mm, preferably comprised between 7 mm and 13 mm.

9. The ventilatory tube according to one or more of the preceding claims, characterized in that the walls of said tubular body (2) comprise at least one first channel (12) which leads to said first cuff (3) and at least one second channel (13) which leads to said second cuff (4), said first channel (12) and said second channel (13) comprising, at their proximal portions, respective connectors (14, 15) for connection to inflation apparatuses.

10. The ventilatory tube according to one or more of the preceding claims, characterized in that the distal front (16) of said tubular body (2) has an oblique end face, shaped substantially like the mouthpiece of a recorder, the maximum overall protrusion of said distal front (16) from said first cuff (3) being comprised between 1 mm and 15 mm, preferably comprised between 8 mm and 12 mm.

11. The ventilatory tube according to one or more of the preceding claims, characterized in that the distal front (16) of said tubular body (2) accommodates a light source that is powered by means of an electrical cable associated with the side walls of said tubular body (2) and connected, at its proximal portion, to an electric power supply unit.

12. The ventilatory tube according to one or more of the preceding claims, characterized in that the distal front (16) of said tubular body (2)
comprises a protruding flattened lower portion (17), the maximum overall protrusion of said flattened lower portion (17) from said first cuff (3) being comprised between 5 mm and 100 mm, said flattened portion constituting a protective shield for the inner surface of the trachea, in order to avoid accidental contact with the instruments used during tracheotomy.

13. The ventilatory tube according to claim 12, characterized in that said flattened portion (17) is hollow and the corresponding internal cavity is connected to the distal end (8) of said first internal longitudinal lumen (5).
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M16/04

According to International Patent Classification (IPC) or to both national classification and IPC:

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols):
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched:

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used):

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:
  - "A" document defining the general state of the art which is not considered to be of particular relevance
  - "E" earlier application or patent but published on or after the international filing date
  - "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  - "O" document referring to an oral disclosure, use, exhibition or other means
  - "P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search: 14 March 2016

Date of mailing of the international search report: 21/03/2016

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Authorized officer:
Cecchi, Stefano
## INTERNATIONAL SEARCH REPORT

**DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
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