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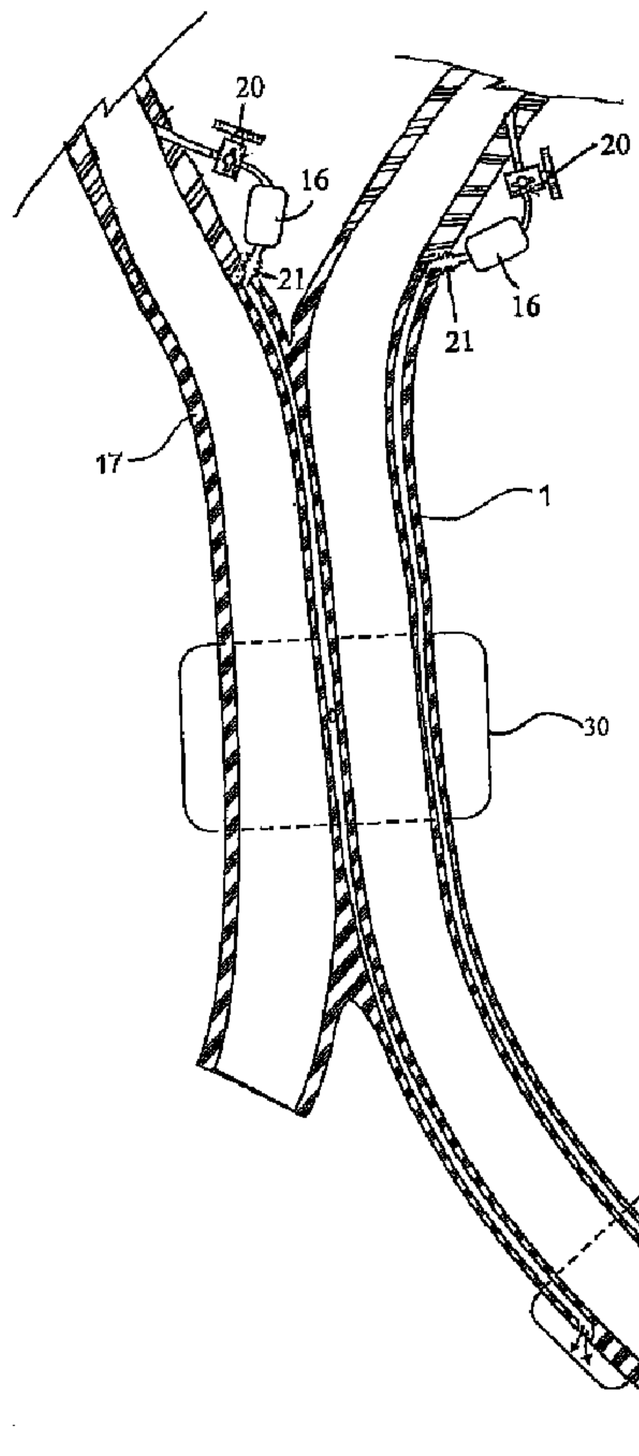


(57) Abrégé/Abstract:
A probe for medical use comprising a tube and a cuff located around the tube in a region of its external wall, the cuff being inflatable through a conduit arranged at the wall of the tube, linking the interior of the tube to the interior of the cuff, the inflation and deflation of the cuff being determined by the rhythms of the inspiration and expiration of air, respectively.

ABSTRACT

A probe for medical use comprising a tube and a cuff located around the tube in a region of its external wall, the cuff being inflatable through a conduit arranged at the wall of the tube, linking the interior of the tube to the interior of the cuff, the inflation and deflation of the cuff being determined by the rhythms of the inspiration and expiration of air, respectively.

A PROBE FOR MEDICAL USE

Field of Invention

The present invention relates to a probe for intubation of patients in several medical/surgical procedures (for example, oro- and nasotracheal, tracheotomy intubation probe, etc.) of the type basically consisting of a tube through which air is supplied into a patient's body, and an inflatable cuff used for preventing extravasation of the supplied air, causing the air flow to go in and out always through the tube (and not through the region between the tube and the intubated tubular organ); for controlling the internal pressure of the airways and further for fixing the probe to the walls of a passageway of the human body, and located around part of the external wall of the tube.

Description of the Prior Art

Several types of probes, which are used for intubating patients, are known.

A serious drawback of the probes of the prior art is that said cuff, which accounts for fixing the probe at a determined place on the human body, remains inflated throughout the intubating period, which may cause injuries to the patients if said period is prolonged, by reason of the total or partial stoppage of blood circulation in the region where the cuff exerts pressure on the walls of the passageway of the human body where the intubation is made, for example, the trachea of a patient. Moreover, in some cases, the cuff is inflated by inserting a fluid (usually iodine) into it by means of a syringe. This procedure is not carried out in a totally precise and safe way. Excessive inflation of the cuff is another factor that contributes to the occurrence of said mentioned injuries.

Moreover, in the case of the probes of the prior art, the conformation of the probe for introduction into the human body is carried out with the help of a metallic thread, inserted into the probe tube. The insertion of the metallic thread into the

probe tube may damage some organ or some tissue of the patient, in case the metallic thread exceeds the length of the probe tube.

U.S. Patent No. 4,697,574 deals with a coronary and circulatory assistance pump that uses cuffs for blocking the aorta and the coronary arteries in diastole. According to that patent, the passageway for blood from the aorta is kept opened by means of a system of two cuffs that are sequentially inflated and deflated, the sequence being determined by signals from an electrocardiogram apparatus, which are used as commands for sequentially inflating and deflating the two cuffs for the purpose of never interrupting the flow of blood in the aorta, which would obviously cause the death of the patient. This solution, however, besides being specific for use in the aorta, is of technically complex construction, needing two cuffs and, chiefly, imposing an artificial rhythm of opening and closing of the blood-circulation passageway, which is undesirable from the physiological point of view.

U.S. Patent No. 4,791,923 relates to a tracheal probe composed of an outer cuff and an inner cuff, the latter being located inside the outer cuff, said cuffs being non-physiologically inflated by conduits. Since they are very thin, they only work under high pressure. Further, these cuffs do not inflate if they are connected to the lumen of the tube. This probe has the purpose of sealing the trachea completely with the outer cuff during inspirations and expiration in pressure peak periods, without letting the gases leak. However, due to the elasticity of the trachea and its consequent dilatation, the inflated gases leak.

Document EP-A-0,766,976 describes a probe with only one suction system. This probe prevents contamination and respiratory problems during the suctions, as well as carries out these suctions uninterruptedly. Since it has an internal cannula for suction, the probe lumen is reduced. Said probe dispenses with the use of a connector with the Y for introduction of the suction catheter.

WO-A-99/38548 relates to a probe that has a suction system for aspirating secretions from the trachea. This probe does not have a valve or tap that connects

the internal and external aspirations. Such aspirations could be effected simultaneously or alternatively, in case the probe had a valve.

U.S. Patent No. 5,452,716 describes a tracheal tube for assisting the breathing of patients with respiratory insufficiency, as long as they are with their breathing under control.

Document WO-A-99/66975 describes an intratracheal ventilation catheter. In this catheter, the whole sucked air passes though the cuff, with the flow of air to the distal end of the catheter until it reaches the trachea, and the expired air is made outside the tube since its distal end is elastic and extensible.

U.S. Patent No. 6,463,927 describes a guide for an endotracheal tube made from a plastic material containing a bendable rod inside it.

French document FR-A-2,826,283 describes an endotracheal medical surgical probe adaptable to all patients' morphologies.

U.S. Patent No. 5,315,992 describes a probe with a mechanism that is intended to make the pressure value in the cuff equal to that of the airway.

Objectives of the Invention

An objective of the present invention is to prevent injuries caused by prolonged intubation of a patient with a probe provided with an inflatable cuff.

Another objective of the present invention is to provide more tranquility to the physician in performing surgeries that require a longer time for intubating the patient, as well as to provide a suitable probe for facilitating intubation in emergency situations.

A further objective of the present invention is to prevent possible injuries caused by inserting the metallic thread into the tube in order to conform the probe.

The invention has also the objective of preventing the use of a laryngoscope.

A further objective of the present invention is to prevent the cuff from being excessively inflated, which would cause injuries to the patient.

Another objective of the invention is to provide a probe especially for patients who remain intubated for a long time.

The above-described objectives of the invention are achieved by means of the probe that will be described in greater detail later.

Summary of the Invention

The present invention has achieved the above-cited objectives by means of a probe for medical use, which basically consists of a tube designed for receiving blown air, and a first cuff arranged around the tube in a region of its external wall, said first cuff being inflatable by means of a first conduit located at the tube wall, which account for communication of the inside of the first cuff with the inside of the tube. Thus, the insufflation of the first cuff is commanded by the flow of air injected into the tube during the aspiratory movement, causing the probe to be fixed to the walls of the passageway of the human body that is being intubated; whereas the deflation of said first cuff takes place when the air is expelled from the patient's lung through the tube during the expiratory movement. This causes the first cuff to deflate temporarily, thus alleviating the mechanical pressure on the walls of said passageway of the human body and making blood circulation possible until a new flow of air is injected, which may come from an artificial breathing apparatus or from the normal breathing of the patient.

Thus, said first cuff is inflated during the inspiration and deflated during the expiration at the natural rhythm of the patient's respiration or artificial breathing apparatus. In this way the above-mentioned problems of the prior art are eliminated and the probe of the present invention has an ideal performance from the physiological point of view. Further, said first cuff may be inflated from a conduit that is not connected to the tube lumen, but rather to one of the legs of the Y connector, connected to the probe or else directly from a source coming from the respirator or another mechanism that follows the same cycle of the respirator.

According to a preferred embodiment of the invention, the probe further comprises means that provide the tube with an elastic memory, located on the tube wall and consisting of a guide thread made of a radiopaque flexible and malleable material. Such means simultaneously allow one to mold the probe tube and to view

the probe on an X-ray photograph, for instance, besides enabling one to mould the probe, adapting its exit from the mouth, nose or tracheotomy orifice, to prevent known lesions caused by probes to lips, gums, teeth, tongue, nose wings and neighboring structures of the tracheotomies. These means having elastic memory enable a simple, rapid non-traumatic intubation, and even without laryngoscope.

According to another embodiment of the invention, the probe for medical use comprises, in addition to the first tube, the first cuff and the first conduit in the tube wall that communicates the interior of the tube with the interior of the cuff, a second and a third conduits in the tube wall, which extend along the length of the tube and are couplable to an external aspiration device.

The second conduit has bores close to an end, which provide communication of the inside of the second conduit with the inside of the tube, the other end being connectable to a suction device, thus allowing the secretions existing inside the probe tube to be sucked, which prevents the tube from being clogged. The orifices remain in the back wall of the tube, at a distance of 1 centimeter from each other and extend from the cuff to the distal end of the tube. Their diameters are equal to or smaller than that of the conduit that has given rise to them.

The third conduit, on its turn, has bores close to one of its ends, which provide communication of the inside of the third conduit with the external region of the tube, the other end being connectable to a suction device, so that the secretions existing inside the tube can also be sucked. The orifices also remain in the back wall of the tube that is related to the back wall of the trachea, have a diameter equal to or smaller than that of the conduit that has given rise to them, and are in number of three in the oropharynx and three in the trachea, over the cuff by one centimeter when the latter is totally inflated, and are away from each other by 1.5 centimeters.

In addition, the second and third conduits are connectable by their ends to a first 3-way connection means, coupled to the external suction device and provided with a switch that permits suction at each of the conduits separately or at both conduits at the same time. In this way, depending upon the position of the switch,

either the secretions existing inside the tube can be sucked (through the second conduit) or the secretions existing in the external region of the tube (through the third conduit), as well as the secretions of both regions at the same time.

According to an embodiment of the present invention, the first conduit is connectable to a second 3-way connection means, provided with a switch that enables one to control the operation mode of the probe. In this way, the probe may also be used in the conventional manner, with non-physiological pressure, depending upon the position of the switch. In this case, the cuff is inflated by injecting a fluid into one of the ways of the connection means and remains permanently inflated.

The probe is further provided with a second monitoring cuff, located around the first conduit, also linked to the inside of the first conduit in the region close to the opening of the tube that receives air insufflation, which is inflated and deflated at the same rhythm as the inflation and deflation of the first cuff takes place. The second cuff is used for monitoring the functioning of the first cuff, since it will only be inflated if the first cuff is intact. It is mainly used as a hypertension relief valve, since the cuff is elastic and extensible, absorbing any excess pressure, so that the cuff, at most, only rests against the trachea without damaging it. The trachea is more resistant than the satellite cuff (or second cuff). For this reason, the satellite cuff expands and even blows out in cases of too high pressure.

Another probe embodiment is also provided, the probe having two tubes coupled side by side, one of them being longer than the other, permitting selective insufflations of one lung, for example, by connecting an artificial breathing apparatus to one of the probe tubes and simultaneously inflating the first cuffs of each tube, the first cuff of the first tube being close to the bronchia, and the first cuff of the second tube being in the trachea region, surrounding the two tubes altogether. For this purpose, the air outlet of the tube cuff that is not connected to the artificial breathing apparatus should be kept closed. If, on the other hand, one wishes to effect the selective inflation of the other lung, for example, one connects

the artificial breathing apparatus to the other tube, closing the air outlet of the tube cuff that is not connected to said breathing apparatus.

Differences between the present invention and the relevant prior arts

In order to facilitate a better understanding of the present invention and to point out the differences of the present medical probe related to the relevant prior art documents, a description is done below:

Document U.S. Patent No. 4791923 relates to a probe composed of two balloons (cuffs), an inner one and an outer one. According to this document, the expired air comes out through the inside of the probe and not through the outside. In addition, the outer cuff, according to the shape of the connector and by the tube gage, needs high pressure to be expanded, which would cause the trachea to expand as well and the air to leak out of the probe, leading the pressure not to rise and the outer cuff not to inflate.

Unlike this, the present invention defines a probe with a single cuff, which inflates totally in inspiration before the gases reach the probe tip.

In U.S. Patent No. 4791923, the inflation of the inner cuff is effected with a syringe, and it remains inflated, closed by a valve. One of the problems of this probe lies in the fact that, when inflating the cuff, it is empirically tried to use the lower positive ventilation pressure. All the conventional probes have their cuffs inflated in this way, with the same concern and care. However, this does not occur in practice. Nobody manages to known for sure if the pressure and the volume of air that is being used is only the minimum necessary for causing the cuff to rest against the trachea. If it were so, there would not be the problems of trachea necrosis due to the “careful” inflations of the probe cuffs with low pressure. In practice, the result

is catastrophic. In addition, in the probe of U.S. Patent No. 4791923, the outer cuff increases the resistance to the inflation of the inner cuff, requiring higher pressure for its inflation, which aggravates the trauma on the trachea. Another important detail is that only the outer cuff is connected to the inside of the probe for the only purpose of preventing gas leakage (peri-cuff) during the peak pressure periods. However, soft the material may be, it will become rigid due to the duplication, since the inner cuff remains inflated, being harmful to the trachea wall. All of this is theoretical, since in practice it will only be possible to inflate the outer cuff, if its conduit has about 1/3 of the probe caliber. For this purpose, the caliber of its conduit has to be quite wider than that of the inner cuff, and it may not be cylindrical, otherwise it would be too thin, in the face of the thickness of the probe wall. It should preferably be convexo-concave, following the thickness form of the tube wall, occupying or even replacing a large part of the probe wall, which is not said or represented in the document in question. Figure 3 of U.S. Patent No. 4791923 shows the inadequateness of the calibers of the cuff conduits, especially of the outer cuff, which may not be equal to each other and whose caliber, as explained, has to be wide, otherwise it will not function.

There is no connection of the tracheal tube with the conduit of the outer cuff, but rather with an L-shaped connector at 90°. In the present invention, the conduit of the cuff has its proximal orifice in the inner face of the probe itself or alternatively in a Y-shaped connector with the angle in the direction of the inspiration air flow. If the cuff conduit is located in the probe itself, this makes it much more simple and functional than if the conduit is connected to one of the legs of the Y. Therefore, the probe of U.S. Patent No. 4791923 does not foresee the outlet of the cuff conduit in its inner face and only in the connector, and at a right angle.

In addition, the 90-degree angle is inappropriate, rendering difficult the inflation of the outer cuff and may even lead to the aspiration thereof, instead of inflating it, due to the preferred flow of air inspired by the lumen of the endotracheal

tube. If this angle of the connector is larger than 90 degrees, that is to say, in Y whose single leg is the one that connects the end of the endotracheal tube, thus remaining contrary to the flow of inspired air, there will invariably be aspiration of the outer cuff during the inspiration and the subsequent inflation in the expiration. In this way, the objective of sealing the tracheal in inspiration will never be achieved.

If the absorption cartridge (U.S. Patent No. 4791923, column 5 line 68) is interposed between the cuff conduit and the connector, it will be virtually impossible to inflate the outer cuff. The air of the ventilation will probably be directed completely to the lumen of the endotracheal tube due to the lower pressure. This can be easily verified by placing a satellite cuff in the cuff conduit, in its free part of the endotracheal tube, as can be verified in the present invention.

The inner cuff, which always remains inflated, cannot avoid brochoaspiration, as stated in U.S. Patent No. 4791923, since all the secretion existing inside and outside the probe will slowly pass into the bronchi, between the cuff and the trachea, mainly when the latter distends. This secretion, which is never aspirated by the health professional, also reaches the lungs at the moments when the cuff is deflated and at the moment of extubation.

As described in document U.S. Patent No. 4791923, the lungs are inflated, the trachea increases the caliber and remains free of contact with the inner cuff. If the inner cuff were kept inflated, the intratube pressure would increase, and the pressure would be insufficient to fill the outer cuff, which would seal the trachea, preventing the waste of gases. It is at this determined point that the problem

appears. Indeed, at the end of the inspiration, much of the gas inspired passes externally between the cuff and the trachea, and such pressure should not rise inside the tube. Thus, the outer cuff would not inflate. In fact, in order for the outer cuff to be inflated, as proposed in the probe of U.S. Patent No. 4791923, the inner cuff has to be inflated with high pressure and volume, distending the trachea and preventing per se the leakage of the gases, rendering unnecessary the existence of the outer cuff.

The probe of U.S. Patent No. 4791923 also do not have a satellite outer cuff connected to the cuff conduit to monitor the filling thereof. The probe of the present invention has such satellite cuff and, besides, it represents one of the most important aspects of this probe: it is characterized by being elastic and distensible, absorbing any excess pressure that occurs in the system, and can even break open, thus causing the system to remain open and the cuff to deflate, before any barotrauma can occur in the trachea or in any segment of the respiratory tree. If the cuff is entire and does not inflate in the inspiration, this will mean that the inner cuff has a leakage and the probe needs to be replaced.

In U.S. Patent No. 4791923, it is argued that, in order to achieve ventilation with positive pressure, it is necessary that the inner cuff should always be inflated. This is not true. In the probe of the present invention, with the cyclic

filling cuff, which inflates and deflates totally at each respiratory cycle, inspiration-expiration, it is entirely possible to make ventilation with positive pressure, including PEEP (Positive End Expiratory Pressure), permitting any mode of ventilation assistance.

In fact, the only concern of the inventor of U.S. Patent No. 4791923 is with the waste of gases upon increase of the pressure in the respiratory tree, due to the distension of the trachea and its consequent displacement from the probe cuff. Unfortunately, not even this objective was achieved by the probe described therein. The probe of the present invention, besides preventing any waste of gases, further prevents barotraumas of the trachea and bronchi, prevents bronchoaspiration, facilitates intubation and provides aspiration of the internal and external secretions of the probe, among others.

Document EP 0766976 A2 relates to a probe with only an aspiration system situated inside it. This probe prevents contamination and respiratory problems during aspirations, as well as performs these aspirations without interruption of the ventilation. The aspiration system, besides being only internally, has many orifices, which causes the uppermost orifices not to be submerged in the secretion which is to be aspirated. This fact prevents the aspirator from working. Due to the lower resistance, what will be aspirated is the air inside the probe related to the upper orifices, not the secretion located beneath (this happens mainly if the patient is with the decubitus raised). By the same reasoning, the models of aspirators of figures 4 and 5 of EP 0766976 do not work because in the aspirator of figure 4 there will be a large uncovered extent and, in that of figure 5, the upper and front part of the orifices with helical arrangement will equally be uncovered, not submerged in the secretion. The aspirators of the present invention are located at the back wall of the probe, that is to say internally and externally, where the secretions accumulate, especially in patients in dorsal decubitus or at 45º, a normal position of intubated patients. In addition, the present probe has few orifices internally and externally in its aspiration tubes, located at the places where

secretions are liable to accumulate, which guarantees the functioning thereof. In addition, it differs from the probes of the prior art, which foreseen either internal or external aspiration, never both simultaneously, as is the case of the present invention.

Document WO 99/38548 presents a probe with an external aspiration system, located at the small curvature of the tube. It does not foresee aspiration of the secretions inside the tube. It does not have little taps in the external aspiration system, which would easily control the aspiration procedure.

U.S. Patent No. 5452715 describes a probe only to assist the breathing of patient with respiratory insufficiency and with their breathing under control. The probe of the present invention may be used on awake patients, breathing spontaneously, either intubated or tracheotomized. This is easily verified by placing the distal end of the probe into the mouth, closing the nose and breathing through the probe. It will then be observed that the cyclic movement of the cuff, being inflated in the inspiration and deflated in the expiration. This probe also enables the use of any mode of ventilation on patients under controlled ventilation. In addition, in the probe of U.S. Patent No. 5452715, the orifice of communication of the cuff with the tube lumen is located at the cuff level, i.e., at the distal end of the probe. Further, it has an angulation contrary to the flow of inspired air. This

generates a problem. Such cuff will never be inflated since the inspired air that passes through the tube will arrive at a high speed and due to the leading angle of the orifice, contrary to the flow, it aspirates the cuff instead of inflating it. This is easily demonstrable by placing a needle with a leading angle contrary to the flow at the distal end of a hose with water flow. The larger the flow of water, in instead of the water coming out through the needle, the greater the aspiration of air from the surrounding environment into the tube. Moreover, this point is the place of most frequent formation of corks that obstruct the probe and consequently obstruct the orifice of communication with the cuff, as well as fills it with secretion, making the probe rapidly ineffective. Also, even if it was admitted that the cuff was temporarily inflated in the inspiration, before being obstructed by the secretions, with the orifice at the tip, a large amount of gas would be wasted at each cycle until the cuff could be inflated, since a large flow, high pressure and big volume of air would be necessary to inflate the cuff and, therefore, most of it would escape outside the probe, thus making it even more difficult to inflate the cuff, because this would balance the extratube pressure with the intratube pressure.

Another difference found is the angle of inclination of the orifice. This inclination causes the cuff to be invariably aspirated instead of inflated, as well as, in the aspiration, favors the leading of all the secretions to the inside of the cuff, thus being totally contrary to the purpose of the invention.

U.S. Patent No. 5452715 also foresees a second cuff that involves the reported one and has an inflation system connected to an external electronic source, provided with sensors capable of decoding the signals coming from electrodes located inside this second cuff, to the effect of keeping it always inflated with low pressure. There is also a link for the respirator that, in cases of dangerous peak pressures, turns it off immediately. In addition to the high cost thereof, it is not practical and requires an electronically reliable system to prevent the occurrence of defects that might hyperinflate the second cuff and maybe even break the trachea. All of this is contrary to the principle of non-aggression to the wall of the

tracheobronchial tree by the cuffs, and maintains the risk of occurrence of barotraumas. In addition, the outer satellite cuff of the present probe, which, by the way, does not exist in the probe of U.S. Patent No. 5452715, besides monitoring the functioning of the endotracheal cuff, is characterized by being elastic and distensible, absorbing any excess pressure that may occur in the tracheobronchial tree, functioning in isolation as an important escape valve, making the occurrence of barotraumas impossible.

WO 99/66975 describes a probe for intratracheal ventilation. In this probe, the lumen at the height of the half part of the cuff, is completely obstructed and the whole air sucked passes through small orifices before the obstruction into the cuff, inflating it, and then passes through further orifices after obstruction of the lumen to the probe tip, which is elastic and retractile in expiration, and then into the tracheobroncheal tree. In expiration, the probe tip retracts and the air is expired from the outside of the tube. Said probe functions as a pump that pumps backward and extratube the whole secretion during the expiration. In this probe, there is no system to monitor the functioning of the cuff. Since the tip is elastic and collapsible, in case of patients with much secretion, this secretion will invariably flood the chamber located between the tip and the point where the lumen is obstructed. In this way, during the expiration and retraction of the tip, this secretion will be pumped backwards against the small distal orifices and into them rapidly, and clogging of these orifices and of the cuff may occur. If this happens, it may be tragic, since the inspired air may get into the cuff and not get out and, since the cuff volume is very

small, quite smaller than the current volume of each inspiration, the cuff will be violently inflated and might break the trachea. This probe may be extremely dangerous, since there is no time for correcting the problem if the distal cuff orifices are obstructed. In the probe of the present invention, this does not happen. The possibility of obstruction of the cuff conduit and of the cuff by secretion is very little, since the conduit is long and is located away from the probe tip; indeed, its origin is in the probe path out of the body, and is easily seen, if it happens. In case it occurs, the worst that may happen is the need to change the probe, without any damage to the ventilation of the patient and little risk of death, since the patient will be ventilated as if he were intubated with a cuff-less probe. In addition, an extratube expiration flow is performed, which prevents bronchoaspiration, provides aspiration inside and outside the probe, prevents barotraumas and may even dispense the use of a laryngoscope, among others.

U.S. Patent No. 6463927 B2 describes a 5mm guide in diameter and 500 mm to 700 mm long, containing an endotracheal tube made from a plastic material and a metallic bendable rod internally. This guide does not have any relationship with the probe of the present invention. The present invention has been developed exactly to make this type of guide unnecessary.

Document FR 2826283 describes an endotracheal probe adaptable to all patients' morphologies. As illustrated, the metallic part is positioned exclusively in the small curvature of the probe and only at the place in the mouth and oropharynx, for the only purpose of adapting the exit of the tube to the patient's mouth. Unlike this, the present invention has a guide thread with memory, radiopaque an graduated, located in the probe wall thickness and throughout the extent of the large curvature as far as the most distal end of the probe, for different purposes: since it is radiopaque, it allows the probe to be located at the RX, especially the probe tip; it allows the probe to assume any shape, facilitating the intubation of difficult patients of the polytraumatized type, with facial, cervical and/or cranial encephalic traumas; and emergency situations, it provides a fast and safe

intubations without guide thread and without a laryngoscope, besides, also and obviously, fitting any morphology of face, teeth and neck, in its path outside and inside the body.

U.S. Patent No. 5315992 presents a probe with a mechanism that is intended to make the pressure value in the cuff equal to that of the airway. However, the cuff remains inflated during the whole ventilation. The circuit presented is very long and thin, complex and with high resistance to the air flow to inflate the cuff. This per se probably renders inadequate or ineffective the functioning of this probe. The air expired gets out through the inside of the probe since the cuff always remains inflated. Basically, if a manometer is connected to the cuff tube and inflating it with the desired pressure, keeping it inflated, there will be no difference with respect to the desired effect of the probe of U.S. Patent No. 5315992.

Brief Description of the Drawings

Figure 1 shows a cross-section view of a first embodiment of the probe for medical use of the present invention, the figure illustrating the probe tube, the first

cuff, the first conduit located at the tube wall, having an opening into the interior of the first cuff and an opening into the interior of the tube, as well as the means that provide the tube with an elastic memory, which consists of a radiopaque flexible rod in the preferred embodiment of the invention, extending throughout the whole tube.

Figure 2 is a top view from the AA' section of the first probe embodiment illustrated in figure 1, which shows the first cuff, the first conduit located at the tube wall along the length of the tube, and the radiopaque flexible rod.

Figure 3 shows a cross-section view of a second probe embodiment according to the present invention, the figure illustrating the probe tube, the first cuff, the first conduit located at the tube wall, having an opening into the interior of the first cuff and an opening into the interior of the tube, the radiopaque flexible rod and the second cuff, which monitors the functioning of the first cuff, and absorbs the excess pressure of the system, thus preventing hypertension in the first cuff.

Figure 4 is a cross-section view of a third probe embodiment of the present invention, illustrating in addition to the components described in figure 3 (probe tube, first cuff, first conduit located at the tube wall with an opening into the interior of the first cuff and a second opening into the interior of the tube, a radiopaque flexible rod and a second cuff), the connection means, which enables the probe to be used as a conventional probe, with active inflation of the first cuff by means of a syringe, or else with passive inflation of the first cuff at the moment of inspiration with the physiological pressure of the airways, the backflow of air during expiration being immediately closed, thus maintaining the first cuff permanently inflated.

Figure 5 shows a cross-section view of a fourth embodiment of a probe for medical use, which illustrates the probe tube, the first cuff, the first conduit located at the tube wall, having an opening into the interior of the first cuff and an opening into the tube, the radiopaque flexible rod, the second and third conduits provided with bores and arranged at the tube wall, through which the secretions existing inside and outside the probe tube are sucked, the first and second connection means, as well as the second cuff for monitoring the first cuff.

Figure 6 is a top view from the BB' section of the fourth probe embodiment illustrated in figure 5, which shows the first cuff, the first conduit, the second conduit and the third conduit, located at the tube wall along the length of the tube, as well as the radiopaque flexible rod throughout the whole tube.

Figure 7 is a cross-section view showing, in detail, the second cuff that communicates with the first conduit, which accounts for monitoring the first cuff, besides being one of the main mechanisms of protection of the trachea wall, since it prevents hypertension in the first cuff.

Figure 8 is a cross-section view of a fifth embodiment of the probe of the present invention illustrating, in addition to the components described in figure 5 (probe tube, first cuff, first conduit, radiopaque flexible rod, second and third conduits, first and second connection means and second cuff), the detail of a portion of the first conduit that is connected to the second cuff and which is external to the tube wall and concertina, whereby its length may be adjusted if it is necessary to cut the probe or increasing it.

Figure 9 shows another embodiment of the probe for medical use with the same characteristics of the above-described embodiments, but further comprising a second tube similar to the first one, laterally coupled to the first tube, having a shorter length than the latter and a first conduit that communicates the interior of the second tube with the interior of the first cuff of the second tube, said first conduit extending to the inside of the first cuff of the first tube. The metallic guide remains located on the larger tube wall until its tip, or at the middle of the two tubes, and from this point to the tip of the larger tube.

Detailed Description of the Figures

Figure 1 illustrates a first embodiment of the probe for medical use of the present invention. This first embodiment comprises a tube 1, provided with at least one opening 2 to receive air insufflations, and a first cuff 3, arranged around the tube 1 in a region of its external wall, being inflatable by means of a first conduit 5 arranged at the wall of the tube 1, having an opening into the interior of the first cuff

3 and another opening to the interior of the tube 1. The inflation of the first cuff 3 occurs by injecting a flow of air into the opening of the probe's tube during the inspiration, bringing about the fixation of the probe to the walls of the trachea and principally sealing or occluding it, so that the inspired air will not escape. The deflation of the first cuff 3, in turn, occurs in the period of time in which air is expelled from the patient's lungs through the probe tube 1, that is, during the expiration, providing a relief of the mechanical pressure that was being exerted by the first cuff 3 on the walls of said passageway of the human body and making blood circulation possible in this region until a new flow of air is injected into the human body. Thus, the inflation and deflation of the first cuff 3 take place following the rhythm itself of the patient's respiration (inspiration and expiration, respectively), which makes the probe physiologically ideal. It should be pointed out that the insufflated air flow into the tube 1 of the probe may also come from an artificial breathing apparatus, on patients with mechanical ventilation or any ventilation mode, including spontaneous breathing.

In addition, figure 1 shows means 4 that provide the probe tube 1 with an elastic memory, located at the tube wall along the length of tube 1. Such means 4 consist of a guide thread made from a flexible and radiopaque material, which enables the molding of the probe tube 1, the viewing of the probe in an X-ray photograph and a tracheal intubation without the use of a laryngoscope. This prevents serious injuries to lips, gums, teeth, nose wings and tracheotomy orifices, besides molding the probe at the exit of the mouth and/or nose and/or tracheotomy orifice, or else other cannulas such as artery and vein cannulas used in heart surgeries or any other types of surgery which needs a flexible plastic tube with elastic memory.

This elastic memory imparts to the tube an important purpose: making it a first option in emergency procedures such as CRA (cardio respiratory arrest), polytraumatisms and facial and cervical injuries since the probe dispenses the guide

thread and the laryngoscope. It makes possible the intubation of the patient in any angulations or position, with no need to immobilize the patient's head and/or neck.

Figure 2 is a top view from the section AA' of the first probe embodiment illustrated in figure 1. In this figure, it is illustrated the first cuff 3, arranged around the tube 1 and the first conduit 5, located at the tube wall along the length of the tube, which has an opening into the interior of the first cuff 3 and a second opening into the interior of the tube 1 or else into the interior of a preferably Y-shaped connector coupled to the tube 1, or else coupled to an independent source from the respirator that has a cycle in the same rhythm of the breathing or else specific equipments for inflating and deflating the cuffs, synchronically with the cycle of the respirator.

Figure 3 illustrates a second probe embodiment for medical use, which also consists of a tube 1, which will receive air insufflation; a first cuff 3, arranged around the tube 1, in a region of its external wall, said first cuff 3 being inflatable by means of the conduit 5 arranged at the tube wall, having an opening into the interior of the first cuff 3 and another opening into the interior of the tube 1; and means 4 that provide the probe tube 1 with an elastic memory, located at the tube wall along the length of the tube 1. It should be pointed out that the inflation and deflation of the first cuff 3 are effected by following the procedure described above for the first embodiment of the probe for medical use.

The probe of this second embodiment, illustrated in figure 3, is further provided with a second monitoring cuff 16 , which is also linked to the inside of the first conduit 5 in the region close to the opening 2 of the tube that receives air insufflation, being inflated and deflated together with the first cuff 3. The second cuff 16 monitors the functioning of the first cuff 3, and is only inflated if the first cuff 3 is intact. This satellite cuff 16 is elastic and extendable, functioning mainly as relief valve for any excess pressure in the tracheal and bronchial cuffs, so that the most that can happen is the cuffs to rest against the trachea and bronchi, and never press upon them, since the satellite cuff 16 has less resistance than the trachea and

bronchi, and as the cuff is distensible, it will expand and absorb the excess pressure. If the pressure is too great, the satellite cuffs will expand until they blow out and, even so, no injury will be caused to the trachea by the cuffs, which will only lean against it. This means that the trachea has much higher distension resistance than the limit pressure to blow out the satellite cuffs.

Figure 4 illustrates a third probe embodiment for medical use, comprising the same elements of the probe embodiment of figure 3, described above. The inflation and deflation of the first cuff 3 is effected by the same procedure of the embodiment of the preceding figure.

In the probe embodiment of figure 4, the first conduit 5 is connected to a connection means 20, provided with a switch that enables the control of the probe operation mode. If desired, the probe can also be used in the conventional manner for a short period of time, for example, to adjust the parameters of the respirator, or when passing the nasogastric or enteral probes, etc., with non-physiological pressure, the first cuff 3 being inflated, in this case, by insertion of a fluid. Even if it is inflated with high pressure, who will absorb the excess pressure is the satellite cuff and not the first cuff, i.e., in any form of functioning there will never be hyperpressure in the cuffs against the wall of the bronchi and trachea. The probe will further be used with passive inflation of the first cuff 3 at the moment of inspiration, with the physiological pressure of the airways, the backflow of air and deflation of the first cuff 3 being prevented by closing the connection means 20. In this way, the first cuff 3 remains permanently inflated, but with physiological pressure of the airways.

Another embodiment of the probe for medical use is shown in figure 5, which also comprises a tube 1, which will receive air insufflation; a first cuff 3, arranged around the tube 1 in a region of its external wall, said first cuff 3 being inflatable through a first conduit 5 arranged at the tube wall, having an opening into the interior of the first cuff 3 and another opening into the interior of the tube 1, or from an indirect source or respirator, or from the Y connected to the probe or a specific

equipment to inflate and deflate the cuffs with low pressure, synchronically with the cycle of the respirator. The inflation and deflation of the first cuff 3 are effected by following the same procedure described above for the first embodiment of a probe for medical use.

Figure 5 also shows the means 4 that provide the probe tube 1 with an elastic memory, located at the tube wall along the length of the tube 1, consisting of a guide thread made of a flexible and radiopaque material that permits the molding of the probe tube 1, the viewing of the probe in an X-ray photograph and the tracheal intubation without the use of a laryngoscope, and principally in emergencies for intubation, such as CRA (cardio respiratory arrest) polytraumatisms, facial and whiplash injury, urgency tracheostomy, facilitates and expedites greatly the intubation procedure, since it dispenses the guide and even the laryngoscope, minutes or seconds less, which may represent the patient's life. It also avoids the risks of injures caused by conventional guides and laryngoscope when effected by inexperienced people, such as breaking teeth, laceration of the gums, tongue, oropharynx , perforation of the oropharynx, stomach, trachea, bronchi, larynx, vocal cords and underlying organs such as the aorta.

In addition, the probe embodiment shown in figure 5 further comprises a second conduit 8 and a third conduit 10, located at the tube wall and extending along the length of said tube 1, said second conduit 8 being provided with bores 9 close to one of its ends, linking the interior of the tube 1 with the interior of the second conduit 8, whereas the other end is couplable to an external suction means, and the third conduit 10 being provided with bores 11 close to one of its ends above the tracheal cuff, linking the interior of the third conduit 10 to the external region of the tube 1, while the other end of the third conduit 10 is couplable to an external suction means which may be automatic, continuous, intermittent or manual, effected by the health professional himself. In this way, the secretions existing inside the tube 1 and in the external region of the tube 1 may be sucked through the second 8 and the third 10 conduits, respectively, thus preventing any obstruction of the

passageway for the flow of air that may be caused by the presence of such secretions. The second 8 and third 10 conduits are also connectable to a first 3-way connection means 12 provided with a switch 13 for controlling the suction of secretions through the second 8 and third 10 conduits, said first connection means 12 being coupled to an external suction means. Depending upon the position of the switch 13, either the secretions located inside the tube 1 alone or those located in the external region of the tube 1 can be sucked, or the secretions of both regions can be sucked at the same time.

According to an embodiment of the present invention, the first conduit 5 is connectable to a second 3-way connection means 14, provided with a switch 15 that enables the control of the probe operation mode. Thus, the probe may also be used in the conventional manner, with nonphysiological pressure, depending upon the position of the switch 15, the first cuff 3 being inflated, in this case, by inserting a fluid into one of the ways of the second connection means 14, and remaining permanently inflated, or else with passive inflation of the first cuff 3 at the time of inspiration, with physiological pressure of the airways, the backflow of air and the deflation of the first cuff 3 being prevented by closing the connection means 14. In this way, the first cuff 3 remains permanently inflated, but with the physiological pressure of the airways.

The probe shown in figure 5 is further provided with a second monitoring cuff 16 located around the first conduit 5, also linked to the interior of the first conduit 5 in the region close to the opening 2 of the tube that receives air insufflation, which is inflated and deflated in conjunction with the first cuff 3. The second cuff 16 monitors the functioning of the first cuff 3 and is only inflated if the first cuff 3 is intact and is one of the main elements responsible for the specially non-traumatic nature of this probe, since it is elastic and distensible, prevents, in any circumstance, the occurrence of hyperpressure in the cuffs, thus preventing the risk of ischemia or mechanical trauma of the trachea or bronchi by the cuffs.

Figure 6 is a top view, from section BB', of the probe embodiment illustrated in figure 5. This figure illustrates the first cuff 3, the first conduit 5, the second conduit 8 and the third conduit 10, arranged at the tube wall along the length of the tube.

Figure 7 shows a second cuff 16 similar to the first one 3, which communicates with the first conduit 5 and is inflated and deflated in conjunction with the first cuff 3. The second cuff 16 is located close to the end of the tube where the opening 2 that receives air insufflation is located. The second cuff 16 is inflated and deflated at the same rhythm of the inflation and deflation of the first cuff 3, being used for monitoring the first cuff 3, since its inflation will only occur if the first cuff 3 is intact and functions as a relief valve for pressure peaks, since it is elastic and distensible.

Figure 8 illustrates a fifth embodiment of a probe for medical use, which comprises the same elements and has the same operation mode of the probe embodiment of figure 5, described above. However, in this probe embodiment, the first conduit 5 has a concertina portion 21 outside the tube wall, close to the end connected to the second cuff 16. In this way, the length of the first conduit 5 may be adjusted, if it is necessary to cut the probe in order to reduce the dead space or else increase it in order to increase the dead space.

Figure 9 shows another embodiment of a probe for medical use with the same characteristics of the embodiments described above, but further comprising a second tube 17, similar to the first one 1, that is to say, being also provided with at least one opening for receiving air insufflation, and a common cuff 30 arranged around the two tubes 1 and 17 in a region of their external walls, inflatable through a first conduit 18 arranged at the tube wall of the second tube 17, having an opening into the interior of the common cuff 30 and another opening into the interior of the second tube 17, this first conduit extending as far as the inside of the first cuff 3 of the first tube 1. The second tube 17, being similar to the first tube 1, may also be provided with a connection means 20, a second cuff 16 and/or a concertina 21. The inflation and deflation of the common cuff 30 of the second tube 17, i.e., of the common tracheal cuff that involves the two tubes, occurs in the same way described previously for the first cuff

3 of the first tube 1. This second tube 17 is laterally coupled to the first tube 1 and is shorter than the first tube 1.

The conduits 5 and 18 which communicate the inside of the probe with the cuffs and that carry part of the inspired air to inflate them, should compulsorily show expansion at the rate of about 1/3 of the probe gage, being located at the thickness of the probe wall, so that they will not project inwards or outwards. This great gage, quite larger than that of conventional probes, will cause the air-flow resistance to be low and the cuffs to be inflated long before the air reaches the end of the probe, guaranteeing that the trachea will be sealed and preventing waste of the inspired gases. If the gage of these conduits is small, equal to that of conventional probes and equal to the probes of documents U.S. Patent No. 4,791,923, EP 0,766,976 and U.S. Patent No. 5,452,715, the resistance is great and the cuffs will not be inflated and so the whole air inspired will leak around the probe, making it ineffective and inadequate for use.

In addition, the location of the air inlet of these ducts has to be either at the proximal end of the probe or at a Y-connector, never near the cuff (as seen in EP 0,766,976 and U.S. Patent No. 5,452,715) be it tracheal or bronchial, for the following reasons:

a) being distant, the cuff will inflate long before the air inspired reaches the probe tip, thus preventing waste of gas. When the volume of air inspired represents the double volume of air in the cuff, the latter will be filled, and the air has only reached the extent of the probe that holds the same volume, that is to say, never having reached the tip. This is very important, since otherwise the cuff does not inflate sufficiently to seal the trachea and permit ventilation with positive pressure;

b) the air inlet of the conduits that communicate with the inside of the probe as cuff may never be at the most distal end of the probe, near the cuff. In this case, the air inspired would reach the tip of the probe at a high speed and, instead of inflating the cuff, the air will suck it by the Venturi effect, drying it even more. The

probe would be completely ineffective, since the cuff would not inflate. Moreover, even if the cuff inflated a little, this would be for a short time, since this location and the size of its orifice would be factors that would lead to its obstruction rapidly, as well as to an almost immediate flooding of the cuff chamber by secretions, which would make the probe ineffective;

c) the angle of attack of the air inlet of the conduit that communicates the cuffs with the tube lumen may never be in the direction contrary to the flow of inspired air, not even at a 90-degree angle. It has to form an obtuse angle with respect to the outer surface of the tube, that is to say, it has to be in the same direction of the inspired air with the legs of the Y. This is fundamental, otherwise the inspired air upon passing through the orifice will generate a Venturi effect, which will aspire the cuff and not inflate it.

It should be understood that the probe for medical use and its components described above are only a few embodiments that might exist. The real scope of the object of the invention is defined in the accompanying claims.

CLAIMS

1. A probe for medical use comprising:

a first tube having at least one opening for receiving air insufflation;

a first cuff, arranged around the first tube in a region of an external wall of the first tube, said first cuff being inflatable through a first conduit of the first tube that has an opening into the interior of the first cuff and another opening into the interior of the first tube;

a second tube laterally coupled to the first tube and having at least one opening for receiving air insufflation; and

a common cuff, arranged around the first and second tubes in a region of respective external walls of the first and second tubes, said common cuff being inflatable through a first conduit of the second tube that has an opening into the interior of the common cuff and another opening into the interior of the second tube;

wherein the first conduit of the second tube extends as far as the inside of the first cuff of the first tube.

2. A probe according to claim 1, wherein the first cuff is located close to the end of the first tube opposite that where the opening that receives air insufflation is located.

3. A probe according to claim 2, comprising a second conduit at the wall of the first tube, the second conduit extending along the length of the first tube, being connectable to an external means, and having, close to one of its ends, bores that communicate the interior of the first tube with the interior of said second conduit.

4. A probe according to any one of claims 1, 2 and 3, further comprising a third conduit at the wall of the first tube, which extends along the length of the first tube, being connectable to an external means, and having, close to one of its ends, bores that communicate the interior of said third conduit with the external region of the first tube.

5. A probe according to anyone of claims 3 and 4, wherein the external means is a suction means.

6. A probe according to claim 4 wherein each of said second and third conduits has another end that extends out of the first tube for coupling a first connection means, which has a switch for controlling the suction at said second and third conduits and being coupled to a suction means.

7. A probe according to any one of claims 1 to 6, wherein said first conduit, which links the interior of the first cuff to the interior of the first tube, is connectable to a second connection means, which has a switch for controlling the operation mode of said probe.

8. A probe according to any one of claims 1 to 7, comprising a second cuff linked to the interior of the first conduit to be inflated and deflated in conjunction with the first cuff, located close to the end of the first tube where the opening that receives air insufflation is located.

9. A probe according to claim 8, wherein the first conduit is a passageway made in the wall of the first tube, having a portion outside the wall of the first tube.

10. A probe according to claim 9, wherein said external portion of the conduit is concertina shaped close to the end connected to the second cuff.

11. A probe according to any one of claims 1 to 10, comprising means that provide the first tube with an elastic memory, located along the wall of the tube.

12. A probe according to claim 11, wherein said means that provide the first tube with an elastic memory are radiopaques.

13 A probe according to claim 1, wherein said second tube is shorter than the first tube.

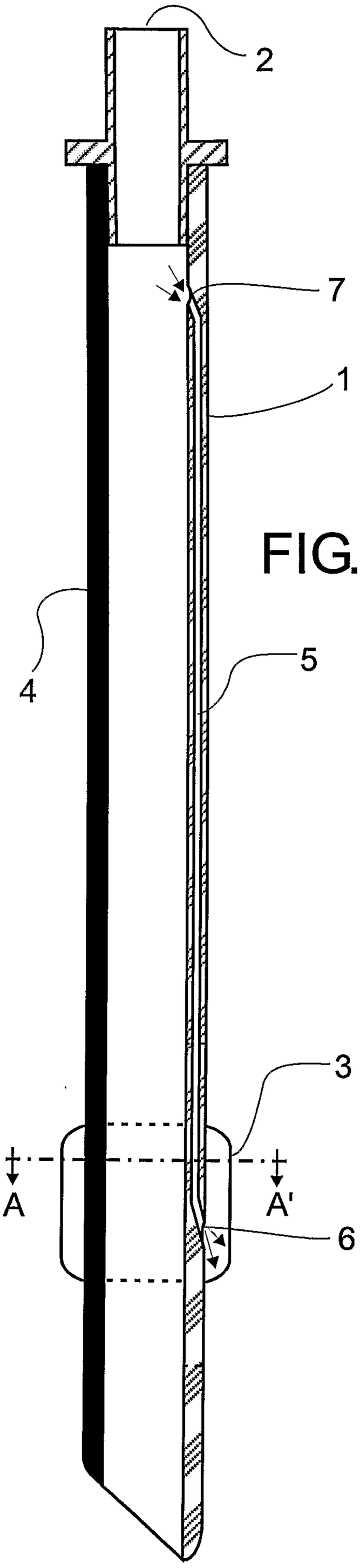


FIG. 1

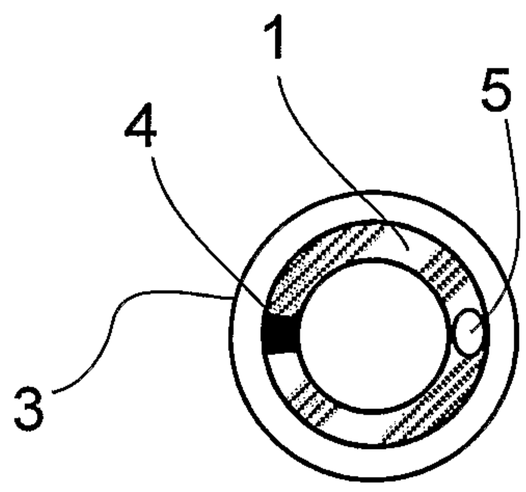


FIG. 2

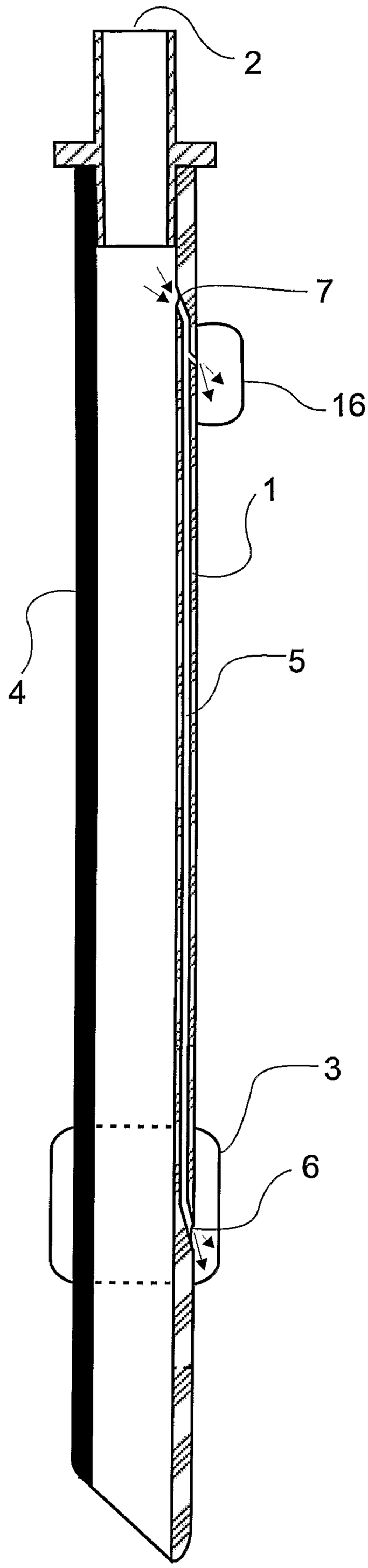


FIG. 3

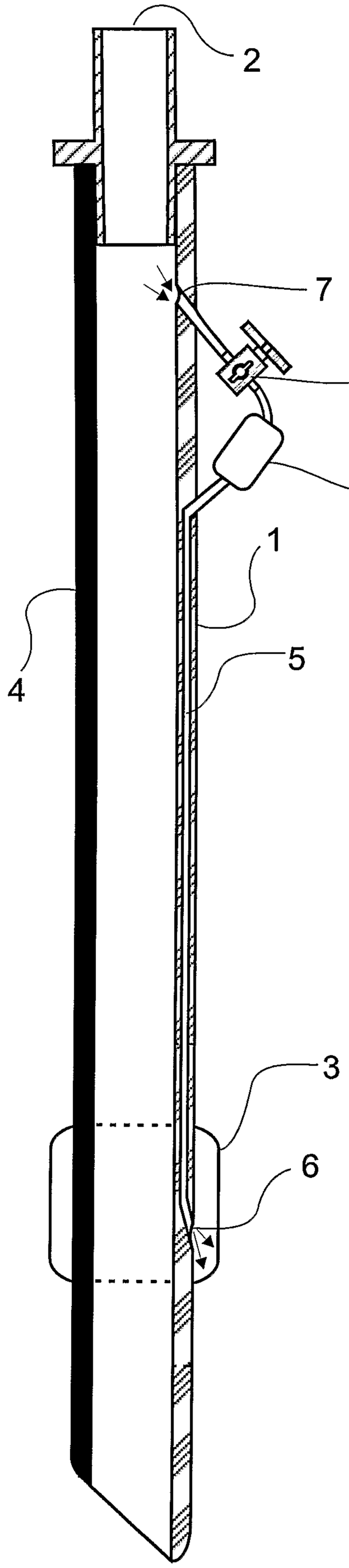


FIG. 4

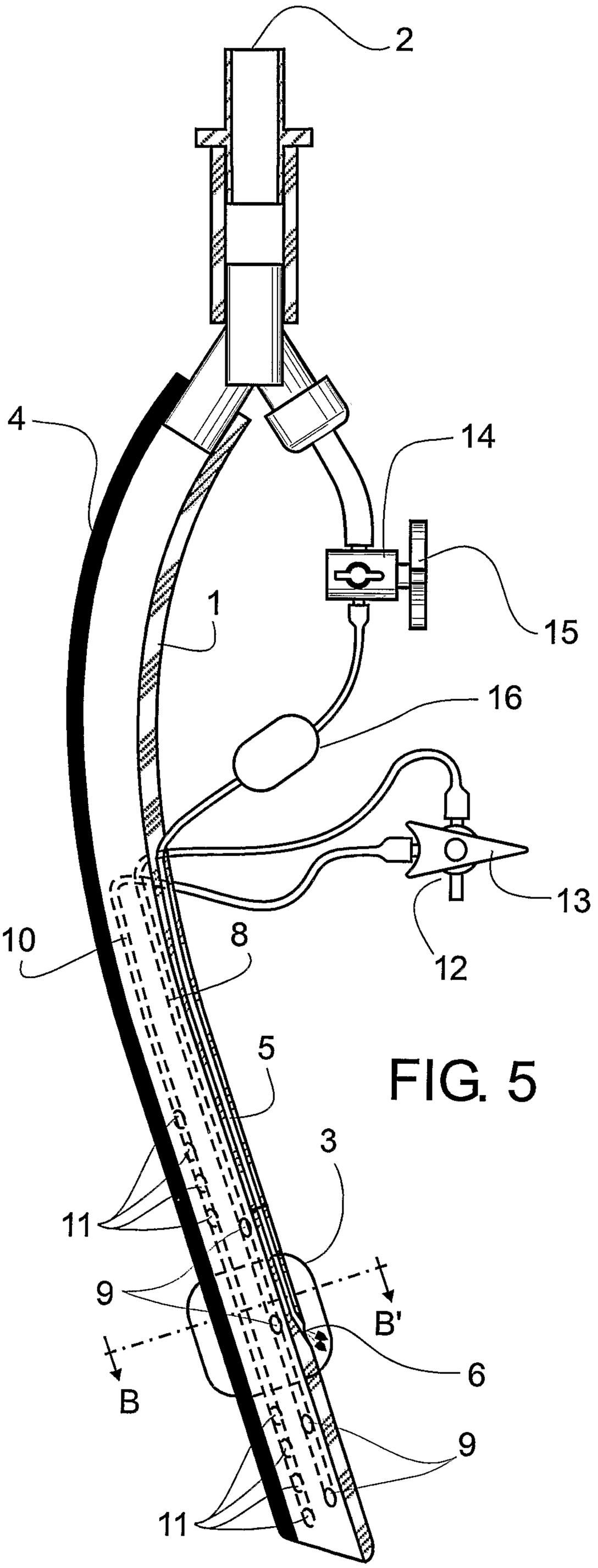


FIG. 5

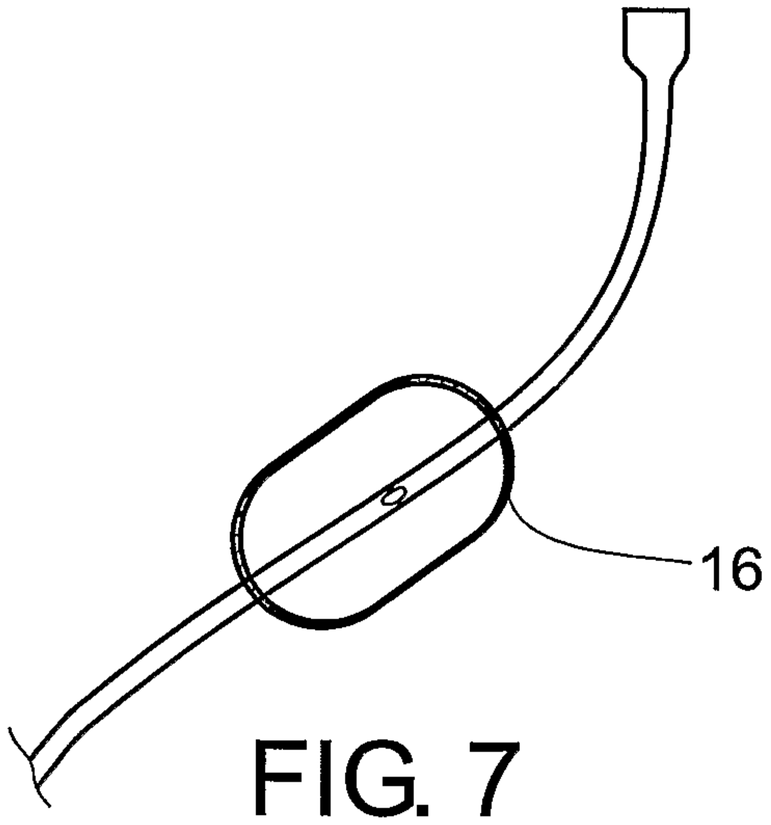


FIG. 7

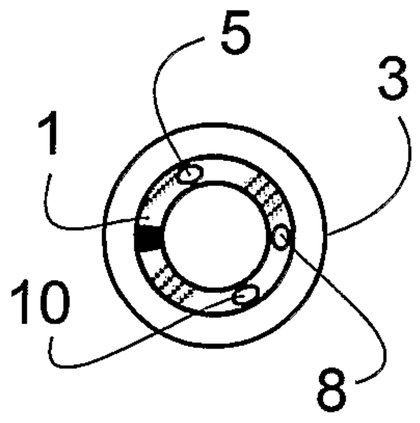


FIG. 6

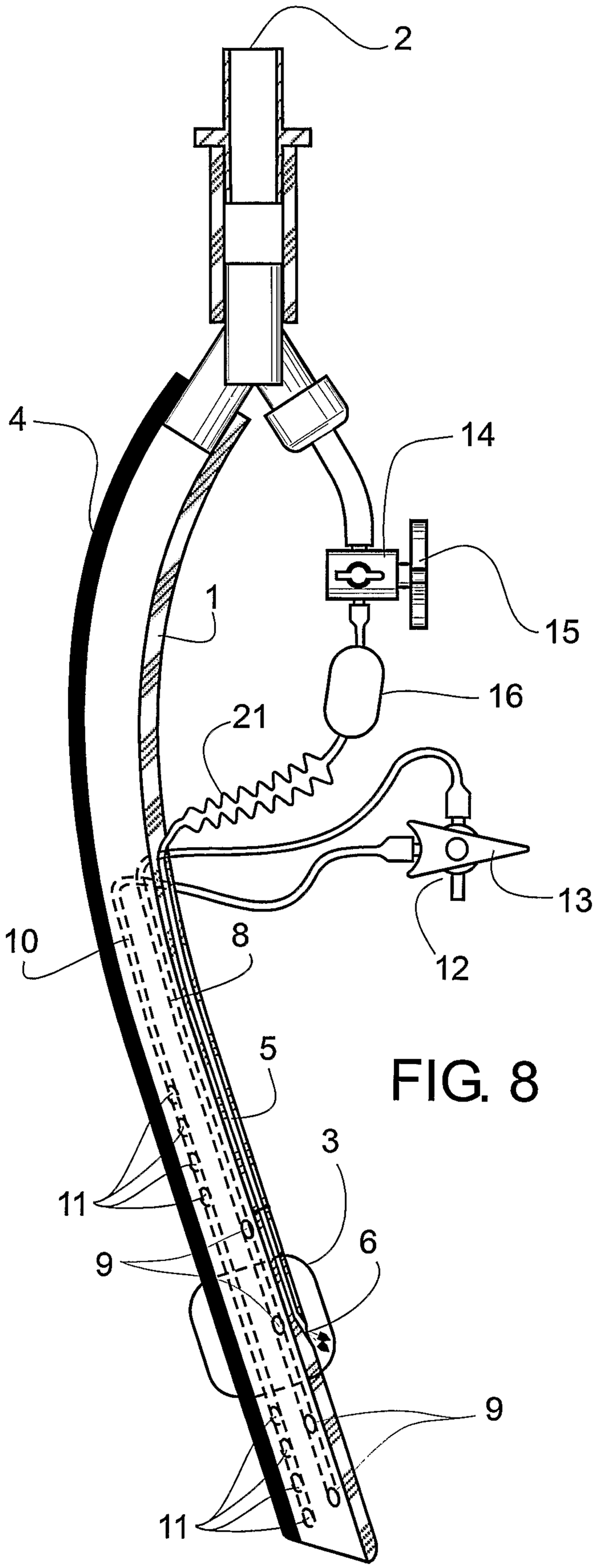


FIG. 8

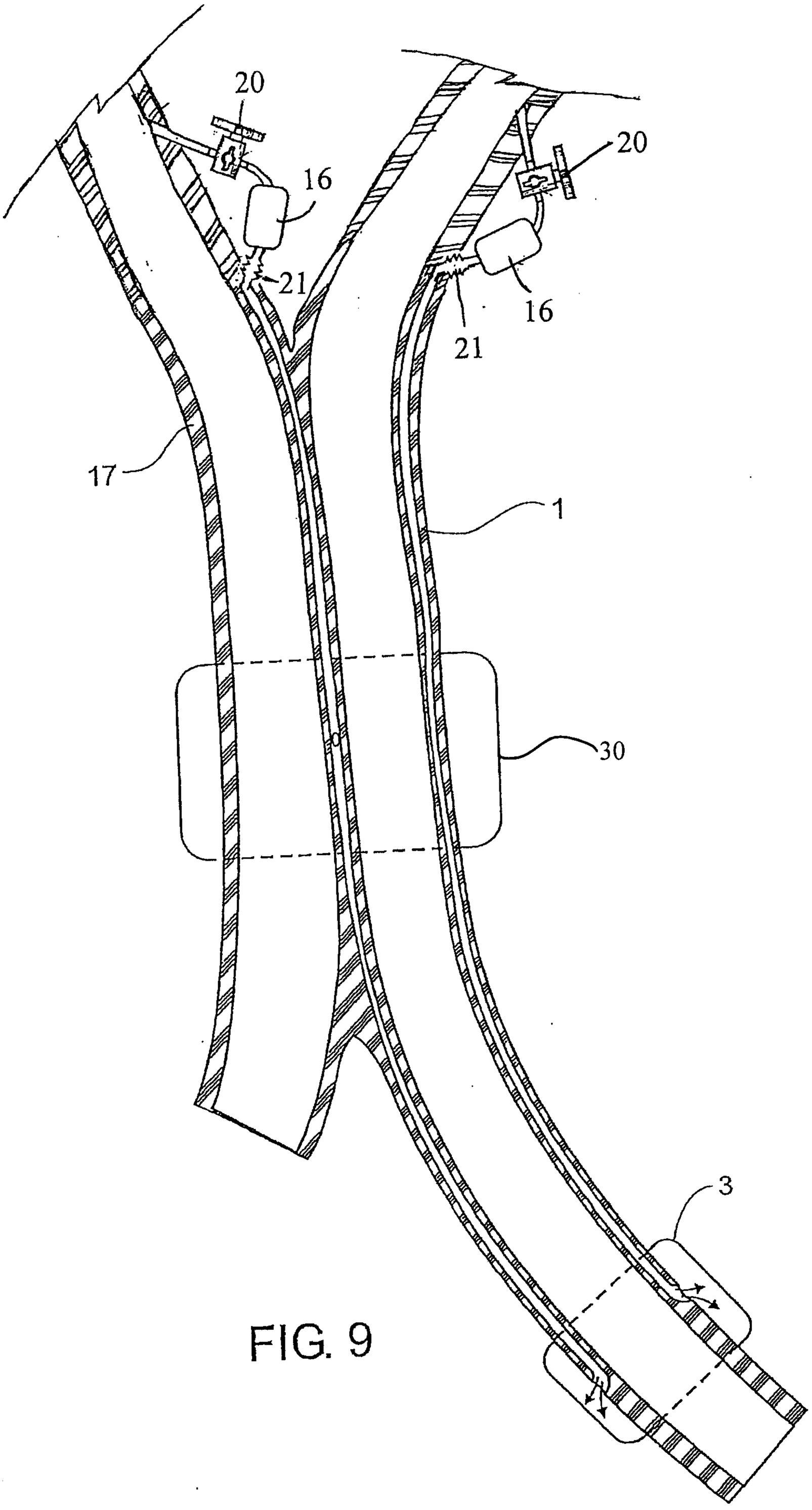
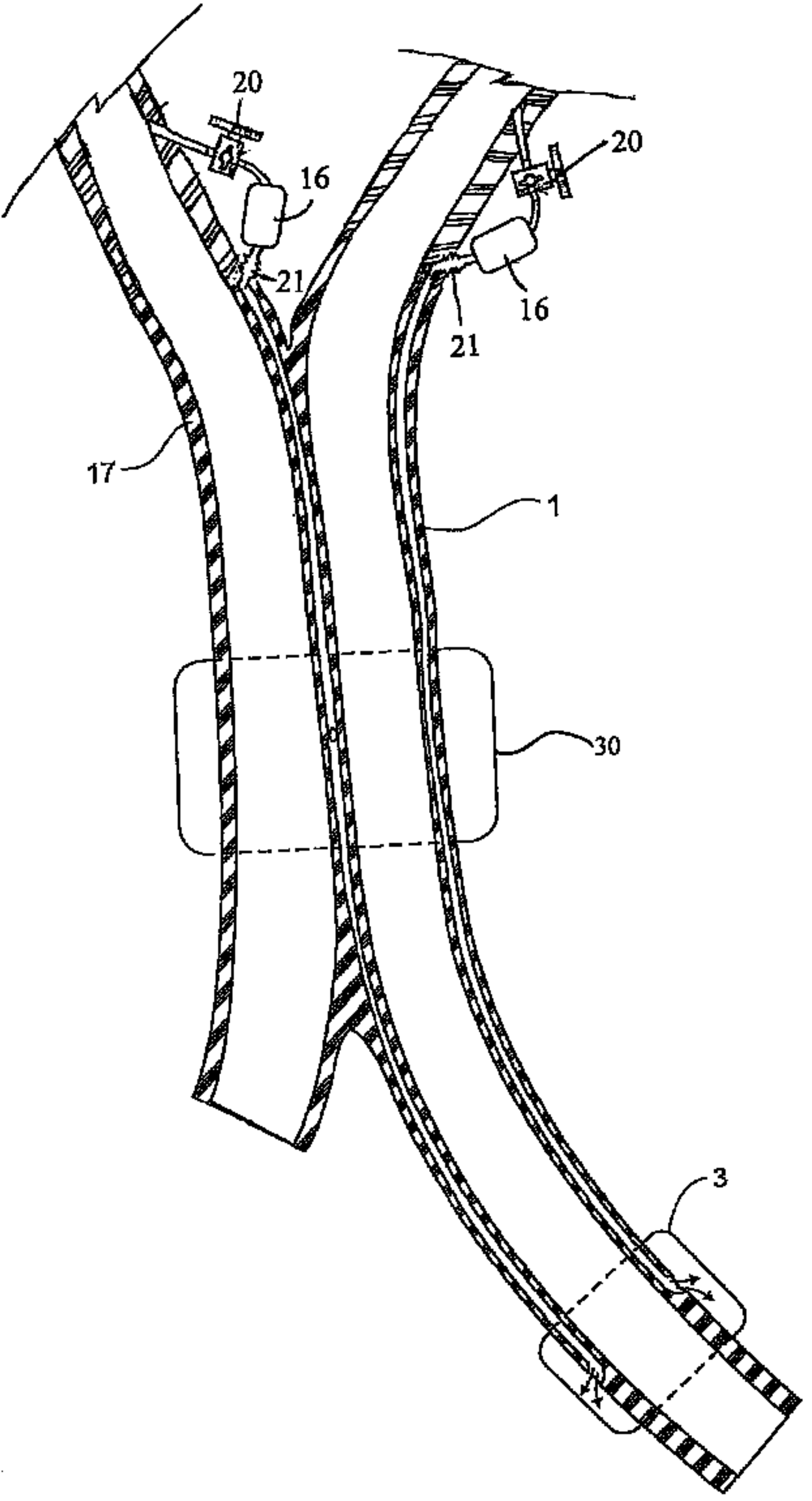


FIG. 9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