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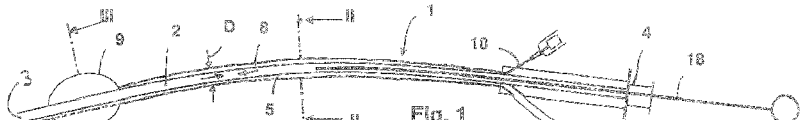
(54) **Title**: JET VENTILATION CATHETER



(57) **Abstract**: The present invention relates to a catheter (1) for ventilating a patient, with a ventilation channel (2) for alternately delivering and removing air and/or oxygen to and from the patient's airways, the catheter having a maximum external diameter of at most 6 mm, preferably 1.5 to 4.5 mm, and the ventilation channel having an open end (3), and a connector end (4) for connection to a supply system (19) for expiratory assistance. According to the invention, the catheter is optionally provided with means or elements for measuring the pressure outside the ventilation channel near the open end. The catheter preferably has a pressure measurement channel (5), with an open measurement end (6) near the open end of the ventilation channel, and a measurement connector piece (7) for connecting a pressure display device. Of particular advantage is a catheter with an expansion body (cuff) (9) that is fluidically connected to a supply channel (8) through which the expansion body can be increased or reduced in size by means of a fluid. The jet ventilation catheter according to the invention permits a novel ventilation principle that can be regarded as a bridge between classical jet ventilation and conventional controlled ventilation and that opens up possibilities for new and improved interventions in the airways.

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JET VENTILATION CATHETER

FIELD OF THE INVENTION

The present invention concerns the ventilation of patients and their examination and treatment in the region of the airways.

BACKGROUND OF THE INVENTION

WO 2008/113752 A1 discloses a gas flow reversing element which allows a human being to be ventilated by way of a relatively thin catheter, for example in emergency situations. Oxygen can thus be introduced into the lung and gas can also be aspirated from the lung again in sufficient quantity. The high flow rate in both directions, despite the small diameter of the catheter, is able to maintain the supply of oxygen and the removal of carbon dioxide when ventilating through a relatively thin catheter.

Various devices for transtracheal ventilation are known from the article "Comparison of four different emergency airway access equipment sets on a human patient simulator" in Anaesthesia, 2004, 59, pages 73-79, in particular from Figure 4, which shows an easy to use device for jet ventilation.

The main aim of the present invention is to extend the field of use of jet ventilation, to make it safer, and to create suitable devices and methods therefor. With classical jet ventilation, a mixture of oxygen and air is blown with a high pressure and flow via a katheter into the airway and used or excessive gas can escape via the airway. In contrast hereto, the concept of the present invention can be described as jet ventilation with expiratory assistance, which can also be used when this escape is not possible or is possible only with difficulty.

Surprisingly, the ventilation method hitherto conceived for emergency care in cases of partially or completely obstructed airways is also suitable for other uses. Hitherto, in operations performed in the re-

gion of the lower airways and the lungs, catheters with relatively large diameters have been used for ventilation purposes and for introducing instruments, but these restrict the possibilities of performing treatment alongside the catheter or of introducing additional catheters and instruments.

An additional and often underestimated problem is that, when a high concentration of oxygen is present in the airways and use is being made of a laser, for example, or of other instruments that generate high temperatures, there is a risk of burning. This concerns the surrounding tissue, but also the catheter and the instruments themselves.

Another often underestimated problem is that with classical jet ventilation, relatively high pressures and flows are needed in order to obtain a proper gas exchange in the lungs before the gas leaves the lungs again through substantially open airways. Jet ventilation with expiratory assistance would be applied with a lower, and therefore safer, pressure. However, in that case a rather high (bypass) backflow could occur through relatively open airways,

An important aspect of jet ventilation is the safety of the patient during its use. In conventional jet ventilation systems, there is a danger that, if the airways are substantially or completely obstructed, too high a pressure will build up in the lung. Consequently, the field of use has hitherto been limited.

The object of the present invention is therefore to make available devices and methods which, in particular during an examination or operation, permit safe and effective ventilation of a patient by means of jet ventilation with expiratory assistance and leave considerable parts of the cross-sectional area of the upper airways free for necessary interventions.

SUMMARY OF THE INVENTION

The foregoing object is achieved by a device and associated method according to the embodiments of the invention described herein.

In one embodiment, the present invention includes a catheter for ventilating a patient with expiratory assistance, preferably structured to be connected to a gas supply sustem, such as a flow reversing element. According to one embodiment the catheter comprises an elongate member defining a ventilation channel therein for alternately delivering oxygen or oxygen containing gas to and removing respiratory gas from the patient's airways. The ventilation channel defines an open end and a connector end for connecting to a supply system or to a gas flow reversing element, preferably to a gas flow reversing element as disclosed in WO 2008/113752 A1. Optionally, the catheter further comprises a pressure sensor located outside the ventilation channel for measuring the pressure near the open end of the ventilation channel or deeper down the airways. Using such a catheter it is now possible to ventilate (inhalation and expiration) a patient sufficiently only through the ventilation channel of the catheter.

A supply system preferably comprises at least the function of delivering oxygen or oxygen containing gas to and removing respiratory gas from the patient´s airways via the catheter. Preferably a gas flow reversing element is used as supply system or as part of the supply system.

In one embodiment, the elongate member has a maximum external diameter of approximately 6 mm. In another embodiment, the elongate member has an external diameter of approximately 1.5 to 4.5 mm. In yet another embodiment, at least a portion of the outer surface of the elongate member is made of a noncombustible, nonflammable and/or laser-resistant material and, preferably the outer surface of the elongate member insofar as it is to be inserted into the airways of a patient. In still another embodiment, at least a portion of the outer surface of the elongate member is coated with a noncombustible, nonflammable and/or laser-resistant material.

In one embodiment, the pressure measuring means comprises at least one electronic pressure sensor with signal lines integrated within the elongate member of the catheter. In another embodiment, the elon-

gate member further defines a pressure measurement channel therein, the pressure measurement channel defining an open measurement end near the open end of the ventilation channel and a second connector end. According to this embodiment, the pressure sensor comprises a measurement connector piece and a pressure display device, the measurement connector piece being operably connected to the second connector end and the pressure display device to measure the pressure within the pressure measurement channel. In another embodiment, the pressure measuring means comprises a lumen containing a liquid, the lumen defining a distal open measurement end and a closed proximal end, the proximal end containing a compressible gas between the liquid and the closing. The lumen further comprises a scale readable for the medical professional during use.

In another embodiment, the elongate member, at least in the area of the open end of the elongate member, has a needle-like shape, being structured in particular for piercing the trachea and for performing transtracheal ventilation of a patient.

In another embodiment, the catheter comprises at least one expansion body positioned on the outside of the elongate member in the area of the open end of the elongate member, wherein the at least one expansion body is structured to be increased and reduced in size by delivering and removing a fluid, respectively. In one embodiment, the catheter comprises a supply channel defined within the elongate member or on the elongate member, the supply channel being fluidically connected to the expansion body. In yet another embodiment, the expansion body comprises at least one stabilizing structure that provides a minimum volume to the expansion body in the condition of reduced size and maintains at least the minimum volume of the expansion body relative to an external overpressure or underpressure of at least 10 mbar.

In one embodiment, the present invention includes a method for ventilating a patient, comprising the steps of providing a supply system

and providing a catheter comprising an elongate member defining a ventilation channel therein for alternately delivering oxygen or oxygen containing gas to and and removing expiratory gas from the patient's airways, wherein the ventilation channel defines an open end and a connector end for connecting to the supply system, the catheter further optionally comprising a pressure sensor located outside the ventilation channel for measuring the pressure near the open end of the ventilation channel. The method includes inserting the catheter from the outside into the trachea. Jet ventilation with expiratory assistance is performed through the catheter. In one embodiment, the performing step is conducted using a supply system and/or a gas flow reversing element having processor-controlled valves for delivering and removing oxygen, oxygen containing gas and/or respiratory gas that is operably connected to the catheter. The pressure near the open end of the ventilation channel is measured; and the intervals for delivering and removing oxygen and/or air are determined based upon pressure measurement values.

In another embodiment, the catheter further comprises an expansion body and the method of the invention further comprises the step of intermittently modifying the size of the expansion body, the timing of the intermittent modifications in size being synchronized with the delivery and removal of air and/or oxygen in the performing step. In one embodiment, the step of intermittently modifying the size of the expansion body comprises increasing and reducing the size of the expansion body. In another embodiment, the step of intermittently increasing and decreasing the size of the expansion body comprises delivering and removing a noncombustible gas or a nonflammable liquid to the expansion body, respectively. In yet another embodiment, the noncombustible gas comprises nitrogen or a noble gas. And in yet another embodiment the nonflammable liquid comprises water or saline solution.

In one embodiment, the insertion step comprises inserting the catheter so far into the patient's airway that the expansion body is being positioned deeper than a site in the airway that is to be treated or ex-

amined, and the expansion body is at least intermittently expanded to such an extent that it holds the catheter sealingly in place relative to the surrounding tissue of the patient, and wherein the performing step is performed before, during and/or after the treatment of the site that is to be treated.

In one embodiment, the measuring step comprises measuring the pressure near the open end of the ventilation channel using an electrical pressure sensor positioned within the elongate member near the open end. In another embodiment, the elongate member further defines a pressure measurement channel therein, the pressure measurement channel defines an open measurement end near the open end of the ventilation channel and a second connector end, wherein the pressure sensor comprises a measurement connector piece and a pressure display device, the measurement connector piece being operably connected to the second connector end and the pressure display device, and wherein the measuring step comprises measuring the pressure near the open end of the ventilation channel using the pressure display device.

In still another embodiment, the present invention comprises a method of ameliorating a breathing obstruction in a subject, comprising the steps of providing a supply system; providing a catheter comprising an elongate member defining a ventilation channel therein for alternately delivering and removing air and/or oxygen to and from the patient's airways, wherein the ventilation channel defines an open end and a connector end for connecting to the supply system; inserting the catheter from the outside into the trachea; and performing jet ventilation with expiratory assistance through the catheter such that the subject is normoventilated. In one embodiment, the catheter further comprises an expansion body and the method of the invention further comprises the step of intermittently modifying the size of the expansion body, the timing of the intermittent modifications in size being synchronized with the delivery and removal of air and/or oxygen in the performing step. In one embodiment, the step of intermittently modifying the size of the expansion

body comprises increasing and reducing the size of the expansion body. In another embodiment, the catheter further comprises a pressure measuring means located outside the ventilation channel for measuring the pressure near the open end of the ventilation channel and the method further comprises the steps of measuring the pressure near the open end of the ventilation channel; and determining the intervals for delivering and removing oxygen and/or air based upon pressure measurement values. In another embodiment, the ventilation channel has a maximum diameter of 3 mm. In another embodiment, the flow rate of the inspirated and aspirated gas through the catheter is approximately 8 to 20 liters per minute. In still another embodiment, the flow rate of the inspirated and aspirated gas through the catheter is approximately 15 liters per minute.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Further details and advantages of the invention and preferred illustrative embodiments are explained in more detail below with reference to the drawings, in which:

Figure 1 shows a catheter according to one embodiment of the invention for ventilation, particularly in examinations and operations;

Figure 2 shows a cross section through the catheter according to Figure 1 along the line II-II;

Figure 3 shows a cross section through the catheter according to Figure 1 along the line III-III;

Figure 4 shows a catheter according to another embodiment of the invention designed as a needle at the front for jet ventilation with expiratory assistance; and

Figure 5 shows an example of the arrangement of the catheter according to one embodiment of the invention with peripheral devices.

DETAILED DESCRIPTION OF THE INVENTION

The detailed description begins with a general description of the invention and then concludes with a description of the embodiments of the invention illustrated in Figures 1-5.

For practically all uses of jet ventilation it is advantageous if a ventilation catheter introduced into the airways has, in the area of its open end, means or elements according to the invention for pressure measurement. Although this requires an additional channel or measurement conduits, this is offset by the gain in safety and by the possibilities of more precise dosing and control of the inhalatory and exhalatory gas flows. This broadens the possibilities of safe use of jet ventilation, particularly in connection with a supply system or a gas flow reversing element, for example as described in WO 2008/113752 A1. Another embodiment of a supply system comprises a simple coupling of two lumen with the ventilaton channel of the catheter of the present invention. One of these two lumen is delivering oxygen or oxygen containing gas to the ventilation channel and the other lumen removes the respiratory gas flowing from the patient through the ventilation channel.

Although the measurement principle itself is not of importance, the measurement principle and the place of measurement should nevertheless be chosen in such a way that the actual ambient pressure near the open end of the catheter is measured, not the pressure in the interior of the channel for jet ventilation. Under these conditions, the jet ventilation according to the invention can even be used for transtracheal ventilation for example (i.e. via a cannula or needle (collectively refered to herein as a "cannula")) inserted through the skin into the trachea or via a catheter positioned in this way) if it is feared that the airways in the head-neck area are substantially or completely obstructed.

If the means or elements for pressure measurement include an additional channel, this can easily be kept open during introduction of the cannula or catheter, e.g. by an inner removable wire. Such a wire can also avoid buckling during the advance of the cannula or catheter.

In addition to a transtracheal cannula or transtracheal catheter

intended particularly for emergency care and having means or elements for pressure measurement, the combination of the effect of a supply system or a gas flow reversing element, for example as described in WO 2008/113752 A1, with a jet ventilation catheter according to the invention, as described below, defines a novel method of ventilation that can be regarded as a bridge between classical jet ventilation and conventional controlled ventilation and that opens up possibilities of new and improved interventions in the airways.

In an illustrative embodiment described in detail here and shown in the drawing, the special jet ventilation catheter is flexible, measures at least 200 mm, preferably 250 to 600 mm in length, even more preferably at least 300 mm, and has an external diameter typically of at most 6 mm, preferably 1.5 to 4.5 mm, even more preferably 1.5 to 3 mm. It has a ventilation lumen with an internal diameter measuring at most approximately 4.5 mm, preferably at most 2.5 mm, even more preferably between 2.2 and 2.4 mm, and with one or more openings at its ends, and, optionally, has a supply channel which leads to an expansion body located at the tip, here an inflatable cuff, and a pressure measurement channel, and it is preferably made from a noncombustible/nonflammable material or is coated with such a material. Resistance to laser radiation caused by lasers used in the medical field is also important in some applications, in order to ensure that the catheter cannot be damaged when such devices are used in its vicinity.

The tubular, flexible jet ventilation catheter is pushed through the mouth or nose into the trachea or, if it has a suitable length, as far as the bronchial system of the left or right lung of a patient. In contrast to the conventional bronchial blockers often used in unilateral surgery of the thorax, the jet ventilation catheter can be used to ventilate the "blocked lung", while at the same time the "unblocked lung" on the side to be operated on is able to collapse optimally (as is desired in such interventions).

Such a jet ventilation catheter can also be very easily positioned using a flexible fiber optic with a working channel. For this purpose, the

tip of the jet ventilation catheter is fixed on the tip of the fiber optic by means of a filament or wire, which is guided through the catheter (for example through the pressure measurement lumen) and secured on the tip and which is then threaded back from the front end through the work channel of the fiber optic, and it is brought to the desired position with the fiber optic. The fiber optic is then pulled back. The filament or wire can be removed or left in place. The latter option allows the jet ventilation catheter to be repositioned at any time with the aid of the fiber optic.

The small external diameter ensures that the airway is only minimally obstructed by the jet ventilation catheter, such that plenty of room remains for diagnostic and therapeutic interventions, even in the deeper airways.

A ventilation lumen of less than 4.0 mm results in a considerably delayed passive exhalation. Consequently, adults can no longer be sufficiently ventilated by conventional means using such tubes. Because of the relatively high flow resistance of the ventilation lumen, e.g. with a diameter of 4.5 mm or even 3 mm, or a length that exeeds 75 mm, the special jet ventilation catheter requires active support of exhalation by suction (e.g. by means of a gas flow reversing element) unless it is also possible (as in classical jet ventilation) for air to escape from the lung alongside the jet ventilation catheter. By means of the inflatable cuff, the special jet ventilation catheter can seal off the trachea or a bronchus and thus separating the airways downstream and upstream of the expansion body.

Of particular advantage is a cylindrical cuff which (when inflated) holds the tip of the jet ventilation catheter in position in the middle of the trachea or of the bronchus and reduces the risk of dislocation during manipulations in the airway.

By means of the folds of the cuff material, even the "unblocked" cuff (that is to say emptied by suction) ensures that the opening(s) of the ventilation lumen are not sucked onto the wall of the trachea. However, it is also conceivable to use clasps (e.g. lying in the cuff) which hold the tip

of the jet ventilation catheter in the lumen of the trachea or of a bronchus even when the cuff is completely empty.

The cuff can be inflated either continuously for the duration of an operation/intervention or intermittently at each ventilation cycle.

If the cuff is "blocked" continuously with a pressure of 20 to 30 mbar which is also customary in endotracheal tubes (in conventional controlled ventilation it is necessary to build up pressures of 20 to 30 mbar for sufficient gas exchange), the airway above the cuff is completely separated from the airway below the cuff (i.e. toward the lung periphery).

The airway above the cuff is then open to the outside, while the airway below the cuff by contrast is closed off from the outside. Thus, from classical jet ventilation (in what is generally an open airway), normoventilation - controlled ventilation with suction-assisted exhalation - is created, even in a blocked airway.

With the cuff blocked, the patient can even be given pure oxygen without increasing the oxygen-dependent risk of burns or flames which, in laser surgical interventions using electrocautery and in classical jet ventilation, necessarily arises with an increased oxygen concentration.

Alternatively, by intermittent inflation of the cuff during inhalation and emptying/collapsing of the cuff during exhalation, it is very easy, i.e. without needing to measure the intrapulmonary pressure, to avoid the build-up of too high a positive pressure or negative pressure in the lung.

Alternatively, it is also advantageous if the cuff is inflated and emptied again by suction automatically and in synchrony with the ventilation not via a separate channel, but instead via openings through which the cuff communicates with the ventilation lumen of the catheter. If the material of the cuff is elastic, the inflated cuff collapses still more quickly under the restoring forces of the cuff material.

Thus, during inhalation, it is possible to suppress the venturi effect, which characterizes jet ventilation and by which air is entrained from the upper airway into the lung and the inhalatory oxygen concentration is reduced, and it is possible to ensure a pressure compensation with

the outside air upon each exhalation.

Moreover, by incomplete inflation of the cuff ("leaking" cuff) or inflation at a very low pressure (for example 5 mbar), it is possible to ensure that, in the presence of an overpressure or underpressure in the lung, the cuff becomes untight and then functions as an overpressure or underpressure valve.

The cuff and the sealing of the ventilated lung, which takes place at least during inhalation, also ensure that in laser surgical interventions with electrocautery, it is not possible for toxic fumes, virus particles or cell fragments, released by interventions above the cuff, to pass into the ventilated lung. Moreover, the ambient air in which the operating surgeon has to work is not additionally charged with the gas that flows out from the lung and that entrains such gases or particles.

By means of the cuff, it is very easy to switch from classical jet ventilation to jet ventilation with assisted expiration when so required, particularly during laser surgical interventions using electrocautery, and then to go back to classical ventilation again after the actual intervention and then allow the patient to wake.

After complete emptying of the cuff by suction, the jet ventilation catheter can then initially remain without any problem in the trachea of the wakened patient. It is then possible for oxygen to be administered through the jet ventilation catheter very effectively and without any danger and the patient in an emergency situation can even receive further (supportive) ventilation.

The jet ventilation catheter can also be used for renewed intubation or reintubation. For this purpose, the jet ventilation catheter simply has to be lengthened in a suitable way and can then serve as a guide for a conventional tube. Alternatively, a flexible wire is inserted through the lumen of the jet ventilation catheter into the deeper airways, the jet ventilation catheter is removed, and a suitable flexible rod (tube changer) is then engaged onto the flexible wire and positioned in the trachea, after which a conventional tube is advanced over this flexible rod into the tra-

chea.

Although it is in principle possible to measure the intrapulmonary pressure through the ventilation lumen during a brief pause in ventilation, it is nevertheless desirable to provide an additional pressure measurement channel that permits continuous monitoring of the pressure. In tests, the lumen of an epidural catheter has already proven sufficient for this purpose. Although an air column in a channel with such a small lumen permits only a slightly delayed and attenuated measurement of the pressures during inhalation and exhalation, it nonetheless allows very simple and precise monitoring of the profile of the mean pressure (as the crucial parameter). In principle, it is of course also possible to carry out a precise measurement via a liquid column, by filling the pressure measurement channel with a sterile liquid and then connecting it for example to a transducer system. A miniaturized electronic pressure sensor can also conceivably be used and may be advantageous from the point of view of space requirements and production technology. However, an air or liquid column appears to be less susceptible to technical defects, and its functionality can be easily ensured and verified by flushing it through.

Pressure measurement in the ventilated lung then affords the possibility of controlling a ventilation device, for example based on the gas flow reversing element described in WO 2008/113752 A1 in such a way that the gas flows directed to and from the patient can be exactly adapted, in terms of their strength and duration, to the respective ventilation situation. In light of the increasing numbers of in particular laser surgical interventions with electrocautery in the region of the airways, the jet ventilation catheter should as far as possible be made of a noncombustible/nonflammable material. This is essential in particular in the case of ventilation with pure oxygen, since potentially life-threatening burns can otherwise occur in the airways of patients.

A catheter 1 according to the invention, and of a substantially tubular shape, is shown in Figure 1. This catheter 1 has a maximum external diameter D of 6 mm, preferably of less than 4.5 mm. The catheter 1

does not necessarily need to have a circular cross section and instead can also have an oval cross section. Extending through the interior of the catheter 1 there is a ventilation channel 2, also called a lumen, for delivering oxygen or oxygen containing gas and removing respiratory gas. This ventilation channel 2, which also does not need to have a circular cross section, has a maximum internal diameter of up to 4.5 mm, preferably of up to 3 mm, and affords the possibility of jet ventilation with expiratory assistance in which respiratory gas has to flow through the ventilation channel 2 in both directions. Accordingly, the structure of the catheter must be suitable to ensure that the cross-sectional area of the ventilation channel is maintained largely unchanged in the event of pressure and underpressure and in the event of bending. The ventilation channel 2 has an open end 3 through which respiratory gases can flow to and from the airways of a patient. The other end of the ventilation channel 2 is designed as a connector end 4 to which it is possible to connect a supply system 19 (in Figure 5) or, in particular, to connect a gas flow reversing element instead of or as part of the supply system 19, for delivering oxygen or oxygen containing gas and removing respiratory gas. Also extending through the catheter 1 is a pressure measurement channel 5, which has a measurement end 6 near the open end 3 of the ventilation channel 2, and which has a measurement connector piece 7 at the other end. The measurement end 6 can be arranged slightly offset in relation to the open end 3 of the ventilation channel 2. It is important on the whole that the measurement end 6 is designed and arranged in such a way that it cannot be closed off by tissue, secretions or the like during the aspiration of respiratory air through the ventilation channel 2. The outer surface of the catheter 1 is intended to be covered or coated with nonflammable material, unless it is possible for the entire catheter to be made of such a material. This reduces the risks of burning, particularly in an oxygen-rich environment. At a slight distance from the open end 3 of the ventilation channel 2, an expansion body 9, particularly in the form of a cuff, is arranged about the outer surface. A supply channel 8 leads to this

expansion body 9, through which supply channel 8 it is possible to deliver fluid to and remove fluid from the expansion body 9. At its other end, this supply channel 8 terminates in a supply connector piece 10, which can be connected to customary devices that are known per se for operating such expansion bodies 9. In particular, the expansion body 9, the supply channel 8 and an associated operating element can be filled with a noncombustible and nonflammable fluid or gas, in particular nitrogen, a noble gas, water or saline solution. The expansion body 9 can be supplied by the supply channel 8 with so much fluid that it bears snugly on the walls around the site of its insertion, thereby holding the catheter 1 in position and substantially sealing off from each other the airways downstream and upstream of the expansion body 9. In its interior, the expansion body 9 can also have stabilizing structure 24 (in Figure 3) which, even without expansion by means of a fluid, maintain certain shapes or forces of the expansion body. The intention of the stabilizing structure (which may comprise, for example, straps, a sponge, a gel, etc.) that can be incorporated in the expansion body is to keep the expansion body's shape at least partially expanded if the expansion body is not inflated with gas or liquid.

To illustrate the size ratios, Figure 2 shows a cross section through Figure 1 along the line II-II, from which will be seen the arrangement of the ventilation channel 2 with an internal diameter d, of the pressure measurement channel 5 and of the supply channel 8 in relation to the external diameter D of the catheter. In this illustrative embodiment, the individual channels are formed separately from one another in one tube. However, it is also possible to arrange three separate tubes within a common sleeve or also to arrange the supply channel and pressure measurement channel as separate conduits within the ventilation channel.

Figure 3 shows a cross section through Figure 1 along the line III-III, that is to say in a plane through the expansion body 9, visualizing the ventilation channel 2 with an internal diameter d and the pressure measurement channel 5. Since the supply channel 8 leads only as far as the

start of the expansion body, this channel is no longer present in this cross section or, if present, has no function.

Figure 4 shows a cannula according to the invention for jet ventilation with expiratory assistance. This cannula 11 is cannula-shaped in order to pierce into the trachea of a patient from the outside. A preferred embodiment consists of a cannula, within its interior or on its exterior a trocar designed for piercing into the trachea. For embodiments with the trocar positioned within the interior of the cannula, the trocar can be removed after the insertion and then the cannula is connected to a supply system or a gas flow reversing element. The cannula 11 has a first ventilation cannula channel (lumen) 12 for delivering oxygen and removing respiratory gas, with an open end 13 and a connector end 14. Moreover, the cannula 11 has a pressure measurement channel 15 which extends alongside the first cannula channel 12 and which, near the cannula tip, has a measurement opening 16 and, at the other end, has a measurement connector piece 17. The connector end 14 of the first cannula channel 12 and the measurement connector piece 17 can be connected and used in the same way as in the catheter described in Figure 1. As has been described, not only is oxygen injected into the lungs by jet ventilation with expiratory assistance, respiratory air is also aspirated in alternation with the delivery. Even in airways that are completely obstructed in the head-neck area, this permits the use of effective jet ventilation in the sense of transtracheal ventilation. To ensure that no excessive pressure is built up in the lungs despite the obstructed airways, an independent measurement channel in the cannula is particularly advantageous. Once again, the measurement opening 16 of the pressure measurement channel 15 of the cannula 11 should be arranged and designed such that, with a high degree of safety against blockage of the pressure measurement channel 15, an intermittent or as far as possible continuous measurement of the pressure in the trachea is possible. In another preferred embodiment the measurement channel 15 is separate from the cannula at the moment of piercing into the trachea and only after removal of the cannula is inserted

via the measurement connector piece 7 inside and through the ventilation channel 12. Once again, the measurement opening 16 of the pressure measurement channel 15 of the cannula 11 should be arranged and designed such that, with a high degree of safety against blockage of the pressure measurement channel 15, an intermittent or as far as possible continuous measurement of the pressure in the trachea is possible.

Figure 5 shows a catheter 1 according to the invention with various peripheral devices. First, it is possible to insert a guide wire 18 into the ventilation channel 2 via the connector end 4 of the ventilation channel, in order to give the catheter 1 greater stiffness during positioning and to be able to move the open end 3 to a desired location in the airways of a patient. This guide wire 18 can also be used to push secretions or tissue out of the ventilation channel 2 in the case of blockage. After the guide wire 18 has been removed, the connector end 4 can be connected to a supply system 19 and/or a gas flow reversing element. In the simplest case, this gas flow reversing element can operate according to the principle described in WO 2008/113752. However, it is also possible to use an automated gas flow reversing element or an automated supply system 19 in which valves 25 are controlled by a control processor 21 ensuring that oxygen or oxygen containing gas and respiratory gas is alternately delivered through the ventilation channel and removed from the ventilation channel.

Moreover, a pressure display device 20 is provided, to which the measurement connector piece 7 of the catheter 1 can be connected. Alternatively, Figure 5 also indicates schematically that, instead of a pressure measurement channel 5, it is also possible for an electronic pressure sensor 22 to be integrated with signal lines 23 into the catheter 1, in particular for greater automation of the system. In this case, the sensor signals of the electronic pressure sensor 22 are fed to the control processor 21 for controlling the valves 25 in the gas flow reversing element or in the supply system 19.

The present invention enhances patient safety during jet ventila-

tion with expiratory assistance and opens new areas of use of this method for ventilation via conduits of small cross section.

The catheter and/or cannula according to the present invention can advantageously be used to ventilate patients having an inadequate respiratory function on their own. In particular, the catheter and/or cannula according to the present invention can be used to ventilate patients with partially or fully obstructed, nearly complete or even completely blocked airways. With the catheter and/or needle according to the present invention it is possible to normoventilate these patients through a small lumen, in particular between 1.5 mm and 4.5 mm, preferably 3 mm or less, by jet ventilation with expiratory assistance.

Furthermore, it is advantageous to use a catheter and/or a cannula according to the present invention with an expansion body located at or near the tip of the catheter and/or cannula, which ensures in use inter alia a) that the usual airway is blocked (hereby smoke inhalation during laser resection and aspiration of blood, possibly carcinogenic or viral material or cell debris is avoided for the patient and environmental pollution with infection risk is excluded for medical personnel); b) that the position of the catheter and/or needle according to the present invention is fixed relative to the airway in lateral and/or radial position; c) that the tissue of the airway is not harmed or wounded by the catheter and/or needle. The expansion body comprises preferably an inflatable cuff. The expansion body is in use preferably expanded by insufflating an inert gas like in particular nitrogen or one or more noble gases or a nonflammable liquid in particular water or saline solution into the expansion body. The size and in particular at least one diameter of the expansion body can be controlled by the pressure of the gas or the liquid within the expansion body.

The method for jet ventilation of a patient with expiratory assistance can in particular be used in case of one of the following indications:

a) transtracheal jet ventilation;

b) ventilation via small lumen catheters in case of obstructed, nearly complete or even completely blocked airways due to pharyngeal, laryn-

geal, tracheal or bronchial tumor (e.g. carcinoma, submucosal edema, bleeding, emphysema);

c) one lung ventilation via small lumen catheters; and

d) diagnostic and/or therapeutic intervention in the airway limiting the size of the artificial airway (e.g. endotracheal tube) that can be placed for maintaining adequate ventilation of a patient.

The method for jet ventilation of a patient with expiratory assistance can in particular be used in case of the following medical conditions:

a) pharyngeal, laryngeal, tracheal, bronchial airway obstruction limiting passive backflow from the lungs;

b) pharyngeal, laryngeal, tracheal, bronchial airway obstruction limiting the size of an artificial airway (e.g. endotracheal tube) that can be placed for maintaining adequate ventilation;

c) pharyngeal, laryngeal, tracheal, bronchial airway obstruction limiting the size of the artificial airway (e.g., endotracheal tube) that can be placed for maintaining adequate ventilation during diagnostic and/or therapeutic interventions in the airway;

d) "cannot ventilate, cannot intubate" situation; and

e) support of cardiocirculatory resuscitation by alternately creating negative and positive intrathoracic pressure.

The term “normoventilation” is understood as (in combination with sufficient oxygenation) adequate removal of carbon dioxide accumulated by aerobic metabolism (with an alveolar ventilation rate that produces an alveolar carbon dioxide pressure of about 40 mm Hg at any metabolic rate).

The catheter and/or cannula according to the present invention is preferably made of a non combustible material or a material of low flammability and/or a material being resistant against laser beams, in particular of laser beams usually used in medical applications.

The ventilation method is preferably a manual ventilation method in which the flow of the respiratory gas to and from the patients airways

are controlled manually, i. e. without the help of an automated supply system or an automated gas flow reversing element. In this case the direction of the flow is controlled manually by an operator. Any type of gas flow reversing element can be used with the catheter and/or cannula according to the present invention. Preferred is the use of a gas flow reversing element according to WO 2008/113752 A1 which is incorporated herein by reference, in particular regarding the way the gas flow reversing element is formed or shaped.

Furthermore, a method for jet ventilation of a patient with expiratory assistance by means of a catheter and/or a needle according to the present invention is proposed in which the pressure of the respiratory gas in the airway and/or in the lung of the patient is controlled whereas the pressure is in particular used to control the volume flow of the respiratory gas to and from the airways of the patient.

While certain exemplary embodiments have been described and shown in the accompanying drawings, it is to be understood that such embodiments are merely illustrative of and not restrictive on the broad invention, and that this invention not be limited to the specific constructions and arrangements shown and described, since various other changes, combinations, omissions, modifications and substitutions, in addition to those set forth in the above paragraphs, are possible. Those skilled in the art will appreciate that various adaptations and modifications of the just described embodiments can be configured without departing from the scope and spirit of the invention. Therefore, it is to be understood that, within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

Patent claims

1. A catheter for ventilating a patient with expiratory assistance, the catheter comprising:

an elongate member defining a ventilation channel therein alternately delivering oxygen or oxygen containing gas to and removing respiratory gas from the patient's airways, wherein said ventilation channel defines an open end and a connector end for connecting to a supply system,

wherein said ventilation channel has an internal diameter of at most 4.5 mm, preferably of at most 3 mm, and

measures at least 200 mm in length.

2. A catheter according to Claim 1, wherein said elongate member has a maximum external diameter of approximately 6 mm, preferably of approximately 1.5 to 4.5 mm.

3. A catheter according to Claim 1 or 2, wherein the supply system is a gas flow reversing element.

4. A catheter according to Claim 1, 2 or 3, wherein a pressure measuring means, preferably a pressure sensor, is located outside said ventilation channel for measuring the pressure near said open end of said ventilation channel.

5. A catheter according to Claim 4, wherein said elongate member further defines a pressure measurement channel therein, said pressure measurement channel defining an open measurement end near said open end of said ventilation channel and a second closed end, wherein said pressure measurement channel comprises a liquid and a gas part, said gas part being compressable by movement of the liquid part and

said pressure measurement channel further defines a scale to measure the pressure within said pressure measurement channel.

6. A catheter according to Claim 4, wherein said pressure measuring means comprises at least one electronic pressure sensor with signal lines integrated within said elongate member of the catheter.

7. A catheter according to Claim 4 or 6, wherein said elongate member further defines a pressure measurement channel therein, said pressure measurement channel defining an open measurement end near said open end of said ventilation channel and a second connector end, wherein said pressure sensor comprises a measurement connector piece and a pressure display device, said measurement connector piece being operably connected to said second connector end and said pressure display device to measure the pressure within said pressure measurement channel.

8. A catheter according to any one of Claims 1 to 7, wherein said elongate member, at least in the area of said open end of said elongate member, has a needle-like shape, being structured in particular for piercing the trachea and for performing transtracheal ventilation of a patient.

9. A catheter according to any one of Claims 1 to 8, further comprising at least one expansion body positioned on the outside of said elongate member in the area of said open end of said elongate member, wherein said at least one expansion body is structured to be increased and reduced in size by delivering and removing a fluid, respectively.

10. A catheter according to Claim 9, further comprising a supply channel defined within or on said elongate member, said supply channel being fluidically connected to said expansion body.

11. A catheter according to Claim 9, wherein said expansion body comprises at least one stabilizing structure that provides a minimum volume to said expansion body in the condition of reduced size and maintains at least the minimum volume of said expansion body relative to an external overpressure or underpressure of at least 10 mbar.

12. A catheter according to any one of Claims 1 to 11, wherein at least a portion of the outer surface of said elongate member is made of a noncombustible, nonflammable and/or laser-resistant material.

13. A catheter according to any one of Claims 1 to 11, wherein at least a portion of the outer surface of said elongate member is coated with a noncombustible, nonflammable and/or laser-resistant material.

14. A method for ventilating a patient, comprising:

providing a supply system;

providing a catheter comprising an elongate member defining a ventilation channel therein for alternately delivering oxygen or oxygen containing gas to and removing respiratory gas from the patient's airways, wherein the ventilation channel defines an open end and a connector end for connecting to the supply system, the catheter further comprising a pressure sensor located outside the ventilation channel for measuring the pressure near the open end of the ventilation channel;

inserting the catheter from the outside into the trachea;

performing jet ventilation with expiratory assistance through the catheter;

measuring the pressure near the open end of the ventilation channel; and

determining the intervals for delivering and removing oxygen and/or air based upon pressure measurement values.

15. A method according to Claim 14, wherein said performing step is conducted using a gas flow reversing element having processor-controlled valves for alternately delivering oxygen or oxygen containing gas to and removing respiratory gas that is operably connected to the catheter.

16. A method according to Claim 14 or 15, wherein the catheter further comprises an expansion body and further comprising the step of modifying the size of the expansion body until the expansion body seals off the airways.

17. A method according to Claim 16, wherein the insertion step comprises inserting the catheter so far into the patient's airway that the expansion body is being located deeper than a site in the airway that is to be treated or examined, and the expansion body is at least intermittently expanded to such an extent that it holds the catheter sealingly in place relative to the surrounding tissue of the airway, and wherein said performing step is performed before, during and/or after the treatment of the site that is to be treated.

18. A method according to Claim 14, wherein the catheter further comprises an expansion body and further comprising the step of intermittently modifying the size of the expansion body, the timing of the intermittent modifications in size being synchronized with alternately delivering oxygen or oxygen containing gas to and removing respiratory gas in said performing step.

19. A method according to Claim 18, wherein the step of intermittently modifying the size of the expansion body comprises increasing and reducing the size of the expansion body.

20. A method according to Claim 19, wherein said step of in-

termittently increasing and decreasing the size of the expansion body comprises delivering and removing a noncombustible gas to the expansion body, respectively.

21. A method according to Claim 20, wherein the noncombustible gas comprises nitrogen or a noble gas.

22. A method according to Claim 14, wherein said measuring step comprises measuring the pressure near the open end of the ventilation channel using an electrical pressure sensor positioned within the elongate member near the open end.

23. A method according to Claim 14, wherein the elongate member further defines a pressure measurement channel therein, the pressure measurement channel defines an open measurement end near the open end of the ventilation channel and a second connector end, wherein the pressure sensor comprises a measurement connector piece and a pressure display device, the measurement connector piece being operably connected to the second connector end and the pressure display device, and wherein said measuring step comprises measuring the pressure near the open end of the ventilation channel using the pressure display device.

24. A method of ameliorating a breathing obstruction in a subject, comprising:

providing a supply system;

providing a catheter comprising an elongate member defining a ventilation channel therein for alternately delivering and removing air and/or oxygen to and from the patient's airways, wherein the ventilation channel defines an open end and a connector end for connecting to the supply system;

inserting the catheter from the outside into the trachea; and

performing jet ventilation with expiratory assistance through the catheter such that the subject is normoventilated.

25. A method according to Claim 24 wherein the catheter further comprises a pressure sensor located outside the ventilation channel for measuring the pressure near the open end of the ventilation channel and the method further comprising:

measuring the pressure near the open end of the ventilation channel; and

determining the intervals for delivering and removing oxygen and/or air based upon pressure measurement values.

26. The method according to Claim 24 or 25 wherein the ventilation channel has an internal diameter of at most 4.5 mm, preferably.of at most 3 mm; and measures at least 200 mm in length.

27. The method according to any of Claims 24 to 26, wherein the flow rate of the inspirated and aspirated gas through the catheter is approximately 12 to 20 liters per minute, preferably approximately 15 liters per minute.

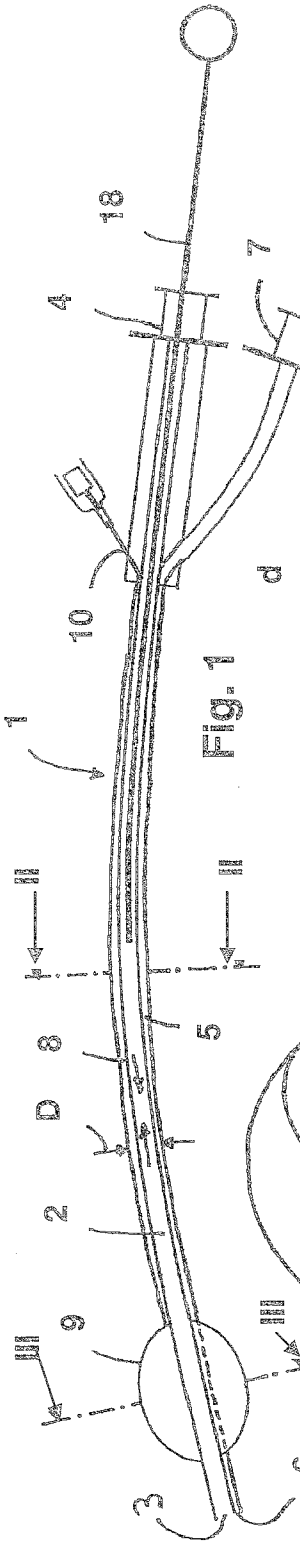

Fig. 1

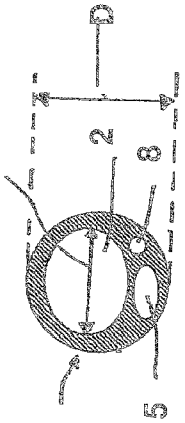

Fig. 2

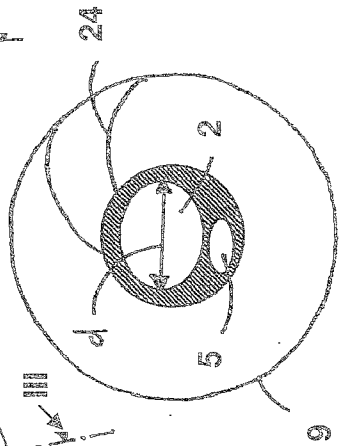

Fig. 3

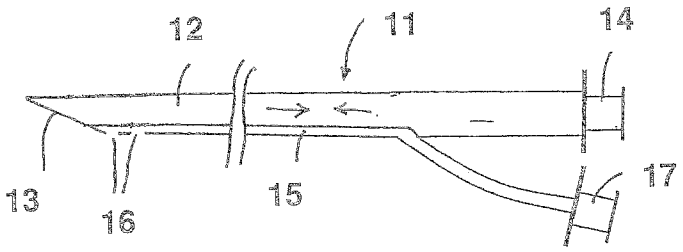

Fig. 4

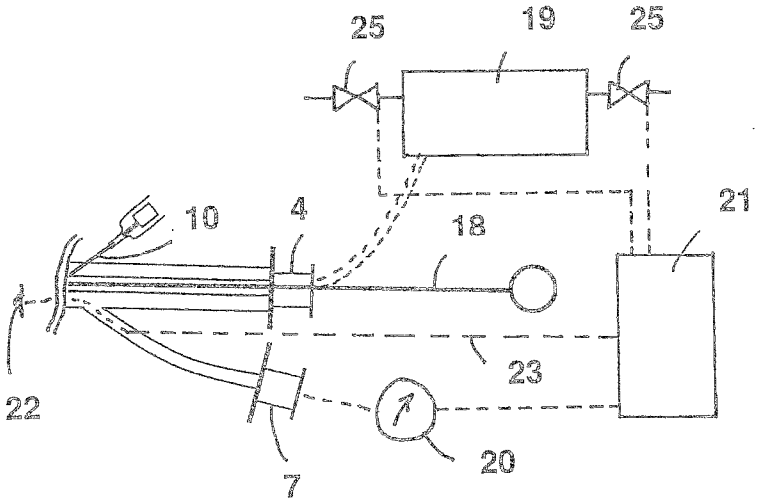

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/053445

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/04
ADD.

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 874 504 B1 (RASPALLO LOUISE D [US]) 5 April 2005 (2005-04-05) column 3, lines 14-35 column 4, lines 16-37 figure 1	1-13
X	WO 01/34221 A2 (EVANS JONATHAN GARETH WESTON [US]; TODD CHRISTINA MICHELLE [US]) 17 May 2001 (2001-05-17) Whole document, especially page 10, line 5-page 11, line 18, page 12, line 19-page 13, line 7, and fiigures 3, 4A, 4B	1-13
X	US 5 954 636 A (SCHWARTZ ROY E [US] ET AL) 21 September 1999 (1999-09-21) column 5, lines 37-56; figures 7,9	1-13

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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 document 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

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 May 2010	27/05/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Borowski, Aleksander

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/053445

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/003814 A1 (BANNER MICHAEL J [US] ET AL) 8 January 2004 (2004-01-08) the whole document	1-13
X	US 6 758 217 B1 (YOUNES MAGDY [CA]) 6 July 2004 (2004-07-06) the whole document	1-13
X	WO 01/23025 A1 (INSTRUMENTARIUM CORP [FI]) 5 April 2001 (2001-04-05) The wghole document, especially page 8, lines 1-5 and 1 and 3	1-13
X	WO 02/074376 A1 (RIGSHOSPITALET [DK]; ENGHOLM MARTIN PETER [DK]) 26 September 2002 (2002-09-26) The whole document, especially claims 1-3 and figures 1 and 2	1-13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2010/053445

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 14-27
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy: a method for ventilating a patient.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2010/053445

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO 02074376 A1	26-09-2002	NONE	