Title: ENDO TRACHEAL INTUBATION SYSTEM INCLUDING A SELF-EXPANDING CUFF

Abstract: In some embodiments, an intubation system comprises: a. a ventilation tube 260 having proximal and distal ends; and b. a radially self-expanding cuff 220 tapered having a wider cuff center and tapered towards its distal and proximal ends relative to the cuff center, the cuff being mounted onto the ventilation tube, the cuff 220 being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating 224.
ENDO TRACHEAL INTUBATION SYSTEM WITH SELF EXPANDING CUFF

RELATED APPLICATION INFORMATION

This application claims priority from U.S. Provisional Application Serial Numbers 61497687, filed June 16, 2011; 61548726, filed October 19, 2011, and 61560242 filed November 15, 2011. The contents of all these previously-filed US provisional are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

The present invention relates to apparatus and methods for ventilation intubation of patients.

BACKGROUND AND RELATED ART

During administration of anesthesia to a patient, or in situations in which a patient is undergoing intensive care, it is standard practice to intubate the patient by introducing an endotracheal tube (ETT) into the trachea, to facilitate pulmonary ventilation. An embodiment of such a tube is illustrated in Fig. 1, which is Fig. 4a of U.S. Patent No. 6,843,250. As shown therein, the ETT 100 which is inserted into a patient airway 111 typically includes an inflatable balloon or cuff 112 near its distal end. The cuff 112, when inflated, performs a dual function: (a) it occludes the air passageway, thus establishing a closed system whereby the gas pressure in the airway distal to the inflated cuff can be maintained at a desired level, thus providing means of controlling the exchange of blood gasses in lungs; and (b) it provides a barrier against inflow of aspirated gastric contents or other matter foreign to the lungs.
Several complications may be associated with such intubation. First, intubated patients may develop ventilation associated pneumonia (VAP). It may occur because the insertion of the ETT bypasses the protective system of the tracheo-bronchial tree. Secretions, mucous or aspirated gastric material, which normally would be directed harmlessly through the digestive system, follow the path of the tube into the airways. Although the use of the balloon or cuff is supposed to prevent such fluids from entering the lungs, the cuff is not infallible. *Inter alia*, the inflatable cuff, on a typical commercially available endotracheal tube, is in the form of an oval-shaped balloon which is biased against the tracheal wall. The oval-shaped balloon permits these secretions to pool around the surface of the balloon proximal to the oral cavity, particularly in the vicinity of the region where the balloon contacts the tracheal wall. Sometimes these fluids bypass the balloon and enter the tracheo-bronchial tree. This passage of unwanted fluids past the inflated cuff of the tracheal tube device is thought to be due to the patient's breathing cycle producing fluctuating inhalation/exhalation pressures on the downstream ovate surface of the inflated cuff, causing the cuff and/or the tracheal conduit to act somewhat in the manner of a peristaltic pump. VAP and associated complications may increase patient time in intensive care and other hospital units, which raises the cost of patient care, and can be fatal.

While it is standard protocol to attempt to suction the region in which fluid tends to collect, suctioning is awkward and, done blindly, may result in insufficient suctioning of the pharynx. In some designs, a tube device is provided not only with an inflation line to the cuff but also with a suction line opening to a region above the cuff. In practice however, due to the finite axial length accommodated by the tape or other fastening means required to attach the cuff sealingly to the main tube of the structure, the opening from the suction line is disposed too far above the upstream ovate surface of the cuff to ensure removal by suction of all the unwanted fluids collecting in that region. Moreover, the oval shape of the cuff inevitably leads to having the most crucial area of fluid collection, at the contact between the cuff and the tracheal surface,
being too narrow for the reach of any suction device. Hence, suction above oval balloons may not ensure complete removal of all secretions.

Furthermore, when the cuff is deflated for removal, fluid collected on the upper surface of the cuff, proximal to the oral cavity, may flow into the lungs.

A second major set of complications arising from tracheal intubation is associated with the cuff sealing pressure. To prevent the leakage of air from between the inflated cuff and the tracheal wall during mechanical ventilation, the pressure in the cuff must be equal to or greater than the peak inspiratory pressure within the airway. Peak inspiratory pressures may be as high as 50 mm of mercury (about 69 cm of water). Since the pressure within the standard cuff is static, in order to achieve continuous good sealing during all parts of the ventilatory cycle, the cuff pressure must ideally be maintained at this relatively high pressure (equal to or greater than peak airway pressure) throughout the entire cycle. However, applying such sealing pressure carries a risk of tissue anoxia and other complications. As the cuff pressure exceeds the capillary pressure of the tracheal tissues (which is normally about 25 mm of mercury, or about 35.5 cm of water), tissue anoxia occurs, and varying degrees of tracheal injury may result. The injuries range from mild erosion of the mucosa, to destruction of the tracheal cartilage rings, to segmental tracheomalacia with dilatation of the trachea. More dramatic is full thickness erosion, with perforation of the innominate artery anteriorly or posteriorly into the esophagus; both of these events are associated with a high rate of mortality. Late complications of tracheal stenosis, from mild to incapacitating obstruction, are most often observed in patients requiring long-term ventilatory support, such as patients hospitalized in the ICU.

As illustrated in Fig. 1, all cuffed ETTs currently in use employ a soft inflatable cuff balloon 112 that, when inflated within the trachea, assumes a fusiform shape providing a surface in contact with the trachea mucosa. The cuff balloon 112 is inflatable from outside of the patient via an inflating lumen 116. Any prolonged pressure above 25 torr increases the risk of tracheal necrosis.
The state of the art in dealing with excess cuff pressure is described in US patent number 5937861. In some high end present art ETTs, there is an integrated suction lumen 122 with a distal port opening above the cuff balloon 112 and connected at the other end to an outside suction device 126, by which fluids collecting above the balloon can be sucked out. Therefore, all present art cuffed ETT devices with an integral suction lumen disclose three lumens projecting out of the patient; the ETT breathing tube 100, the cuff inflating tube 112, and the suction lumen 126.

One of the contributing factors to the development of VAP in patient intubated with an ETT is the blocking of fluids cleared upwardly by the cilia lining the trachea. In a healthy patient, fluids and contaminations (including particles and bacteria) are continuously cleared out from the lungs by cilia lining the tubes into the lungs, and are further pushed upwardly in the trachea towards the vocal cords, and eventually cleared out by natural means, such as coughing. The cuff of a conventional ETT blocks the cilia action mid-way through the trachea. Thus, the contaminated fluids collect and drip back into the lungs.

One salient feature of ETTs is that when in use they may be connected to a ventilation device (for example, via a collared gas connector 262 at proximal end of ETT). The ventilation device may provide gas flow in a distal direction into the human patient according to flow rates and/or pressure parameters known in the art, for example according to FDA or other applicable guidelines.

We believe the state of the art with regard to presently-used cuffs and the associated suction devices is represented by US patents nos. 5259371, 5638813, 7089942, 3964488, 4979505, 5520175, 5937861, 6062223, 7089942, and 7293561 and US patent publications nos. 20030024534 and 20080115789, and references therein. These patents and patent publications, as well as all other publications mentioned herein, are incorporated herein by reference.
SUMMARY OF EMBODIMENTS

Disclosed are systems, kits and methods for facilitating intubation of a patient. In some embodiments, a system includes a ventilation tube (e.g., an ETT tube or a tracheostomy tube) that longitudinally traverses the interior of a cuff. Preferably, the cuff is outwardly biased, includes a fibrous skeleton, and is only partially covered by an elastic, substantially-liquid-impermeable coating. The partial coating is such that at least 10% of the cuff skeleton proximal section is left permeable to liquids penetration through the spaces in between fibers. Some embodiments relate to an apparatus technique for preventing downward movement of liquid by a connecting the cuff distal end to an ETT.

Some embodiments relate to methods and apparatus of delivery and removal of the ETT according to the presently disclosed subject matter.

Some embodiments relate to kits which, when assembled, provide any ETT system disclosed herein. Some embodiments relates to method of assembling, method of deploying, and methods of removing the ETT system or a portion thereof.

In some embodiments, an intubation system comprises:

a. a ventilation tube having proximal and distal ends;
b. a secondary tube traversed by and slideable over the ventilation tube;
and
c. a radially self-expanding cuff having a wider cuff center and tapered towards its distal and proximal ends relative to the cuff center, the cuff being attached proximally to the secondary tube and attached distally to the ventilation tube, the cuff being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating.

In some embodiments, an intubation system comprises:

a. a ventilation tube having proximal and distal ends;
b. a secondary tube traversed by and slideable over the ventilation tube;
and
c. a radially self-expanding cuff attached respectively at its proximal and distal ends onto the secondary tube and onto the ventilation tube,
the cuff being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating.

In some embodiments, an intubation system comprises:

a. a ventilation tube having proximal and distal ends;
b. a secondary tube traversed by and slideable over the ventilation tube; and
c. a radially self-expanding cuff attached respectively at its proximal and distal ends onto the secondary tube and onto the ventilation tube respectively around outer surfaces of the secondary and ventilation tubes,

the cuff being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating.

In some embodiments, an intubation system comprises:

a. a ventilation tube having proximal and distal ends;
b. a secondary tube traversed by and slideable over the ventilation tube; and
c. a radially self-expanding cuff tapered having a wider cuff center and tapered towards its distal and proximal ends relative to the cuff center, the cuff being mounted onto the ventilation tube, the cuff being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating.

In some embodiments, a length of the secondary tube is at most 50%, or at most 40%, or at most 30%, or at most 20%, or at most 10%, of that of the ventilation tube.

In some embodiments, a length of the secondary tube is at least 50% that of the ventilation tube.

In some embodiments, a most distal portion of the cuff is coated with the impermeable coating.

In some embodiments, a majority of the cuff is coated with the impermeable coating.

In some embodiments, at least 10% of the cuff skeleton proximal section is left permeable to liquids penetration through the spaces in between fibers.
In some embodiments, in the neighborhood of said proximal connection of the cuff to the ventilation tube, an uncoated portion of the cuff skeleton proximal section comprising at least 10% of the surface area of the cuff skeleton is uncoated and remains permeable to fluids. 

In some embodiments, at least 30% by length of the fibrous skeleton is coated with the elastic, liquid-impermeable coating.

In some embodiments, the intubation tube is an endotracheal tube (ETT).

In some embodiments, the cuff comprises a radially bulging section between the proximal and distal ends.

In some embodiments, an equilibrium-state radius of the radially bulging section exceeds an equilibrium-state radius of the cuff at the proximal or distal section by at least 20%.

In some embodiments, a length of cuff is between 1 and 8 cm and/or the distal end of the cuff is attached onto the ventilation tube within 5 cm of a distal end thereof.

In some embodiments, comprising a collar mounted to the secondary tube and mounted at a proximal end thereof.

In some embodiments, an intubation system comprises:

a. a ventilation tube having proximal and distal ends;

b. a radially self-expanding cuff, the cuff being permanently and tightly constricted at its distal end around an outer surface of the ventilation tube, proximal and distal ends of the cuff being permanently constricted so as to be more narrow than one or more intermediate cuff locations therebetween, a most distal portion of the cuff being substantially impermeable to liquids, at least a portion of a proximal half of the cuff being permeable to liquids.

In some embodiments, an intubation system comprises:

a. a ventilation tube having proximal and distal ends;

b. a radially self-expanding cuff tapered having a wider cuff center and tapered towards its distal and proximal ends relative to the cuff center, the cuff being mounted onto the ventilation tube, the cuff being constructed of
a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating.

In some embodiments, the cuff is substantially impermeable to liquids over a portion of the distal taper region towards the distal.
In some embodiments, the cuff is substantially impermeable to liquids over a majority of the distal taper region towards the distal.
In some embodiments, at least a portion of a proximal half of the cuff being permeable to liquids.

In some embodiments, an intubation system comprises:

a. a ventilation tube having proximal and distal ends;
b. a radially self-expanding cuff, the cuff being permanently constricted at both more proximal and more distal locations so that a cuff width at one or more intermediate cuff locations exceeds the cuff width at both the more proximal and more distal locations, the cuff being substantially impermeable to liquids at the more distal location, at least a portion of a proximal half of the cuff being permeable to liquids.

In some embodiments, a distance between the more proximal and the more distal locations is at least 1 cm, or at least 2 cm.

In some embodiments, the cuff is constructed of a fibrous skeleton.

In some embodiments, a proximal end of the cuff is permanently formed into a proximal ring having an inner diameter that exceeds and is substantially equal to an outer diameter of the ventilation tube, the proximal ring being slidable over the ventilation tube.

In some embodiments, the ring is not attached onto any rigid element having a length that exceeds 30% of a length of the ventilation tube and that is located mostly proximal to the ring.

In some embodiments, the ring is not attached onto any rigid element having a length that exceeds 30% of a length of the ventilation tube and that is located mostly proximal to the ring and that is lengthwise oriented along a central axis of the ventilation tube.
In some embodiments, the ring is not attached onto any rigid element having a length that exceeds 20% of a length of the ventilation tube and that is located mostly proximal to the ring.

In some embodiments, the ring is not attached onto any rigid element having a length that exceeds 20% of a length of the ventilation tube and that is located mostly proximal to the ring and that is lengthwise oriented along a central axis of the ventilation tube.

In some embodiments, further comprising a secondary tube traversed by and slideable over the ventilation tube.

In some embodiments, the cuff has an intermediate section having a length that is at least 20% that of the cuff and a diameter that exceeds a proximal end cuff diameter by at least 20%.

In some embodiments, the cuff has an intermediate section having a length that is at least 20% that of the cuff and a diameter that exceeds a proximal end cuff diameter by at least 20%.

In some embodiments, the cuff has an intermediate section having a length that is at least 20% that of the cuff and a diameter that exceeds a proximal end cuff diameter by at least 20%.

In some embodiments, the cuff has an intermediate section having a length that is at least 20% that of the cuff and a diameter that exceeds a proximal end cuff diameter by at least 20%.

In some embodiments, an intubation system comprises:

a. a ventilation tube having proximal and distal ends;

b. a secondary tube traversed by and slideable over the ventilation tube;

and

c. a radially self-expanding cuff which in an equilibrium state:  
   i. has a bulging intermediate portion that is wider than more proximal and more distal portions;
   ii. includes proximal and distal rings each of which has an inner diameter that exceeds and is substantially equal to an outer diameter of the ventilation tube, the distal ring being attached onto the ventilation tube, the proximal ring being slidable relative to the ventilation tube.

In some embodiments, the cuff is constructed of a fibrous skeleton.
In some embodiments, the proximal ring is not attached onto any rigid element having a length that exceeds 20% of a length of the ventilation tube and that is located mostly proximal to the ring.

In some embodiments, the ventilation tube longitudinally traverses the cuff.
In some embodiments, the ventilation tube longitudinally traverses the cuff to provide a longitudinal presence over an entire length of the cuff.
In some embodiments, the self-expanding cuff is not a balloon.
In some embodiments, the self-expanding cuff is not inflatable.

An intubation system comprising:

- a ventilation assembly comprising a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and
- a cuff mounted on said ventilation assembly such that a distal end thereof is attached to said ventilation tube, and a proximal end thereof is attached to said sheath.

In some embodiments, said cuff is radially self-expanding to an equilibrium diameter.
In some embodiments, said cuff is constructed of fibrous skeleton (e.g. coated with a coating - e.g. an elastic coating).
In some embodiments, said equilibrium diameter is at least 0.4 cm or at least 0.5 cm or at least 0.6 cm or at least 0.7 cm or at least 0.8 cm or at most 1 cm.
In some embodiments, said equilibrium diameter is at most 2.5 cm or at most 2.2 cm or at most 2 cm or at most 1.8 cm or at most 1.5 cm.
In some embodiments, said ventilation assembly has an outer diameter which is at most 50% of said equilibrium diameter of the cuff.
In some embodiments, the outer diameter of said ventilation assembly is at most 40% of said equilibrium diameter of the cuff.
In some embodiments, a wall thickness of the cuff is at most 10% of said equilibrium diameter.
In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of at most than or 200 cm of water or at most 100 cm or water.

In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no greater than 65 cm of water.

In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no greater than 25 cm of water.

In some embodiments, wherein said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of at least 2 cm of water or at least 5 cm of water or at least 10 cm of water.

In some embodiments, said cuff comprises, at least in an equilibrium state thereof, a portion which extends substantially parallely to said ventilation tube, the diameter of said portion being said equilibrium diameter.

In some embodiments, said cuff comprises, at least in an equilibrium state thereof, a radially bulging portion between said distal and proximal ends thereof.

In some embodiments, at least in an equilibrium state of the cuff, said distal and proximal ends thereof are radially closer to the ventilation assembly than is an area of the cuff therebetween.

In some embodiments, a free area of said cuff between said distal and proximal ends thereof, when cuff is fully and non-plastically extended, is of a length which does not exceed 6 cm.

In some embodiments, said length of the free area is no less than 2 cm.

In some embodiments, a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

In some embodiments, said cuff is in an equilibrium state thereof, said distal portion and ventilation assembly forms a proximally-facing collection basin.

In some embodiments, said cuff comprises a porous frame carrying a liquid-impermeable coating on its distal portion.
In some embodiments, said coating extends to within 1 mm of a distal edge of said frame.

In some embodiments, said coating extends beyond a distal edge of said frame by at least 5 mm.

In some embodiments, said coating is made from a biocompatible material. In some embodiments, said material comprises a polymer. In some embodiments, said material comprises at least one of silicone, polyurethane and latex.

In some embodiments, said frame comprises a fibrous skeleton. In some embodiments, said skeleton is made of a shape memory material. In some embodiments, said shape memory material is selected from a group including a metal alloy and a polymer. In some embodiments, said fibrous skeleton is coated with an elastic material. In some embodiments, further comprising a suction tube having an inlet port located, at least during use, between said distal and proximal ends of the cuff.

An intubation system comprising:

- a ventilation assembly comprising a ventilation tube, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and
- a radially self-expanding cuff having distal and proximal ends being mounted to said ventilation assembly;

wherein a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

In some embodiments, said ventilation further comprises a sheath, said ventilation tube being slidable within said sheath. In some embodiments, said distal end of the cuff is attached to the ventilation tube, and said proximal end of the cuff is attached to said sheath. In some embodiments, said cuff comprises a porous frame carrying a liquid-impermeable coating on its distal portion.

In some embodiments, said coating extends to within 1 mm of a distal edge of said frame.
In some embodiments, said coating extends beyond a distal edge of said frame by at least 5 mm.
In some embodiments, said coating is made from a biocompatible material.
In some embodiments, said material comprises a polymer.
In some embodiments, said material comprises at least one of silicone, polyurethane and latex.
In some embodiments, said frame comprises a fibrous skeleton.
In some embodiments, said skeleton is made of a shape memory material.
In some embodiments, said shape memory material is selected from a group including a metal alloy and a polymer.
In some embodiments, said fibrous skeleton is coated with an elastic material.
In some embodiments, said cuff is radially self-expanding to a equilibrium diameter.
In some embodiments, said equilibrium diameter is no less than 0.6 cm.
In some embodiments, said equilibrium diameter is no greater than 2.2 cm.
In some embodiments, said ventilation assembly has an outer diameter which is no greater than 50% of said equilibrium diameter of the cuff.
In some embodiments, the outer diameter of said ventilation assembly is no greater than 40% of said equilibrium diameter of the cuff.
In some embodiments, a wall thickness of the cuff is no greater than 10% of said equilibrium diameter.
In some embodiments, wherein said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no greater than 200 cm of water.
In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no greater than 65 cm of water.
In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no greater than 25 cm of water.
In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no less than 5 cm of water.

In some embodiments, said cuff comprises, at least in an equilibrium state thereof, a portion which extends substantially parallelly to said ventilation tube, the diameter of said portion being said equilibrium diameter.

In some embodiments, said cuff comprises, at least in an equilibrium state thereof, a radially bulging portion between said distal and proximal ends thereof.

In some embodiments, at least in an equilibrium state of the cuff, said distal and proximal ends thereof are radially closer to the ventilation assembly than is an area of the cuff therebetween.

In some embodiments, when said cuff is in an equilibrium state thereof, said distal portion and ventilation assembly forms a proximally-facing collection basin.

In some embodiments, a free area of said cuff between said distal and proximal ends thereof, when cuff is fully and non-plastically extended, is of a length which does not exceed 6 cm.

In some embodiments, said length of the free area is no less than 2 cm.

In some embodiments, further comprising a suction tube having an inlet port located, at least during use, between said distal and proximal ends of the cuff.

An intubation system comprising:

- a ventilation assembly comprising a ventilation tube, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and
- a radially self-expanding bulging and/or fusiform cuff having distal and proximal ends being mounted to said ventilation assembly.

In some embodiments, said cuff is radially self-expanding to a equilibrium diameter.

In some embodiments, said equilibrium diameter is no less than 0.6 cm.

In some embodiments, said equilibrium diameter is no greater than 2.2 cm.
In some embodiments, said ventilation assembly has an outer diameter which is no greater than 50% of said equilibrium diameter of the cuff.

In some embodiments, the outer diameter of said ventilation assembly is no greater than 40% of said equilibrium diameter of the cuff.

In some embodiments, a wall thickness of the cuff is no greater than 10% of said equilibrium diameter.

In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no greater than 200 cm of water.

In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no greater than 65 cm of water.

In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no greater than 25 cm of water.

In some embodiments, said cuff exerts, when radially compressed to 80% of its equilibrium diameter, an outwardly directed radial pressure of no less than 5 cm of water.

In some embodiments, said cuff comprises, at least in an equilibrium state thereof, a portion which extends substantially parallelly to said ventilation tube, the diameter of said portion being said equilibrium diameter.

In some embodiments, said cuff comprises, at least in an equilibrium state thereof, a radially bulging portion between said distal and proximal ends thereof.

In some embodiments, at least in an equilibrium state of the cuff, said distal and proximal ends thereof are radially closer to the ventilation assembly than is an area of the cuff therebetween.
In some embodiments, a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

In some embodiments, said cuff comprises a porous frame carrying a liquid-impermeable coating on its distal portion.

In some embodiments, wherein said coating extends to within 1 mm of a distal edge of said frame.

In some embodiments, said coating extends beyond a distal edge of said frame by at least 5 mm.

In some embodiments, said coating is made from a biocompatible material.

In some embodiments, said material comprises a polymer.

In some embodiments, said material comprises at least one of silicone, polyurethane and latex.

In some embodiments, said frame comprises a fibrous skeleton.

In some embodiments, said skeleton is made of a shape memory material.

In some embodiments, said shape memory material is selected from a group including a metal alloy and a polymer.

In some embodiments, said fibrous skeleton is coated with an elastic material.

In some embodiments, when said cuff is in an equilibrium state thereof, said distal portion and ventilation assembly form a proximally-facing collection basin.

In some embodiments, said ventilation further comprises a sheath, said ventilation tube being slidable within said sheath.

In some embodiments, said distal end of the cuff is attached to the ventilation tube, and said proximal end of the cuff is attached to said sheath.

In some embodiments, a free area of said cuff between said distal and proximal ends thereof, when cuff is fully and non-plastically extended, is of a length which does not exceed 6 cm.

In some embodiments, said length of the free area is no less than 2 cm.

In some embodiments, further comprising a suction tube having an inlet port located, at least during use, between said distal and proximal ends of the cuff.

An intubation system comprising:
a ventilation assembly comprising a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and

a cuff mounted on said ventilation assembly such that a distal end thereof is attached to said sheath, and a proximal end thereof is attached to said ventilation tube.

In some embodiments, being an endotracheal tube.

A method of deploying a incubation system comprising a ventilation tube and an elastic, self-expanding cuff directly or indirectly mounted thereto, the method comprising:

At a time when the cuff it outside of a patient's trachea, applying an extension force to the elastic, self-expanding cuff so as to stretch the beyond its equilibrium length so as to radially retract the cuff;

inserting the ventilation tube and the mounted, radially-retracted cuff into the patient's trachea; and

ceasing or reducing a magnitude of the extension force to allow the cuff to self-expand so that the cuff applies an outward force upon an inner surface of the trachea.

A method of deploying a incubation system comprising a ventilation tube and an elastic, self-expanding cuff directly or indirectly mounted thereto into an enclosing tube, an equilibrium radius of the cuff exceeding an inner radius of the enclosing tube, the method comprising:

At a time when the cuff it outside of a enclosing tube, applying an extension force to the elastic, self-expanding cuff so as to stretch the beyond its equilibrium length so as to radially retract the cuff;

inserting the ventilation tube and the mounted, radially-retracted cuff into the enclosing tube; and

ceasing or reducing a magnitude of the extension force to allow the cuff to self-expand so that the cuff applies an outward force upon an inner surface of the enclosing tube.
In some embodiments, said distal end of the cuff is attached to the ventilation tube, and said proximal end of the cuff is attached to said sheath.

In some embodiments, a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

In some embodiments, one end of the cuff is mounted to the ventilation tube and another end of the cuff is mounted to an sheath thereof, and wherein the extension force is applied by sliding the ventilation tube relative to the sheath.

In some embodiments, after the cuff self-expands and is within the trachea of enclosing tube, the cuff blocks distal motion of liquid within the enclosing tube or trachea at a time when the sheath remains within the trachea or enclosing tube.

In some embodiments, after the cuff self-expands and is within the trachea of enclosing tube, the cuff blocks distal motion of liquid within the enclosing tube or trachea at a time so that the distally-moving liquid accumulates within a collection basin having an inner boundary defined by an outer surface of the ventilation tube and an outer boundary defined by an inner surface of the cuff, at a time when the sheath remains within the trachea or enclosing tube.

In some embodiments, said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 200 cm of water.

In some embodiments, said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 65 cm of water.

In some embodiments, said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 25 cm of water.

A method according to any one of claims 93 through 102, wherein said inserting positions said cuff between the patient's vocal chords and carina. A method of deploying an endotracheal tube (ETT), the method comprising:

- providing said ETT comprising a ventilation assembly having a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; the ETT further comprising a radially self-
expanding cuff having distal and proximal ends being mounted to said ventilation assembly;
co-disposing said ventilation tube and sheath so as to radially retract said cuff;
subsequently to said co-disposing, inserting said ETT within a patient's trachea; and
moving said ventilation tube relative to said sheath so as to allow said cuff to radially self-expand.
A method of removing an endotracheal tube (ETT) from a patient's trachea, the method comprising:
providing said ETT comprising a ventilation assembly having a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; the ETT further comprising a radially self-expanding cuff having distal and proximal ends being mounted to said ventilation assembly;
co-disposing said ventilation tube and sheath so as to radially retract said cuff;
subsequently to said co-disposing, removing said ETT.
A method of blocking distal motion of fluid within a trachea, the method comprising:
providing an endotracheal tube (ETT) comprising a ventilation assembly having a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; the ETT further comprising a radially self-expanding cuff having distal and proximal ends being mounted to said ventilation assembly, wherein a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids;
co-disposing said ventilation tube and sheath so as to radially retract said cuff;
subsequently to said co-disposing, inserting said ETT within a patient's trachea; and

moving said ventilation tube relative to said sheath so as to allow said cuff to radially self-expand;

wherein the self-expansion of said cuff gives rise to a collection basin configured for said blocking, and being defined between said distal portion of the cuff and the ventilation assembly.

In some embodiments, said distal end of the cuff is attached to the ventilation tube, and said proximal end of the cuff is attached to said sheath.

In some embodiments, a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

In some embodiments, said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 200 cm of water.

In some embodiments, said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 65 cm of water.

In some embodiments, said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 25 cm of water.

A method according to any one of claims 101 through 106, wherein said inserting positions said cuff between the patient's vocal chords and carina.

An intubation system comprising:

a) a ventilation tube 260 defining a ventilation lumen 264 open to a distal port at or near the distal end of the ventilation tube;

b) an self-expanding bulging cuff 220 constructed from a fibrous skeleton, the cuff 220 having an equilibrium radius that significantly exceeds an outer radius of ventilation tube 260, the cuff being internally and longitudinally traversed by ventilation tube 260, each of the proximal and distal ends of the bulging cuff 220 being mounted to an outer surface of the ventilation tube or of an enclosing sheath thereof, the cuff including:

i. a distal portion which is coated by a biocompatible material so as to be impermeable to liquids and
ii. a proximal portion which is permeable to liquids, the cuff 220 being arranged so that liquids traveling outside of ventilation tube in a distal direction cross through the liquid-permeable proximal portion and are retained in a collection basin between the liquid-permeable distal portion and the outer surface of the ventilation tube or the sheath thereof.

An intubation system comprising:

a ventilation assembly comprising a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and

a cuff mounted on said ventilation assembly such that one of a distal end thereof and a proximal end thereof is attached to said ventilation tube, and the other of the distal end thereof and the proximal end thereof is attached to said sheath.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the presently disclosed subject matter and to show how the same may be carried into effect, reference will now be made, purely by way of example, to the accompanying drawings in which like numerals designate corresponding elements or sections throughout.

With reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the embodiments of the presently disclosed subject matter only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects thereof. In this regard, no attempt is made to show structural details of the presently disclosed subject matter in more detail than is necessary for a fundamental understanding thereof, the description taken with the drawings
making apparent to those skilled in the art how the several forms of the presently disclosed subject matter may be embodied in practice.

Embodiments of the presently disclosed subject matter will be explained below in greater detail with reference to the accompanying drawings, in which:

Figs. 1A illustrates a typical design and employment of an endotracheal tube (ETT), as known in the art.

Fig. 3a illustrates the core structure of a cuffed ventilation tube according to some embodiments;

Figs. 4a-4f illustrate some embodiments of a ventilation tube apparatus including an expandable cuff and a connecting element deployed within a trachea;

Figs. 5A-5B are a table of some exemplary device parameters;

Fig. 6 illustrates a cross section of an embodiment of the presently disclosed subject matter where the ventilation tube is deployed in the trachea;

Fig. 7 illustrates apparatus and techniques related to a cuff loading/closing mechanism according to some embodiments;

Figs. 8a-c illustrate embodiments with proximal cuff end attachment to an secondary-tube while distal cuff end is attached to the ventilation tube;

Figs. 9a-c illustrate embodiments with suction lumen attached to the secondary-tube and not to the ventilation tube; and

Figs. 10a-c illustrate an embodiment of the full ventilation tube according to the presently disclosed subject matter.

DETAILED DESCRIPTION OF EMBODIMENTS

The claims below will be better understood by referring to the present detailed description of embodiments with reference to the figures. The description, embodiments and figures are not to be taken as limiting the scope of the claims. It should be understood that not every feature of the presently disclosed methods and apparatuses is necessary in every implementation. It should also be understood that throughout this disclosure, where a process or method is shown or described, the steps of the method may be performed in
any order or simultaneously, unless it is clear from the context that one step
depends on another being performed first. As used throughout this application,
the word "may" is used in a permissive sense (i.e., meaning 'having the
potential to'), rather than the mandatory sense (i.e., meaning "must").

Before explaining at least one embodiment of the invention in detail, it
is to be understood that the invention is not limited in its application to the
details of construction and the arrangement of the components set forth in the
following description or illustrated in the drawings. The invention is applicable
to other embodiments or of being practiced or carried out in various ways.
Also, it is to be understood that the phraseology and terminology employed
herein is for the purpose of description and should not be regarded as limiting.

List of numbered elements:
210: trachea lumen wall tissue;
260: ventilation tube;
262: air ventilation connector to ventilation tube 260;
264: ventilation lumen, going through the ventilation tube 260;
422: suction lumen (can be partly embedded or partly integrally formed with
the ventilation tube 260, and/or partly attached to the ventilation tube
260);
420: distal suction port of suction lumen 422;
220: self expanding biased cuff;
222: wire skeleton of self-expanding cuff 220;
224: impermeable coating of at least a portion of the wire skeleton 222;
226: optional distal extension of the impermeable coating 224 beyond distal
end of the wire skeleton 222;
251: distal end of cuff 220 which is permanently attached onto an outer
surface of ventilation tube 260 In some embodiments, the 'distal end'
may be the 'functional distal end' - i.e. the distal part of the collection
basin of the cuff;
proximal end of cuff 220 which, in an equilibrium state, is formed as a ring having a diameter that is greater than and substantially equal to an outer diameter of ventilation tube 260 - proximal end 252 may, in some embodiments, be permanently attached onto a secondary tube. In some embodiments, the 'proximal end' may be the 'functional proximal end' - i.e. the attachment location where the cuff is proximally formed into a ring having a diameter about that of the ventilation tube.

inner surface of cuff 220 facing towards the tube 260.

pre-bending corners of cuff 220;

secondary tube traversed by and slideable over the ventilation tube 260;

optional proximal fixation connector of secondary tube to patient;

air ventilation connector to ventilation tube 260 in the case where fixation connector 991 is used.

suction proximal connector between suction lumen and suction source.

Embodiments of the present invention relate to systems including a ventilation tube and a cuff and to related methods. One example of ventilation tube is an ETT - another example is a tracheostomy tube. Throughout the present disclosure, some examples may be explained in terms of ETT or tracheostomy tubes- this is not a limitation and any feature explained for an ETT may also be provided for other ventilation tubes such as tracheostomy tubes.

As illustrated in Fig. 3a, there is provided an intubation system, which is generally indicated at 200. The intubation system 200 comprises a cuff 220 (e.g. radially-expandable and/or outwardly biased) and a ventilation tube 260. The intubation system may further comprise a suction lumen 422.

One example of a ventilation tube is a tracheostomy tube. Another example of a ventilation tube is an endotracheal tube (ETT). Various features of ETTs are discussed in WO 2010/151713 incorporated herein by reference in its entirety. For example, the distal end of the ETT may be tapered and/or include a Murphey eye. For example, a collared gas tube connector 262 may be present at the proximal end.
The cuff 220 comprises a frame, which may be constructed so as to have a shape memory (i.e., it returns to a pre-deformation shape when a force which caused the deformation has been removed). Cuff 220 may comprise a fibrous skeleton 222, which, in some embodiments, may be made from a shape memory material, such as a suitable metal alloy or polymer. In some embodiments, the fibrous skeleton may be coated with an liquid-impermeable and/or elastic material. It may be constructed in the form of a mesh, a braid, a weave, or any other configuration suitable for assembling fiber into a tubular shape. The cuff may be any suitable length - for example, at least 1 cm or at least 2 cm and/or at most 10 cm or at most 8 cm or at most 7 cm at most 6 cm (i.e. any combination is possible). It may be provided with a biocompatible coating, which may include one or more of silicone, polyurethane and latex.

As will be discussed below, in some embodiments, the cuff may provide one or more (i.e. any combination of) the following features:

(i) a distal end of the cuff is directly and permanently attached onto and around an outer surface of ventilation tube 260. Towards this end, the cuff may be formed so that in an equilibrium state, a cuff width (diameter) exceeds and substantially equal to an outer width (diameter) of an outer surface of the ventilation tube. The 'permanently attached' cuff may be glued or welded onto the outer surface of ventilation tube or integrally formed therewith;

(ii) cuff 220 is impermeable to liquids towards a distal end 251 thereof (i.e. at the distal end). For example, a certain fraction of the cuff at the most distal portion of cuff 220 (e.g. at least the most distal 10% or at least the most distal 20% or at least the most distal 30% or at least the most distal 50% of the cuff) is liquid impermeable - e.g. a fibrous skeleton in these locations is coated with a liquid impermeable (e.g. elastic) material;

(iii) at least one or more proximal locations (e.g. in the proximal half of cuff 220 or the proximal third or quarter or tenth thereof) are permeable to liquids allowing fluids to enter a region within cuff 220 and outside of ventilation tube 260 to form a collection basin;
(iv) the proximal end 252 of cuff 220 is permanently formed into a ring having an inner diameter that exceeds and is substantially equal to outer diameter of the ventilation tube. In some embodiments, the ring may have more rigidity than other locations of cuff. In some embodiments, the ring is a 'glue ring' formed by treating the proximal end with glue. In one example described in the figures, the proximal end 252 of cuff 220 permanently attached onto an outer surface of secondary tube 265 which is traversed by and slideable over ventilation tube. This secondary tube may have any length. In another example, the proximal end 252 of cuff 220 permanently attached onto an outer surface of ventilation tube 260. In yet another example, proximal ring is not attached onto any rigid element having a length that exceeds 20% of a length of the ventilation tube and that is located mostly proximal to the ring.

(v) cuff 220 is mounted to ventilation tube 260 at a distal end (not shown) thereof - for example, a distance between a distal end of ventilation tube 260 and a center (or distal end of) cuff 220 may be at most 5 cm or at most 3 cm or most 2 cm.

Due to its shape memory, the cuff 220 has an associated equilibrium state, i.e., its state when not acted on by external forces. In this equilibrium state, proximal and distal portions (e.g. at or near proximal 252 and distal 251 ends thereof) of cuff are permanently constricted so that a cuff width in the proximal and distal portions is less than the cuff width in one or more intermediate locations 249. For example, a cuff width at one or more intermediate locations may be at least 10% or at least 20% or at least 30% or at least 40% or at least 50% greater than an outer diameter of ventilation tube 260.

An equilibrium dimension of cuff 220, e.g., an equilibrium diameter, thereof is considered to be the respective dimension when the cuff is not acted on by external forces, i.e., the respective dimension when the cuff is in its pre-deformation state. In some embodiments, the equilibrium diameter at the widest longitudinal cross-section (i.e., perpendicular to the longitudinal axis of the cuff) may be between 0.4 cm and 2 cm. According to some embodiments, the equilibrium diameter at the widest longitudinal cross-section may be at least
0.5 cm or at least 0.75 cm or at least 1 cm and/or at most 2 cm or at most 1.75 cm or at most 1.5 cm (e.g. between 1 cm and 1.5 cm) (i.e. any combination is possible). According to other embodiments, the equilibrium diameter at the widest longitudinal cross-section may be between 1 cm and 1.7 cm.

In some embodiments, this 'deformable' or 'shape memory property' is useful as follows: (i) the cuff 220 may have an equilibrium radius that equal to about that of (e.g. slightly larger than) that of the trachea but significantly larger than an outer radius of the ventilation tube (e.g. ETT or tracheostomy ventilation tube); (ii) as such, it may be difficult to deploy the cuff within the trachea when it has its equilibrium shape; (iii) in order to deploy the cuff, a 'inward-deforming-force' may be applied to the cuff (e.g. by stretching the cuff) to reduce a width of the cuff to a value less than that in the equilibrium configuration but larger than that of the outer surface of the ventilation tube - this allows downward motion of the ventilation tube and the cuff mounted thereon within the confines of the trachea; (iv) because the cuff is self-expanding, when it is desired to deploy the cuff, the 'inward-deforming-force-ceases or is significantly reduced in magnitude - this causes the cuff to return to its equilibrium width which is, for example, slightly greater than a width of the trachea - as such the cuff now applies an outer force to the trachea.

In order to remove the cuff, it is possible to once again apply the 'inward-deforming-force' and then to remove the cuff from the trachea (i.e. by 'proximal' or 'upward' motion).

The cuff 220 may be capable of being deformed such that the cross-sectional diameter at the widest longitudinal cross-section is at most 80% or at most 70% or at most 60% or at most 50% or at most 40% or at most 30% an equilibrium diameter of the equilibrium diameter at the same location (i.e. any combination is possible).. In some non-limiting embodiments, stretching the cuff may cause the cross section of the cuff to decrease in area and/or may cause the diameter of the cuff to contract to a below its equilibrium value.

The cuff 220 may be capable of being deformed such that the cross-sectional diameter at the widest longitudinal cross-section is at least 1 mm or at
least 1.5 mm or at least 2 mm less than the equilibrium diameter at the same location. According to some embodiments, the cuff may be capable of being compressed such that the cross-sectional diameter at the widest longitudinal cross-section is at least 3 mm, or at least 4 mm, or at least 5 mm less than the equilibrium diameter at the same location.

The cuff 220 may characterized in that when deformed to 80% of its equilibrium diameter, it exerts an outwardly directed radial pressure which is at least 2 cm of water or at least 5 cm of water or at least 10 cm of water or at least 15 cm of water or at least 20 cm of water and/or at most 200 cm of water or at most 100 cm of water or at most (i.e. any combination is possible).

. The outwardly directed radial pressure may be less than 50 cm of water. According to some embodiments, the outwardly directed radial pressure may be less than 200 cm of water, 100 cm of water, 65 cm of water, 60 cm of water, 40 cm of water, or 25 cm of water. According to some embodiments, the outwardly directed radial force may be between 0.5 kPA (kilopascals) and 5 kPA. It will be appreciated that when the cuff is placed with a human trachea (of typical radius less than 1.4cm) and released to self-expand on its own biased force, the portion of the cuff having the largest external diameter will exert a pressure on the tracheal wall as per the above.

The cuff 220, in an equilibrium state thereof, may have an approximately circular cross-section perpendicular to its cylindrical symmetry, i.e., the cross-section of the cuff at any position along the longitudinal axis of the tube 260 is approximately circular. It is noted that according to this embodiment, while the longitudinal cross-section is circular, the diameter of the cross-section may vary along the longitudinal axis. For example, the cuff 220 may have a cylindrical mid-section and frusto-conical ends, which then distally tapers off in a conical manner towards the distal connection 251 to the ventilation tube 260. In some other embodiments, the biased cuff has an overall shape of non-cylindrical symmetry, such as oval, or "horseshoe" shapes.

The cuff may have a bulging or fusiform shape, i.e., a central portion thereof may have a larger cross-sectional diameter than the distal and proximal
ends. According to one embodiment, the central portion having the larger
cross-sectional diameter may extend longitudinally, i.e., the sidewalls of the
cuff in the vicinity thereof may extend substantially perpendicularly to the
ventilation assembly and/or the ventilation tube.

According to some embodiments, for example as illustrated in Figs. 4a
and 4b, the cuff may be formed to be partly constricted or/and tapered towards
its distal and/or proximal ends relative to the cuff center. In some
embodiments, the cuff has pre-bent angles 231, 232 near distal and proximal
attachments areas 251, 252 of the cuff to the ventilation assembly. The pre-bent
angles may be formed such that distal and proximal ends of the cuff 220 are
directed inwardly. Alternatively, for example as illustrated in Figs. 4c and Fig.
4d, the pre-bent angles 231, 232 may be formed such one or both of the distal
and proximal ends of the cuff 220 are directed outwardly. The pre-bent angles
231, 232 can be formed, for example, by heat treatment and freezing of the cuff
skeleton 222 with the bended angle.

The fibrous skeleton, i.e., the frame of the cuff 220, may be coated along
at least a distal portion thereof with a material which is impermeable to liquids.
The material may be an elastic material. According to some embodiments, the
coated distal portion (i.e., the portion of the cuff which is coated) may comprise
at least 20% or at least 30% or at least 50% or at least 70%, or at least 90%
and/or at most 90% or at most 70% or at most 50% or at most 30% (i.e. any
combination is possible) of the length of the fibrous skeleton of the frame.
According to some embodiments, the coated distal portion may be at least 1 cm
long, e.g., it may be at least 2 cm or at least 3 cm long. It may be no more than
6 cm, e.g., no more than 3 cm or 2 cm long. In any event, the liquid
impermeable coating may be provided from a distal end at least until it reaches
a portion of the fibrous skeleton which has the widest longitudinal cross-
section.

A proximal portion of the cuff is permeable to liquids, e.g., it may be
free of a liquid impermeable coating. This proximal portion may comprise at
least 10% or at least 20% or at least 30% or at least 50% of the surface area of
the cuff, and/or extend at least 10% or at least 20% or at least 30% or at least 50% of the length of the cuff.

As illustrated in Figs. 4e and Fig. 4f, the liquid impermeable coating may extend distally beyond the edge of the fibrous skeleton, as indicated at 226. The portion of the coating which extends beyond the fibrous skeleton may be attached to the ventilation assembly.

The liquid-impermeable distal portion may define a surface of a collection basin at the distal end of the cuff. For example, liquids traveling in a distal direction may cross through a liquid-permeable proximal portion of the cuff 220 to enter a volume of space outside of ventilation tube but within cuff. The liquid-impermeable distal portion of the cuff may block distal motion of liquid. For example, when the cuff is outwardly-biased to apply outward pressure to a tracheal wall, liquids descending distally down the trachea external to the ventilation assembly may be blocked by the liquid-impermeable distal portion of cuff to remain within collection basin 298 (i.e. rather than traveling further in the distal direction).

In the event that the cuff is bulging and/or fusiform, the liquid-impermeable coating may extend to at least 10% or at least 20% or at least 30% or at least 50% of the surface of the portion of the cuff having the largest cross-sectional diameter. In particular, it may extend to and cover the most distal 10% or at least 20% or at least 30% or at least 50% thereof.

For delivery into a human trachea, a longitudinal pulling force is applied to the cuff 220, longitudinally extending it. This causes deforms cuff 220 causing it to radially retract, e.g., so that its diameter is substantially uniform (i.e. but less than an 'equilibrium diameter'), and is close to the ventilation tube 260. The ventilation tube 260 is then inserted into the trachea, and when the cuff 220 is in a suitable position, e.g., between the vocal folds (i.e., the vocal chords) and the carina. The longitudinal pulling force is then released, and the cuff 220, owing to its shape memory, radially self-expands towards its original shape. As its maximum equilibrium diameter may be larger than the inner diameter of the trachea, the cuff 220, especially the coated distal portion
thereof, may bias itself against the tracheal lumen wall tissue, creating a seal and giving rise to the collection basin.

According to some embodiments, the ventilation assembly 202 further comprises a sheath 265 (see, for example, FIG. 8) around the ventilation tube such that the ventilation tube is slidable within the sheath. For example, the inner diameter of the sheath may be at most 40% or at most 30% or at most 20% or at most 10% and/or at least 5% or at least 10% or at least 30% or about 30% larger than the outer diameter of the ventilation tube.

The sheath is not required to extend an entire length of the ventilation tube. In the example of FIG. 8, a portion of ventilation tube distal to a distal end of sheath 265 extends beyond a distal-most location of sheath 265. In some embodiments, a length of sheath 265 is at least 10% or at least 20% or at least 30% or at least 40% or at least 50% (i.e. at least a majority of) or at least 60% or at least 75% (i.e. at least a substantial majority of) that of the ventilation tube. In some embodiments, the sheath 265 remains deployed within the trachea while the cuff functions to block distal motion of fluids within the trachea.

As noted above, the distal end of the cuff may be connected to the ventilation tube. According to some embodiments, the proximal end of the cuff may also be connected to the ventilation tube. In such a case, the sheath is configured to slide over the ventilation tube 260 and cuff 220, thereby radially compressing cuff 220. The entire cuff, or a majority thereof, may be so compressed within the sheath.

Alternatively or additionally, the proximal end of the cuff is connected to the outside of the sheath, near the distal end thereof, for example within about 1 cm thereof. The ventilation tube may project distally from the sheath, for example by at least 2 cm. In such a case, the sheath may be longitudinally retracted relative to the ventilation tube, thereby applying a longitudinal pulling force to the cuff. This causes it to radially retract, as described above. According to this and other embodiments, a mechanism may be provided to selectively restrict movement of the sheath relative to the ventilation tube. This
ensures that, for example, when the sheath and ventilation tube are co-disposed so as to apply a longitudinal pulling force on the cuff so as to radially retract it, they maintain this co-disposition until the mechanism is released.

In some embodiment, it is useful to suction liquid from the collection basin 298 where it has accumulated. The suctioned liquid may, for example, enter suction lumen 422 (for example, provided as a separate tube or integrated into the wall of the ventilation tube or the sheath or in any other manner apparent to the skilled artisan after reading the present disclosure) via distal port. As illustrated in Fig. 4b, it comprises a distal port 420. According to some embodiments, the distal port 420 is located within the collection basin 298, i.e., between the internal surface of coated and/or liquid-impremeable distal portion of the cuff 220 and an outer surface of ventilation assembly (e.g., an outer surface of ventilation tube or a sheath 265 thereof). The distal suction port 420 may be situated more distally than the proximal end of the impermeable coating 224 of the cuff.

FIGS. 6A-6C illustrate collection basin 298 where liquid travelling in a distal direction outside of ventilation tube accumulates. This liquid crosses through cuff 220 in a liquid-permeable proximal portion of cuff 220 and is blocked from further motion in the distal direction by the liquid-impermeable distal portion of cuff 220. As noted above, this liquid may be proximally suctioned out of collection basin 298 through suction port 420.

Figs. 9a and 9b illustrate an embodiment of the intubation system wherein the suction lumen 422 is attached to or integrated with the sheath 265 instead of the ventilation tube 260. Hence, in such embodiments the distal port 420 of the suction lumen 422 is movable relative to ventilation tube 260 by virtue of its attachment to the slidable secondary tube 265.

According to some embodiments, for example as illustrated in Fig. 10b, a suction tube 994 may be attached to the suction lumen 422 of the ventilation tube 260, and passed through an open cut through the wall of the secondary tube 265 enveloping the ventilation tube. The suction lumen 422 is in fluid
communication with the suction tube 294, and terminates with a proximally located connector element 293 for connection to an external source of suction.

In use, according to one embodiment, the ventilation assembly comprises the ventilation tube slidably received within the sheath. The distal end of the cuff is connected to the ventilation tube, and the proximal end thereof is connected to the outside of the sheath, near a proximal end thereof. The cuff is fusiform and/or bulging, with its widest portion thereof extending substantially parallely to the ventilation assembly when the cuff is in its equilibrium position. A liquid-impermeable coating is provided on the distal portion of the cuff, which extends from its area of connection with the ventilation tube at least until the widest portion thereof. The bulging portion may have an equilibrium diameter of about 3 cm. Prior to introduction into the patient's trachea, the sheath is slid proximally relative to the ventilation tube and maintained in that position. This exerts a longitudinal pulling force on the cuff, which causes it to retract radially. The retracted diameter of the cuff is close to the diameter of the sheath, which may be about 1.2 cm. The ventilation assembly is introduced into the patient's trachea, which may have a diameter of about 2.4 cm. Once the cuff is in the proper place, between the vocal folds and the carina, the sheath is released. Due to the shape memory of the cuff, it radially self-expands (pulling the sheath distally with it). A convex proximally-facing collection basin is defined between the between the coated distal portion of the cuff and the ventilation assembly. Since the equilibrium diameter of the widest part of the cuff is larger than the diameter of the trachea, the cuff exerts a pressure against, i.e., is biased against, the trachea lumen wall tissue.

**Additional discussion**

Fig. 3a illustrates an image of an ETT device including a biased cuff 220. The cuff 220 is comprising of a wire skeleton 222, and where the at least a portion of the distal section of skeleton 222 is coated with an impermeable coating 224, thereby creating a thin wall of the cuff. The cuff wall is enclosing around a longitudinal axis and traversed by the ventilation tube 260. The cuff and its coating is connected at the distal end to the ventilation tube 260 at
within 5cm from the distal tip of the tube 260, said distal cuff connection section is highlighted by label 251 in Fig. 4a.

The biased cuff 220 may be constructed from a fibrous skeleton or fibrous structure that is coated along at least a portion of its length with a coating of elastic material so that said portion of the cuff is substantially impermeable to liquids, said portion being more that 20% or 30% or 50% or 70% or 90% of length of the fibrous skeleton; a length of the cuff being at least 1 cm (for example, at least 2 cm or at least 3 cm) and/or preferably at most 6 cm, and/or at most 3 cm, and/or at most 2 cm (this may refer to either the total length of the cuff or the length of the coated portion of the cuff), the cuff being radially expandable and outwardly biased to provide an expanded/equilibrium radius REXPANDED at its widest cross section location perpendicular to the longitudinal axis of the cuff (i.e. the radius when is allowed to expand to its equilibrium radius in the absence or external forces or attachment) that is between 0.4 cm and 2 cm (in some embodiments, between 1.45 cm and 1.5 cm), and capable of being compressed to a compressed radius RCOMPRESSED that is less than 80% (in some embodiments, less than 70% or less than 60% or less than 50%) of the expanded/equilibrium radius REXPANDED and/or to a compressed radius that is at least 2 mm (in some embodiments, at least 3 mm or at least 4 mm or at least 5 mm) less than the fully-expanded radius REXPANDED of the cuff.

The cuff 220 may provide elasticity properties so that when the cuff is deployed within a rigid tube having a tube radius RTCUBE that is less than the expanded/equilibrium radius REXPANDED (for example, the tube radius RTCUBE is between 0.7 and 0.9 times (for example, 0.8 times) the expanded/equilibrium radius REXPANDED) the cuff exerts an outward pressure upon the outer tube whose value is at least 5 cm of water and at most 50 cm of water and/or between 0.5 kPA (kilopascals) and 5 kPA. Thereby, when the cuff is placed with a human trachea (of typical radius less than 1.4 cm) and release to self-expand on its own biased force, the cuff external surface engages the trachea wall tissue 210 at least at the widest perimeter of the expanded cuff and in a
portion of at least 10% of the surface area of the coated portion 224 of the cuff 220.

In some embodiments as illustrated in Fig. 4, the cuff skeleton proximal end is attached to tube 260 at connection section 252. In the neighborhood of said proximal connection of the cuff 220 to the tube 260, an uncoated portion of the cuff skeleton proximal section is uncoated and remains permeable to fluids. Said uncoated portion comprises at least 10% of the surface area of the cuff skeleton. Thereby, when placed inside a human trachea as illustrated in Fig. 6, external fluids descending under the force of gravity from the proximal towards the distal tip of the tube 260 are blocked by the cuff 220 and collected in a collection basin formed between the internal surface 320 of the cuff and the external surface of the ventilation tube 260.

In some embodiments, the biased cuff 220 has an approximately cylindrical symmetry in the sense that there is a longitudinal axis where the cross section of the cuff at any position along the tube 260 is approximately circular. It is noted that this locally circular cross section does not limit the cuff to overall cylinder geometry. For example, in some embodiments, as illustrated in Fig. 10, the cuff 220 has a cylindrical mid-section which then distally tapers off in a conical manner till the distal connection 251 to the ventilation tube 260. In some other some embodiments, the biased cuff has an overall shape of non-cylindrical symmetry, such as oval, or "horseshoe" shapes.

In a first example, the fibrous skeleton may be constructed in the form of a mesh, or a braid, or a weave, or other textile form of assembling fiber into a tubular shape.

In some embodiments, the cuff formed to partly constricted or/and tapered towards its distal and/or proximal ends relative to the cuff center. In some some embodiments, the cuff has pre-bended angles 231 and/or 232 near attachments distal/proximal
attachments 251/252 of the cuff to the ventilation tube. The pre-bending can be
constructed, for example, by heat treatment and freezing of the cuff skeleton 222 with
said bended angle prior to coating with impermeable coating 224.

Fig. 4b illustrates a schematic cross section of the tube 260 with attached
cuff 220. As

45 illustrated in Fig. 4b, in some embodiments, the system further comprise of a suction
lumen 422, where said suction lumen has a distal port 420 situated in a location within

8 the collection basin between the internal surface 320 of the cuff and the ventilation lumen 264 of the ventilation tube 260. The distal suction port 420 is preferably distance by an offset to be situated more distally than the proximal end of the impermeable coating 224.

In some embodiments, the suction lumen 422 is integrally formed in the ventilation tube 260. In some other embodiments the suction lumen 5 is formed at least
partly as a separate tube which is attached to the ventilation tube 260. Fig. 4c and Fig. 4d illustrate and highlight alternative attachments and bending configuration options of the cuff 220 to the ventilation tube 260. As highlighted in the

difference between Fig. 4b and 4d, the variation is in the 232 bending orientation
distally/proximally of the cuff near proximal attachment 252 of the cuff to the tube.

Fig. 4e and Fig. 4f illustrate a preferred embodiment where the impermeable cover layer
224 has an extension portion 226 which is extending distally beyond the distal edge of
15 the skeleton 222 of the cuff 220. Said distal end of said extended potion 226 is then attached to the ventilation tube 260.

For delivery from the outside into a human trachea, the cuff 220 may need to be first delivered and maintained in a compressed state around the ventilation tube 260. Then, when positioned in the desired location within the trachea, the cuff is release to expand under its own biased tension (optionally with some assisted force) and engage the trachea lumen tissue.

In some embodiments where both the cuff distal end and the proximal end are attached directly onto the ventilation tube 260, there is a need to supplement the system with an loading-tube. One loading tube may have a radius radius loadingtube that is substantially larger than the radius of the ventilation tube rett tube within a tolerance of 30% from the ventilation tube radius, the loading tube positioned so that at least a portion the cuff is compressed within the loading tube between the ETT tube and the loading tube.

In some embodiments, a majority of the cuff is compressed within the loading tube between the ETT tube and the loading tube.

In some embodiments, substantially an entirety of the cuff is compressed within the loading tube between the ETT tube and the loading tube 530.

Figs. 8a,b illustrate yet another configuration of attachment of both ends of the cuff 220 to the ventilation tube 260. Clearly, since the ventilation tube 260 is substantially non stretchable, in such embodiments there is no freedom for range of motion of the proximal cuff end attachment 252 relative to the distal cuff end attachment 251. In contrast, as illustrated in Fig. 8c and 8d, in some embodiments the distal end of the cuff 220 is attached onto the ventilation tube 260, while the proximal end of the cuff 220 is attached onto a secondary tube 265 which is slideable relative to the ventilation tube 260.

Thereby, in such embodiments there does exist a degree of freedom for range of motion of the proximal cuff end attachment 252 relative to the distal cuff end attachment 251. As illustrated in Fig. 8d, a preferred range of motion is such that the cuff can be stretched enough to be substantially
flattened around the underlying ventilation tube 260. Another illustration of this action is provided in Fig. 10b,c which show images of a working prototype according to the above principles. Preferably, the secondary tube distal end extends less than 1cm below its distal connection 5 to the cuff.

Figs. 9a,b illustrate an alternative preferred embodiment of the system where the suction lumen is attached to or integrated with the secondary tube 265 instead of the ventilation tube 260. Hence, in such embodiments the suction lumen port 420 is movable relative to ventilation tube 260 by virtue of its attachment to the slidable secondary tube 265.

In some embodiments, said suction lumen has a distal port 420 situated in a location within the collection basin between the internal surface 320 of the cuff and the ventilation lumen 264 of the ventilation tube 260. The distal suction port 420 is preferably distance by an offset to be situated more distally than the proximal end of the impermeable coating 224, and therefore the distal end of the secondary tube is also extended to such depth in these embodiments.

In some embodiments, the slidable secondary tube 265 and be optionally locked into a fixed position to the ventilation tube 260, so as to temporarily impede their relative motion.

Fig. 10a illustrates a cross section of a full system embodiment incorporating a slideable secondary tube 265 as discussed above. The ventilation tube 260 is longer than the secondary tube 265 by at least 2cm. The secondary tube 265 is therefore enveloping the ventilation tube 260 along a portion of its length. In some embodiments, the human patient anchoring is done to the proximal end of said secondary tube via collar element 991.

In some embodiments. The ventilation circuit is connected to the proximal end of the ventilation tube 260 via a connector element 292.

As illustrated in Fig. 10b, in some embodiments the suction tube 294 is attached to the suction lumen 422 of the ventilation tube 260, and passed through an open cut through the wall of the secondary tube 265 enveloping the ventilation tube. The suction lumen 422 continues into the suction tube
attachment 294 and terminates with a connector element 293 for connection to an external suction machine/source.

As illustrated in Fig. 10c, the cuff 220 is stretched substantially flat over the ventilation tube 260 by the action of sliding the secondary tube relative to the ventilation tube 260 such as to increase the longitudinal axis distance between the positions of the proximal and distal ends of the cuff 220. This action can be achieved by pulling on the collar 291 of the secondary tube towards the ventilation tube proximal end connector 292.

In some embodiments, the biocompatible coating of the cylindrical cuff includes one or more of silicone, polyurethane and latex.

In some embodiments, the length of the cuff is between 2 cm and 6 cm.

In some embodiments, a value of radius the expanded/equilibrium radius is between 1 cm and 1.7 cm.

In some embodiments, according to the elasticity feature, when the cuff is deployed within a rigid tube having a tube radius $R_{TUBE}$ that is 0.8 times the fully-expanded radius $R_{EXPANDED}$, the cuff exerts an outward pressure upon the outer tube whose value is at least 5 cm of water and at most 100 cm of water.

In some embodiments, according to the elasticity feature, when the cuff is deployed within a rigid tube having a tube radius $R_{TUBE}$ that is 0.8 times the fully-expanded radius $R_{EXPANDED}$, the cuff exerts an outward pressure upon the outer tube whose value is at least 5 cm of water and at most 60 cm of water.

In some embodiments, according to the elasticity feature, when the cuff is deployed within a rigid tube having a tube radius $R_{TUBE}$ that is 0.8 times the fully-expanded radius $R_{EXPANDED}$, the cuff exerts an outward pressure upon the outer tube whose value is at least 5 cm of water and at most 40 cm of water.

In some embodiments, according to the elasticity feature, when the cuff is deployed within a rigid tube having a tube radius $R_{TUBE}$ that is 0.8 times the fully-expanded radius $R_{EXPANDED}$, the cuff exerts an outward pressure upon the outer tube whose value is at least 5 cm of water and at most 25 cm of water.
In some embodiments, the cuff provides both the thin wall feature and the elasticity feature.

In some embodiments, the cuff provides only the thin wall feature.
In some embodiments, the cuff provides only the elasticity feature.
In some embodiments, the compressed radius $R_{COMPRESSED}$ that is less than 50% of the expanded/equilibrium radius $R_{EXPANDED}$
In some embodiments, the compressed radius $R_{COMPRESSED}$ that is less than 40% of the expanded/equilibrium radius $R_{EXPANDED}$
In some embodiments, the compressed radius $R_{COMPRESSED}$ that is less than 30% of the expanded/equilibrium radius $R_{EXPANDED}$

In a first example, the fibrous skeleton may be constructed in the form of a mesh, or a braid, or a weave, or other textile form of assembling fiber into a tubular shape.

In some embodiments, any feature of combination of feature(s) disclosed in WO 2010/151713 incorporated herein by reference in its entirety may be provided.

Various embodiments of the invention have been described in detail, but it will be understood by those skilled in the art that variations and modifications can be effected within the spirit and scope of the invention.

Unless otherwise defined, all technical and scientific terms used herein have the same meanings as are commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods are described herein.

All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of
conflict, the patent specification, including definitions, will prevail. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined by the general combination of parts that perform the same functions as exemplified in the embodiments, and includes both combinations and sub-combinations of the various features described hereinabove as well as variations and modifications thereof, which would occur to persons skilled in the art upon reading the foregoing description.

Having thus described the foregoing exemplary embodiments it will be apparent to those skilled in the art that various equivalents, alterations, modifications, and improvements thereof are possible without departing from the scope and spirit of the claims as hereafter recited. In particular, different embodiments may include combinations of features other than those described herein. Accordingly, the claims are not limited to the foregoing discussion.
WHAT IS CLAIMED IS:

1. An intubation system comprising:
   a. a ventilation tube 260 having proximal and distal ends;
   b. a secondary tube 265 traversed by and slideable over the ventilation tube; and
   c. a radially self-expanding cuff 220 having a wider cuff center and tapered towards its distal and proximal ends relative to the cuff center, the cuff being attached proximally to the secondary tube and attached distally to the ventilation tube, the cuff 220 being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating 224.

2. An intubation system comprising:
   a. a ventilation tube 260 having proximal and distal ends;
   b. a secondary tube 265 traversed by and slideable over the ventilation tube; and
   c. a radially self-expanding cuff 220 attached respectively at its proximal and distal ends onto the secondary tube and onto the ventilation tube, the cuff 220 being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating 224.

3. An intubation system comprising:
   a. a ventilation tube 260 having proximal and distal ends;
   b. a secondary tube 265 traversed by and slideable over the ventilation tube; and
   c. a radially self-expanding cuff 220 attached respectively at its proximal and distal ends onto the secondary tube and onto the ventilation tube respectively around outer surfaces of the secondary and ventilation tubes, the cuff 220 being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating 224.

4. An intubation system comprising:
   a. a ventilation tube 260 having proximal and distal ends;
   b. a secondary tube 265 traversed by and slideable over the ventilation tube; and
c. a radially self-expanding cuff 220 tapered having a wider cuff center and tapered towards its distal and proximal ends relative to the cuff center, the cuff being mounted onto the ventilation tube, the cuff 220 being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating 224.

5. The intubation system of any preceding claim wherein a length of the secondary tube 265 is at most 50%, or at most 40%, or at most 30%, or at most 20%, or at most 10%, of that of the ventilation tube 200.

6. The intubation system of any preceding claim wherein a length of the secondary tube 265 is at least 50% that of the ventilation tube.

7. The intubation system of any preceding claim wherein a most distal portion of the cuff is coated with the impermeable coating.

8. The intubation system of any preceding claim wherein a majority of the cuff is coated with the impermeable coating 224.

9. The intubation system of any preceding claim wherein at least 10% of the cuff skeleton proximal section is left permeable to liquids penetration through the spaces in between fibers.

10. The intubation system of any preceding claim wherein in the neighborhood of said proximal connection of the cuff 220 to the ventilation tube 260, an uncoated portion of the cuff skeleton proximal section comprising at least 10% of the surface area of the cuff skeleton is uncoated and remains permeable to fluids.

11. The intubation system of any preceding claim wherein at least 30% by length of the fibrous skeleton is coated with the elastic, liquid-impermeable coating 224.

12. The intubation system of any preceding claim wherein the intubation tube is an endotracheal tube (ETT).

13. The intubation system of any preceding claim wherein the cuff comprises a radially bulging section between the proximal and distal ends.

14. The intubation system of any preceding claim wherein an equilibrium-state radius of the radially bulging section exceeds an equilibrium-state radius of the cuff at the proximal or distal section by at least 20%. 

15. The intubation system of any preceding claim wherein a length of cuff 220 is between 1 and 8 cm and/or the distal end of the cuff is attached onto the ventilation tube within 5 cm of a distal end thereof.

16. The intubation system of claim 6 wherein comprising a collar mounted to the secondary tube 265 and mounted at a proximal end thereof.

17. An intubation system comprising:
   a. a ventilation tube 260 having proximal and distal ends;
   b. a radially self-expanding cuff 220, the cuff 220 being permanently and tightly constricted at its distal end around an outer surface of the ventilation tube, proximal and distal ends of the cuff being permanently constricted so as to be more narrow than one or more intermediate cuff locations therebetween, a most distal portion of the cuff 220 being substantially impermeable to liquids, at least a portion of a proximal half of the cuff being permeable to liquids.

18. An intubation system comprising:
   a. a ventilation tube 260 having proximal and distal ends; and
   b. a radially self-expanding cuff 220 tapered having a wider cuff center and tapered towards its distal and proximal ends relative to the cuff center, the cuff being mounted onto the ventilation tube, the cuff 220 being constructed of a fibrous skeleton and only partly covered by an elastic, liquid-impermeable coating 224.

19. The system of claim 18 wherein the cuff is substantially impermeable to liquids over a portion of the distal taper region towards the distal.

20. The system of claim 18 wherein the cuff is substantially impermeable to liquids over a majority of the distal taper region towards the distal.

21. The system of any of claims 17-20 wherein at least a portion of a proximal half of the cuff being permeable to liquids.

22. An intubation system comprising:
   a. a ventilation tube 260 having proximal and distal ends;
   b. a radially self-expanding cuff 220, the cuff 220 being permanently constricted at both more proximal and more distal locations so that a cuff
width at one or more intermediate cuff locations exceeds the cuff width at
both the more proximal and more distal locations, the cuff 220 being
substantially impermeable to liquids at the more distal location, at least a
portion of a proximal half of the cuff being permeable to liquids.

23. The system of claim 22 wherein a distance between the more proximal and
the more distal locations is at least 1 cm, or at least 2 cm.

24. The intubation system of any of claims 17-23 wherein the cuff 220 is
constructed of a fibrous skeleton.

25. The intubation system of any of claims 17-24 wherein a proximal end of the
cuff is permanently formed into a proximal ring having an inner diameter that
exceeds and is substantially equal to an outer diameter of the ventilation tube,
the proximal ring being slidable over the ventilation tube.

26. The intubation system of claim 25 wherein the ring is not attached onto
any rigid element having a length that exceeds 30% of a length of the
ventilation tube and that is located mostly proximal to the ring.

27. The intubation system of claim 25 wherein the ring is not attached onto
any rigid element having a length that exceeds 30% of a length of the
ventilation tube and that is located mostly proximal to the ring and that is
lengthwise oriented along a central axis of the ventilation tube.

28. The intubation system of claim 25 wherein the ring is not attached onto
any rigid element having a length that exceeds 20% of a length of the
ventilation tube and that is located mostly proximal to the ring.

29. The intubation system of claim 25 wherein the ring is not attached onto
any rigid element having a length that exceeds 20% of a length of the
ventilation tube and that is located mostly proximal to the ring and that is
lengthwise oriented along a central axis of the ventilation tube.

30. The intubation system of any of claims 17-25 further comprising a
secondary tube 265 traversed by and slideable over the ventilation tube.

31. The intubation system of any preceding claim wherein the cuff has an
intermediate section having a length that is at least 20% that of the cuff and a
diameter that exceeds a proximal end cuff diameter by at least 20%.
32. The intubation system of any preceding claim wherein the cuff has an intermediate section having a length that is at least 20% that of the cuff and a diameter that exceeds a proximal end cuff diameter by at least 20%.

33. The intubation system of any preceding claim wherein the cuff has an intermediate section having a length that is at least 20% that of the cuff and a diameter that exceeds a proximal end cuff diameter by at least 20%.

34. An intubation system comprising:
   a. a ventilation tube 260 having proximal and distal ends;
   b. a secondary tube 265 traversed by and slideable over the ventilation tube; and
   c. a radially self-expanding cuff 220 which in an equilibrium state:
      i. has a bulging intermediate portion that is wider than more proximal and more distal portions;
      ii. includes proximal and distal rings each of which has an inner diameter that exceeds and is substantially equal to an outer diameter of the ventilation tube,
         the distal ring being attached onto the ventilation tube, the proximal ring being slidable relative to the ventilation tube.

35. The intubation system of claim 34 wherein the cuff 220 is constructed of a fibrous skeleton.

36. The intubation system of any of claims 34-35 wherein the proximal ring is not attached onto any rigid element having a length that exceeds 20% of a length of the ventilation tube and that is located mostly proximal to the ring.

37. The system of any previous claim wherein the ventilation tube longitudinally traverses the cuff.

38. The system of any previous claim wherein the ventilation tube longitudinally traverses the cuff to provide a longitudinal presence over an entire length of the cuff.

39. The system of any previous claim wherein the self-expanding cuff is not a balloon.
40. The system of any previous claim wherein the self-expanding cuff is not inflatable.

1. An intubation system comprising:
   • a ventilation assembly comprising a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and
   • a cuff mounted on said ventilation assembly such that a distal end thereof is attached to said ventilation tube, and a proximal end thereof is attached to said sheath.

2. The intubation system according to any one of claims 1 and 88, wherein said cuff is radially self-expanding to an equilibrium diameter.

3. The intubation system according to claim 2, wherein said maximum equilibrium diameter is at least 0.4 cm or at least 0.5 cm or at least 0.6 cm or at least 0.7 cm or at least 0.8 cm or at most 1 cm.

4. The intubation system according to any one of claims 2 and 3, wherein said maximum equilibrium diameter is at most 2.5 cm or at most 2.2 cm or at most 2 cm or at most 1.8 cm or at most 1.5 cm.

5. The intubation system according to claim 4, wherein said ventilation assembly has an outer diameter which is at most 50% of said maximum equilibrium diameter of the cuff.

6. The intubation system according to claim 5, wherein the outer diameter of said ventilation assembly is at most 40% of said maximum equilibrium diameter of the cuff.

7. The intubation system according to any one of claims 2 through 6, wherein a wall thickness of the cuff is at most 10% of said maximum equilibrium diameter.

8. The intubation system according to any one of claims 2 through 7, wherein said cuff exerts, when radially compressed to 80% of its equilibrium
diameter, an outwardly directed radial pressure of at most than or 200 cm of water or at most 100 cm or water.

9. The intubation system according to claim 8, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no greater than 65 cm of water.

10. The intubation system according to claim 9, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no greater than 25 cm of water.

11. The intubation system according to any one of claims 8 through 10, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of at least 2 cm of water or at least 5 cm of water or at least 10 cm of water.

12. The intubation system according to any one of claims 2 through 11, wherein said cuff comprises, at least in an equilibrium state thereof, a portion which extends substantially parallelly to said ventilation tube, the diameter of said portion being said maximum equilibrium diameter.

13. The intubation system according to any one of claims 2 through 12, wherein said cuff comprises, at least in an equilibrium state thereof, a radially bulging portion between said distal and proximal ends thereof.

14. The intubation system according to any one of claims 2 through 13, wherein, at least in an equilibrium state of the cuff, said distal and proximal ends thereof are radially closer to the ventilation assembly than is an area of the cuff therebetween.

15. The intubation system according to any one of the preceding claims or claim 88, wherein a free area of said cuff between said distal and proximal ends thereof, when cuff is fully and non-plastically extended, is of a length which does not exceed 6 cm.

16. The intubation system according to claim 15, wherein said length of the free area is no less than 2 cm.
17. The intubation system according to any one of the preceding claims or claim 88, wherein a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

18. The intubation system according to claim 17, wherein, when said cuff is in an equilibrium state thereof, said distal portion and ventilation assembly forms a proximally-facing collection basin.

19. The intubation system according to any one of claims 17 and 18, wherein said cuff comprises a porous frame carrying a liquid-impermeable coating on its distal portion.

20. The intubation system according to claim 19, wherein said coating extends to within 1 mm of a distal edge of said frame.

21. The intubation system according to claim 19, wherein said coating extends beyond a distal edge of said frame by at least 5 mm.

22. The intubation system according to any one of claims 19 through 21, wherein said coating is made from a biocompatible material.

23. The intubation system according to claim 22, wherein said material comprises a polymer.

24. The intubation system according to any one of claims 22 and 23, wherein said material comprises at least one of silicone, polyurethane and latex.

25. The intubation system according to any one of claims 19 through 24, wherein said frame comprises a fibrous skeleton.

26. The intubation system according to claim 25, wherein said skeleton is made of a shape memory material.

27. The intubation system according to claim 26, wherein said shape memory material is selected from a group including a metal alloy and a polymer.

28. The intubation system according to any one of claims 25 through 27, wherein said fibrous skeleton is coated with an elastic material.

29. The intubation system according to any one of the preceding claims or claim 88, further comprising a suction tube having an inlet port located, at least during use, between said distal and proximal ends of the cuff.
30. An intubation system comprising:
   • a ventilation assembly comprising a ventilation tube, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and
   • a radially self-expanding cuff having distal and proximal ends being mounted to said ventilation assembly;

wherein a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

31. The intubation system according to claim 30, wherein said ventilation further comprises a sheath, said ventilation tube being slidable within said sheath.

32. The intubation system according to claim 31, wherein said distal end of the cuff is attached to the ventilation tube, and said proximal end of the cuff is attached to said sheath.

33. The intubation system according to any one of claims 30 through 32, wherein said cuff comprises a porous frame carrying a liquid-impermeable coating on its distal portion.

34. The intubation system according to claim 33, wherein said coating extends to within 1 mm of a distal edge of said frame.

35. The intubation system according to claim 33, wherein said coating extends beyond a distal edge of said frame by at least 5 mm.

36. The intubation system according to any one of claims 33 through 35, wherein said coating is made from a biocompatible material.

37. The intubation system according to claim 36, wherein said material comprises a polymer.

38. The intubation system according to any one of claims 36 and 37, wherein said material comprises at least one of silicone, polyurethane and latex.

39. The intubation system according to any one of claims 33 through 38, wherein said frame comprises a fibrous skeleton.

40. The intubation system according to claim 39, wherein said skeleton is made of a shape memory material.
41. The intubation system according to claim 40, wherein said shape memory material is selected from a group including a metal alloy and a polymer.
42. The intubation system according to any one of claims 39 through 41, wherein said fibrous skeleton is coated with an elastic material.
43. The intubation system according to any one of claims 30 through 42, wherein said cuff is radially self-expanding to a maximum equilibrium diameter.
44. The intubation system according to claim 43, wherein said maximum equilibrium diameter is no less than 0.6 cm.
45. The intubation system according to any one of claims 43 and 44, wherein said maximum equilibrium diameter is no greater than 2.2 cm.
46. The intubation system according to claim 45, wherein said ventilation assembly has an outer diameter which is no greater than 50% of said maximum equilibrium diameter of the cuff.
47. The intubation system according to claim 46, wherein the outer diameter of said ventilation assembly is no greater than 40% of said maximum equilibrium diameter of the cuff.
48. The intubation system according to any one of claims 43 through 47, wherein a wall thickness of the cuff is no greater than 10% of said maximum equilibrium diameter.
49. The intubation system according to any one of claims 43 through 48, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no greater than 200 cm of water.
50. The intubation system according to claim 49, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no greater than 65 cm of water.
51. The intubation system according to claim 50, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no greater than 25 cm of water.
52. The intubation system according to any one of claims 49 through 51, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no less than 5 cm of water.

53. The intubation system according to any one of claims 43 through 52, wherein said cuff comprises, at least in an equilibrium state thereof, a portion which extends substantially parallelly to said ventilation tube, the diameter of said portion being said maximum equilibrium diameter.

54. The intubation system according to any one of claims 43 through 53, wherein said cuff comprises, at least in an equilibrium state thereof, a radially bulging portion between said distal and proximal ends thereof.

55. The intubation system according to any one of claims 43 through 54, wherein, at least in an equilibrium state of the cuff, said distal and proximal ends thereof are radially closer to the ventilation assembly than is an area of the cuff therebetween.

56. The intubation system according to any one of claims 43 through 55, wherein, when said cuff is in an equilibrium state thereof, said distal portion and ventilation assembly forms a proximally-facing collection basin.

57. The intubation system according to any one of claims 30 through 56, wherein a free area of said cuff between said distal and proximal ends thereof, when cuff is fully and non-plastically extended, is of a length which does not exceed 6 cm.

58. The intubation system according to claim 57, wherein said length of the free area is no less than 2 cm.

59. The intubation system according to any one of claims 30 through 58, further comprising a suction tube having an inlet port located, at least during use, between said distal and proximal ends of the cuff.

60. An intubation system comprising:
   • a ventilation assembly comprising a ventilation tube, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and
• a radially self-expanding bulging and/or fusiform cuff having distal and proximal ends being mounted to said ventilation assembly.

61. The intubation system according to claim 60, wherein said cuff is radially self-expanding to a maximum equilibrium diameter.

62. The intubation system according to claim 61, wherein said maximum equilibrium diameter is no less than 0.6 cm.

63. The intubation system according to any one of claims 61 and 62, wherein said maximum equilibrium diameter is no greater than 2.2 cm.

64. The intubation system according to claim 63, wherein said ventilation assembly has an outer diameter which is no greater than 50% of said maximum equilibrium diameter of the cuff.

65. The intubation system according to claim 64, wherein the outer diameter of said ventilation assembly is no greater than 40% of said maximum equilibrium diameter of the cuff.

66. The intubation system according to any one of claims 61 through 65, wherein a wall thickness of the cuff is no greater than 10% of said maximum equilibrium diameter.

67. The intubation system according to any one of claims 61 through 66, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no greater than 200 cm of water.

68. The intubation system according to claim 67, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no greater than 65 cm of water.

69. The intubation system according to claim 68, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no greater than 25 cm of water.

70. The intubation system according to any one of claims 67 through 69, wherein said cuff exerts, when radially compressed to 80% of its maximum equilibrium diameter, an outwardly directed radial pressure of no less than 5 cm of water.
71. The intubation system according to any one of claims 61 through 70, wherein said cuff comprises, at least in an equilibrium state thereof, a portion which extends substantially parallely to said ventilation tube, the diameter of said portion being said maximum equilibrium diameter.

72. The intubation system according to any one of claims 61 through 71 wherein said cuff comprises, at least in an equilibrium state thereof, a radially bulging portion between said distal and proximal ends thereof.

73. The intubation system according to any one of claims 61 through 72, wherein, at least in an equilibrium state of the cuff, said distal and proximal ends thereof are radially closer to the ventilation assembly than is an area of the cuff therebetween.

74. The intubation system according to any one claims 60 through 73, wherein a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

75. The intubation system according to claims 74, wherein said cuff comprises a porous frame carrying a liquid-impermeable coating on its distal portion.

76. The intubation system according to claim 75, wherein said coating extends to within 1 mm of a distal edge of said frame.

77. The intubation system according to claim 75, wherein said coating extends beyond a distal edge of said frame by at least 5 mm.

78. The intubation system according to any one of claims 75 through 77, wherein said coating is made from a biocompatible material.

79. The intubation system according to claim 78, wherein said material comprises a polymer.

80. The intubation system according to any one of claims 78 and 79, wherein said material comprises at least one of silicone, polyurethane and latex.

81. The intubation system according to any one of claims 75 through 80, wherein said frame comprises a fibrous skeleton.

82. The intubation system according to claim 81, wherein said skeleton is made of a shape memory material.
83. The intubation system according to claim 82, wherein said shape memory material is selected from a group including a metal alloy and a polymer.

84. The intubation system according to any one of claims 81 through 83, wherein said fibrous skeleton is coated with an elastic material.

85. The intubation system according to any one of claims 74 through 84 when dependent on any one of claims 59 through 71, wherein, when said cuff is in an equilibrium state thereof, said distal portion and ventilation assembly form a proximally-facing collection basin.

86. The intubation system according to any one of claims 60 through 85, wherein said ventilation further comprises a sheath, said ventilation tube being slidable within said sheath.

87. The intubation system according to claim 86, wherein said distal end of the cuff is attached to the ventilation tube, and said proximal end of the cuff is attached to said sheath.

88. The intubation system according to any one of claims 60 through 87, wherein a free area of said cuff between said distal and proximal ends thereof, when cuff is fully and non-plastically extended, is of a length which does not exceed 6 cm.

89. The intubation system according to claim 88, wherein said length of the free area is no less than 2 cm.

90. The intubation system according to any one of claims 60 through 89, further comprising a suction tube having an inlet port located, at least during use, between said distal and proximal ends of the cuff.

91. An intubation system comprising:
   • a ventilation assembly comprising a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and
• a cuff mounted on said ventilation assembly such that a distal end thereof is attached to said sheath, and a proximal end thereof is attached to said ventilation tube.

92. The intubation system according to any one of the preceding claims, being an endotracheal tube.

93. A method of deploying a incubation system comprising a ventilation tube and an elastic, self-expanding cuff directly or indirectly mounted thereto, the method comprising:

• At a time when the cuff it outside of a patient's trachea, applying an extension force to the elastic, self-expanding cuff so as to stretch the beyond its equilibrium length so as to radially retract the cuff;
• inserting the ventilation tube and the mounted, radially-retracted cuff into the patient's trachea; and
• ceasing or reducing a magnitude of the extension force to allow the cuff to self-expand so that the cuff applies an outward force upon an inner surface of the trachea.

94. A method of deploying a incubation system comprising a ventilation tube and an elastic, self-expanding cuff directly or indirectly mounted thereto into an enclosing tube, an equilibrium radius of the cuff exceeding an inner radius of the enclosing tube, the method comprising:

• At a time when the cuff it outside of a enclosing tube, applying an extension force to the elastic, self-expanding cuff so as to stretch the beyond its equilibrium length so as to radially retract the cuff;
• inserting the ventilation tube and the mounted, radially-retracted cuff into the enclosing tube; and
• ceasing or reducing a magnitude of the extension force to allow the cuff to self-expand so that the cuff applies an outward force upon an inner surface of the enclosing tube.

95. A method according to any of claims 93-94, wherein said distal end of the cuff is attached to the ventilation tube, and said proximal end of the cuff is attached to said sheath.
96. A method according to any one of claims 93-95, wherein a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

97. The method according to any one of claims 93-96 wherein one end of the cuff is mounted to the ventilation tube and another end of the cuff is mounted to an sheath thereof, and wherein the extension force is applied by sliding the ventilation tube relative to the sheath.

98. The method according to any of claims 93-97 wherein after the cuff self-expands and is within the trachea of enclosing tube, the cuff blocks distal motion of liquid within the enclosing tube or trachea at a time when the sheath remains within the trachea or enclosing tube.

99. The method according to any of claims 93-97 wherein after the cuff self-expands and is within the trachea of enclosing tube, the cuff blocks distal motion of liquid within the enclosing tube or trachea at a time so that the distally-moving liquid accumulates within a collection basin having an inner boundary defined by an outer surface of the ventilation tube and an outer boundary defined by an inner surface of the cuff, at a time when the sheath remains within the trachea or enclosing tube.

100. A method according to any one of claims 93 through 99, wherein said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 200 cm of water.

101. A method according to claim 100, wherein said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 65 cm of water.

102. A method according to claim 101, wherein said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 25 cm of water.

103. A method according to any one of claims 93 through 102, wherein said inserting positions said cuff between the patient's vocal chords and carina. A method of deploying an endotracheal tube (ETT), the method comprising:

- providing said ETT comprising a ventilation assembly having a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end
thereof providing access to the ventilation lumen; the ETT further comprising a radially self-expanding cuff having distal and proximal ends being mounted to said ventilation assembly;

- co-disposing said ventilation tube and sheath so as to radially retract said cuff;
- subsequently to said co-disposing, inserting said ETT within a patient's trachea; and
- moving said ventilation tube relative to said sheath so as to allow said cuff to radially self-expand.

104. A method of removing an endotracheal tube (ETT) from a patient's trachea, the method comprising:

- providing said ETT comprising a ventilation assembly having a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; the ETT further comprising a radially self-expanding cuff having distal and proximal ends being mounted to said ventilation assembly;
- co-disposing said ventilation tube and sheath so as to radially retract said cuff;
- subsequently to said co-disposing, removing said ETT.

105. A method of blocking distal motion of fluid within a trachea, the method comprising:

- providing an endotracheal tube (ETT) comprising a ventilation assembly having a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; the ETT further comprising a radially self-expanding cuff having distal and proximal ends being mounted to said ventilation assembly, wherein a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids;
co-disposing said ventilation tube and sheath so as to radially retract said cuff; 
subsequently to said co-disposing, inserting said ETT within a patient's trachea; and
• moving said ventilation tube relative to said sheath so as to allow said cuff to radially self-expand; 

wherein the self-expansion of said cuff gives rise to a collection basin configured for said blocking, and being defined between said distal portion of the cuff and the ventilation assembly.

106. A method according to claim 101, wherein said distal end of the cuff is attached to the ventilation tube, and said proximal end of the cuff is attached to said sheath.

107. A method according to any one of claims 101 and 102, wherein a distal portion of said cuff is impermeable to liquids, and a proximal portion of said cuff is permeable to liquids.

108. A method according to any one of claims 101 through 103, wherein said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 200 cm of water.

109. A method according to claim 104, wherein said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 65 cm of water.

110. A method according to claim 105, wherein said cuff bears against a tracheal lumen wall tissue with a pressure between 5 and 25 cm of water.

111. A method according to any one of claims 101 through 106, wherein said inserting positions said cuff between the patient's vocal chords and carina.

112. An intubation system comprising:
   a) a ventilation tube 260 defining a ventilation lumen 264 open to a distal port at or near the distal end of the ventilation tube;
   b) an self-expanding bulging cuff 220 constructed from a fibrous skeleton, the cuff 220 having an equilibrium radius that significantly exceeds an outer radius of ventilation tube 260, the cuff being internally and longitudinally traversed by ventilation tube 260, each of the
proximal and distal ends of the bulging cuff 220 being mounted to an outer surface of the ventilation tube or of an enclosing sheath thereof, the cuff including:

i. a distal portion which is coated by a biocompatible material so as to be impermeable to liquids and

ii. a proximal portion which is permeable to liquids,

the cuff 220 being arranged so that liquids traveling outside of ventilation tube in a distal direction cross through the liquid-permeable proximal portion and are retained in a collection basin between the liquid-permeable distal portion and the outer surface of the ventilation tube or the sheath thereof.

113. An intubation system comprising:

- a ventilation assembly comprising a ventilation tube slidable within a sheath, the ventilation tube defining a ventilation lumen therein and having a port at or near a distal end thereof providing access to the ventilation lumen; and

- a cuff mounted on said ventilation assembly such that one of a distal end thereof and a proximal end thereof is attached to said ventilation tube, and the other of the distal end thereof and the proximal end thereof is attached to said sheath.

114. A method comprising:

deploying the intubation system of any preceding claim so that the ventilation tube is within the ventilation tube and the self-expanding cuff expands outwards so as to press upon a trachea so as to create a substantially liquid-tight seal between a proximal region outside of the ventilation tube and within the trachea and a distal region outside of the ventilation tube and within the trachea.
FIG. 2

Prior art of coated mesh stents
Fig. 3

Collared Gas tube Connector 262

Intermediate Location(s) 220

distal 251

proximal 252

422

260

Proximal End of Ventilation Tube
### FIG. 5A

<table>
<thead>
<tr>
<th>Sample Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radius of Trachea 210</td>
</tr>
<tr>
<td>Radius of ETT 260</td>
</tr>
<tr>
<td>Equilibrium Radius of cuff 220</td>
</tr>
<tr>
<td>Compressed Radius Of cuff 220</td>
</tr>
<tr>
<td>Length of cuff 220</td>
</tr>
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</table>
**FIG. 5B**  

**SAMPLE PARAMETERS (cont)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of ETT 210</td>
<td></td>
</tr>
<tr>
<td>Location of cuff 220 on ETT 268</td>
<td>Around the Middle – Lower 2/3ds</td>
</tr>
<tr>
<td>Thickness Of the cuff</td>
<td>0.1-1.0 mm</td>
</tr>
</tbody>
</table>
FIG. 6A
Liquid Traveling
In a distal direction
Outside of ventilation tube
Proximal trachea region above cuff

Permeable

Collection basin 298

Impermeable
Distal trachea region below cuff

Liquid-retaining

Gravity vector

FIG. 6B
Liquid Traveling In a distal direction Outside of ventilation tube
Proximal trachea region above cuff

Permeable

Gravity vector $g$

Impermeable

Distal trachea region below cuff

Collection basin 298

Impermeable

Liquid-retaining Portion of the cuff (i.e. counteracting Gravity to hold Liquid in Collection basin)

FIG. 6C
Fig. 7

Introducer Tube 530

F2 > F1

OUTSIDE OF THE BODY

ETT 260

Distal
Fig. 8