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» VENTILATION CONCEPTS FCV® AND EVA®



Small Lumen

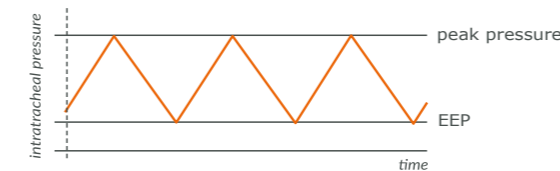


Higher Efficiency



Lower Energy

Our unique ventilation concepts FCV® and its more basic form EVA®, control the expiration as well as the inspiration phase during artificial ventilation of a patient. This is established by generating a continuous, controlled flow into the patient's lungs during inspiration as well as a continuous outwards flow during expiration. The expiratory flow is regulated by suctioning*. This controlled suctioning (active expiration) enables a highly efficient ventilation through narrow bore lumen (of 2 – 3 mm) in an obstructed and sealed airway.



In addition, FCV® controls and adapts the expiratory flow to reach the set I:E ratio, has no notable ventilation pauses and is programmed to result in linear increases and decreases in intratracheal pressures to reach peak pressure and Positive End Expiratory Pressure (PEEP) aimed for. This results in increased ventilation efficiency and lower energy dissipation in the lungs.

Prof. Dr. med. Dietmar Enk is kindly acknowledged for inventing the concepts behind all our products.



Prof. Dr. med. Dietmar Enk

Ventinova Medical develops and markets innovative products for patient ventilation and airway management. We have introduced a **Ventrain**, FCV®, that redefines patient ventilation. FCV® enables patient ventilation through small lumen, with a higher ventilation efficiency and lower energy dissipation in the lungs. This unique technology, initially developed in its most basic form as EVA® (Expiratory Ventilation Assistance), enables control of both the expiration as well as the inspiration phase during artificial ventilation of patients.

We currently market mechanical ventilator **Evone**, manually operated ventilator **Ventrain**, ultrathin endotracheal tube **Evone** and transtracheal catheter **Ventrain**. The development of Ventrain is enabled by The European Regional Development Fund. For the development of Evone, we received funding from the European Union's Horizon 2020 Research and Innovation Programme and Innovation Credit from the Dutch Ministry of Economic Affairs and Climate Policy.



» Our Mission

Let's redefine ventilation

Together, we question, we create, we care, we educate, we celebrate

Patient ventilation with minimal impact and maximal control

We are **VENTINOVA**

* Please note that suction as such does not lead to negative pulmonary pressures as suctioning can be stopped (Ventrain) or automatically stops (Evone) when the required PEEP is reached.



))) **evone**

Evone is the only commercially available ventilator, thus directing the inspiration as well as the expiration of an anesthetized patient requiring mechanical ventilation. Evone's FCV[®] ventilation mode is based on a controlled inspiration and expiration flow from a set PEEP to a set peak pressure and *vice versa*. The inspiratory flow is continuously controlled by advanced mass flow regulators; the expiratory flow is controlled by regulated suctioning. Evone is to be used in combination with our Tritube, an ultrathin endotracheal tube (outer diameter 4.4 mm), enabling highly accurate intratracheal pressure measurements and securing the airway with an inflatable cuff. FCV[®] ventilation requires a sealed airway. Additionally, Evone has a (High Frequency) Jet Ventilation mode, which requires an open airway. Jet ventilation can be used as breathing support while emerging the patient from mechanical ventilation to spontaneous breathing. Therefore, Evone is able to fully ventilate both in case of an obstructed (sealed) airway and an open airway.



Small Lumen



Higher Efficiency



Lower Energy

Small Lumen

Evone in combination with Tritube is being used during a wide variety of surgical procedures. Especially during ENT/laryngeal surgery this combination offers several new surgical options for treatment. Next to all benefits provided by Tritube (see next page), Evone allows adequate ventilation independent of airway patency. Moreover, the patient can be liberated from ventilation using Evone's jet ventilation mode with a deflated cuff, reducing cuff-related stimuli in the trachea. With a deflated cuff, Tritube is well tolerated when left *in situ* post-operatively, allowing patients to freely breathe and talk. This could be an elegant option for maintaining an airway.

Higher Efficiency

Evone's FCV[®] mode provides more efficient ventilation as compared to conventional Volume Controlled Ventilation (VCV) protocols. FCV[®] provides a continuous inspiratory and expiratory flow, without notable pauses which are present during conventional ventilation at the end of inspiration and expiration. Additionally, FCV[®] aims for linear increases and decreases in intratracheal pressures, in contrast to conventional ventilation techniques that show rapid airway pressure declines during passive expiration. Studies revealed that FCV[®] increases alveolar aeration lung recruitment and oxygenation in both healthy and diseased lungs.

Lower Energy

Because FCV[®] gradually changes airway pressure and volume over time, this ventilation mode effectively reduces the net energy applied to the lungs as compared to both VCV and Pressured Controlled Ventilation (PCV). Importantly, *in-vivo* data indicate the lung protective potency of FCV[®] as less lung damage was observed in addition to improved oxygenation in lung-diseased (ARDS) animals.

For a complete overview of all literature available, refer to:

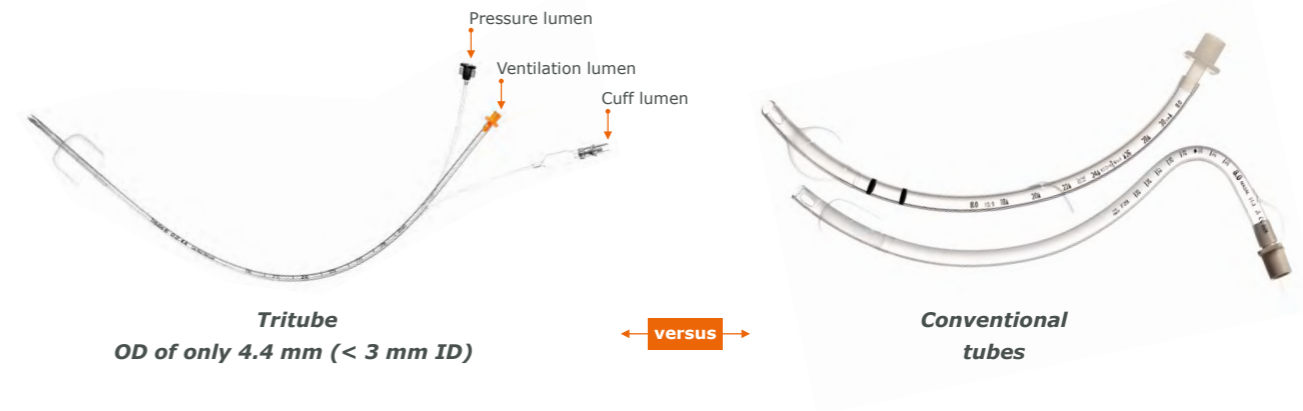
» More space during laryngeal surgery

» Full respiratory control

» Studies show an increased oxygenation



Evone on trolley



tritube

With an outer diameter (OD) of only 4.4 mm, Tritube is an ultrathin ventilation tube, intended to obtain endotracheal access to the airway and to ventilate an adult patient. Tritube can exclusively be used together with Evone or Ventrain. Tritube has three lumen:

- A ventilation lumen - with Murphy eye and an inner diameter (ID) smaller than 3 mm;
- A cuff lumen - to inflate and deflate the high volume, low pressure cuff;
- An intratracheal pressure measurement lumen - for continuous intratracheal pressure measurements.

Tritube (including its cuff) is completely manufactured of high quality PolyUrethane (PU). Additionally, Tritube has a malleable stylet to facilitate intubation.

The combination of Tritube with Evone and/or Ventrain is our solution for anesthesiologists and surgeons in the field of upper airway surgery and oral surgery, providing:

- Easy access to the airway;
- Effective ventilation in open and obstructed airway;
- A secured airway;
- A hygienic and clear sight for the surgeon;
- A large surgical exposure.



Small Lumen

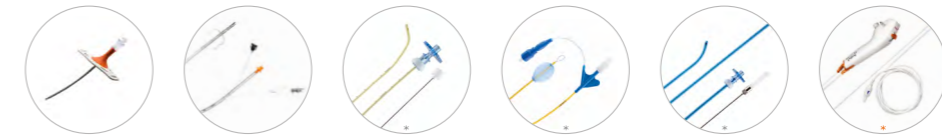
» More space during laryngeal surgery

» Polyurethane HVLP cuff

» Easy access to the airway



Flow may range from 2 L/min for ventilating pediatrics or 4 L/min for a collapsed adult lung up to 12 or 15 L/min for normo-ventilating adults. Ventrain is the only ventilation device that provides for full ventilation in an obstructed airway situation, without the high risk on air trapping and barotrauma.



* Permission for use granted by Cook Medical, Bloomington, Indiana.
 • Ambu® aScope™ 3 Large is manufactured by Ambu A/S. Ambu®

ventrain

Active expiration

The EVA® technology (which is the basic form of FCV® as applied by Evone), creates active expiration by suction. This shortens expiration time, increases the achievable minute volume and reduces the risk on air trapping and associated risks on barotrauma and circulatory collapse, when compared to other small lumen ventilation techniques in obstructed airways (e.g. jet ventilation). Ventrain is a single use ventilation device, dedicated to manage and prevent difficult or challenging airway situations. Ventrain allows adequate ventilation in any patient (pediatrics emergency only), in combination with any narrow bore lumen (e.g. transtracheal catheter Cricath, airway exchange catheter, rigid bronchoscope, etc.) via any route of airway access (oral, nasal, FONA). It is easy in use as inspiration, supplying O₂ and expiration, removing CO₂, are initiated by using just a thumb. The only requirement is O₂ from a high pressure gas source, with a pressure compensated flow meter.



Small Lumen

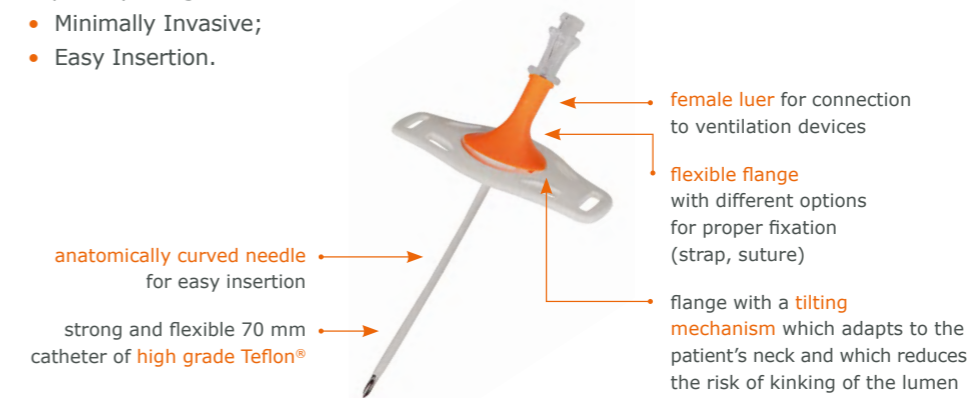


Higher Efficiency



Cricath is a cricothyrotomy catheter with an ID of 2.0 mm, especially designed to be used with Ventrain.

- Minimally Invasive;
- Easy Insertion.



» Effective ventilation of a patient with an obstructed upper airway with Ventrain

» Saving lives in CICO situations

» Ventrain has a connection for side-stream capnometry



» APPLICATIONS

During upper airway surgery, ventilation may be challenging: A clear and hygienic surgical exposure is demanded and any potential sudden airway obstruction and aspiration needs to be handled. In combination with Evone or Ventrain as the ventilator, Tritube fulfills these needs. Tritube's ultrathin OD of only 4.4 mm in combination with a sealed airway preventing turbulences of air nearby the surgical site, creates a large surgical exposure. Our ventilation techniques FCV® and EVA enable full ventilation through small bore lumen, providing adequate ventilation even in cases involving critically obstructed airways. In comparison to jet ventilation, it strongly reduces the risk on barotrauma.



Enough working space for the surgeon is of utmost importance to enable an optimal surgical performance. Lung isolation techniques have been developed to increase working space by deflating one of the lungs and ventilating the other one. A major drawback of ventilating one lung is the increased risk of hypoxemia (*i.e.* arterial oxygenation <90%), which may develop due to a ventilation-perfusion mismatch and dissociation of O₂ from hemoglobin (Bohr effect). Oxygenation of the deflated non-dependent lung may be required in this case, traditionally by using continuous positive airway pressure (CPAP). However, this is not always sufficient and moreover, it can result in an undesired re-inflation of the lung.

This scenario can be prevented using Ventrain in combination with a bronchial blocker or double lumen tube. Ventrain provides effective additional ventilation in order to prevent or rapidly overcome cases of hypoxemia. The flow-based inspiration and suction-supported expiration enable inspiration and expiration at any speed desired with very small, but effective tidal volumes ensuring the non-dependent lung remains collapsed. Therefore, no delay or postponement of surgery. If required, the active expiration can also initiate a more effective and faster collapse. With Ventrain even ventilating a single lobe through a specific blocker is possible.

In an emergency situation, often 'Cannot Intubate, Cannot Oxygenate', Cricath offers rapid access to the trachea, by means of a needle cannula cricothyrotomy technique. Using Cricath in combination with Ventrain is key to rapidly and safely re-oxygenate and ventilate.



Ventrain is the solution in life-threatening situations to establish rapid re-oxygenation via a small bore lumen. The type of lumen and route of airway access (oral, FONA by needle cricothyrotomy or by scalpel bougie technique) is not of interest as long as the lumen has a Luer connector. The ventilation provided by Ventrain has several advantages: it enables minimal invasive ventilation through a small bore tube of < 3 mm ID, it provides full ventilation: oxygenation and CO₂ removal and it allows side-stream capnometry.

» ADDRESSES

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