Clinical use, pre-clinical validation and technological development of our products have been published. Also the products of Ventinova Evone®, Ventrain®, Tritube® and Cricath® are included in various handbooks. Publications regarding FCV® or EVA® ventilation during General Surgery, Intensive Care, Upper Airway Surgery, Lung Separation Procedures, Emergency or regarding Technology Development are presented.

Specific features of FCV® and EVA described are indicated:

- Small Lumen
- Higher Efficiency
- Lower Energy

**evone**

**General Surgery**

*Evone – In-Vivo study - General Surgery*

The workgroup of Prof. Schumann was the first to execute a comparative study, evaluating a commonly applied VCV protocol with FCV® mode by Evone. This study in healthy pigs shows that FCV® improves lung aeration via elevated mean tracheal pressure and consequently improves arterial oxygenation at unaltered positive end-expiratory pressure (PEEP) and peak inspiratory pressure (PIP). Moreover, these findings suggest the FCV® mode provided by Evone is a new approach for protective lung ventilation.


**Intensive Care**

*Evone – In-vivo study - Intensive Care*

The workgroup of Prof. Schumann demonstrated in porcine ARDS, that FCV® ventilation stabilizes alveolar walls and shifts ventilation distribution from atelectatic to aerated lung tissue. Consequently, FCV® ventilation improves oxygenation and facilitates CO₂ removal with a lower MV. This study illuminates the higher ventilation efficiency and lung protective potency of FCV® in ARDS.

Dr. Kristensen and colleagues were the first to describe Tritube’s clinical use in seven adult Ear-Nose-Throat surgical patients with airway narrowing or whose surgical access was facilitated by this small-bore endotracheal tube. In combination with Ventrain adequate ventilation was achieved in all patients and intratracheal pressure was kept between 5 and 20 cm H₂O.

They concluded that: "The 2.4 mm internal diameter Tritube seems to facilitate tracheal intubation and to provide unprecedented view of the intubated airway during oral, pharyngeal, laryngeal or tracheal procedures in adults."

Additionally, they state that: "This technique has the potential to replace temporary tracheostomy, jet-ventilation or extra-corporal membrane oxygenation in selected patients"  

Dr. Ahmad and colleagues present a case of a patient with severe upper airway obstruction undergoing surgical intervention, avoiding the need for tracheostomy. The patient sternly refused an awake elective tracheostomy or wide-bore cricothyroid cannula, so a 2-stage airway management technique was performed: an awake fiberoptic intubation with a small diameter endotracheal tube, followed by needle cricothyroidotomy with Cricath after anesthetic induction. Ventrain was used to adequately ventilate the patient for 75 minutes (SpO₂ 100%, PaCO₂ 46 mmHg). Post-operatively Cricath was left in situ for 24 hours. No complications occurred. The patient was discharged home 2 days later. View this elegant two-stage airway management technique: http://links.lww.com/AACR/A133  

Dr. Fearnley and colleagues reported the elective use of Ventrain in a patient with post radiation fibrosis that had previously prevented passive expiration during attempted high frequency jet ventilation. Ventrain was found simple and easy to use and provided perfectly adequate transtracheal ventilation for > 1 hour, allowing laser resection of the stenosis. They have used our transtracheal catheter Cricath, which was found kink resistant. Ventrain has now become their first choice device when emergency needle cricothyroidotomy is performed.  
Dr. Borg and colleagues reported the successful and uneventful elective use of Ventrain in combination with a transtracheal catheter (2 mm I.D.) with 20 min of adequate ventilation and oxygenation in a patient with partial obstruction of the laryngeal inlet.


Dr. Monnier and colleagues reported a new surgical technique in a patient with an early stage squamous cell carcinoma of the glottis with involvement of both vocal cords and impossible transoral access to the larynx, due to a medical history of head and neck radiation. While the larynx was accessed transthyrohyoidly, Ventrain was used for transtracheal ventilation during the first part of the surgery, followed by high frequency jet ventilation when the airway was patent. This setup proved to be extremely safe for securing the airway and allowed endoscopic resection of the tumor.


Dr. Kalkoff described the first successful use of Ventrain in combination with an intubating catheter in an elective setting, in a patient undergoing microlaryngoscopy with a partly obstructed airway.


In Ethiopia, Dr. Braga and colleagues electively used Ventrain in combination with a transtracheal catheter as a safe ‘bridge to intubation’ in a young patient presented for free flap surgery to cover a complex type IV NOMA defect.


Ventrain - In-vivo studies – Upper Airway Surgery

The workgroup of Prof. Enk demonstrated with an early prototype of Tritube that small-bore ventilation with Ventrain is optimized in a cuffed airway. A pressure measurement line in the prototype Tritube enabled a reliable airway pressure monitoring using a cuff manometer. During the 30 minutes of ventilation with Ventrain (PaO$_2$ 61 [52-69] kpa; PaCO$_2$ 4.9 [4.2-6.2] kPa) hemodynamics were stable. This elegant study was executed in healthy pigs.

Dr. Paxian and colleagues demonstrated that Ventrain can ensure sufficient oxygenation and ventilation through a small-bore transtracheal catheter in live pigs when the airway is open, partly obstructed, or completely closed. Additionally, the minute ventilation and avoidance of high airway pressures were superior in comparison with traditional hand-triggered jet ventilation, particularly in the event of complete upper airway obstruction. M. Paxian, N.P. Preussler, T. Reinz, A. Schlueter and R. Gottschall. Transtracheal ventilation with a novel ejector-based device (Ventrain) in open, partly obstructed, or totally closed upper airways in pigs. Br J Anaesth 2015 Aug;115(2):308-16. (Also referred in section “Emergency”)

**Ventilation during lung separation procedures**

**Ventrain - Clinical case – Ventilation during lung separation procedures**

In a patient undergoing thoracoscopic esophagectomy and concomitant wedge resection, an iatrogenic lesion in the left main bronchus was observed following deflation of the right lung. Repair of the lesion required deflation of the bronchial cuff. This challenging situation was resolved by Dr. Evers. She used Ventrain to oxygenate the patient through an Arndt Endobronchial Blocker through the lumen beyond the bronchial defect. With the use of this technique, oxygenation was maintained at an acceptable level during repair. V.M. Evers, R.V. Immink, W.J.P. van Boven, M.I. van Berge Henegouwen, M.W. Hollmann and D.P. Veelo. Intraoperative Use of the Ventrain for Single Lung Ventilation After Iatrogenic Trauma to the Left Main Bronchus During Thoracoscopy: A Case Report. AA Case Rep 2017 Aug 15; 9(4):116-118

**Emergency**

**Ventrain - Clinical cases - Emergency**

Dr. Escribá presents the rescue of a difficult airway in a pediatric patient with subglottic stenosis with Ventrain. When the patient desaturated, the device enabled immediate ventilation during airway assessment through a rigid bronchoscope and restoration of normal oxygen saturation. Then, post intubation, ventilation with the Ventrain was valuable again, when conventional mechanical PICU ventilation was very difficult due to elevated pressures. This case clearly indicates that the new ventilation device Ventrain offers advantages over devices available until now. F.J. Escribá Alepuz, J. Alonso García, J.V. Cuchillo Sastriques, E. Alcalá, P. Argente Navarro. Emergency Ventilation of Infant Subglottic Stenosis Through Small Gauge Lumen Using the Ventrain®. A A Prac 2018 Mar 15;10(6):136-138

Dr. Wahlen and colleagues described a case in which Ventrain in combination with a tube exchanger was used to ventilate a patient with life-threatening tracheal stenosis. After a failed initial intubation with an endotracheal tube (ID 5.0 mm) the tube exchanger was inserted allowing allowed adequate ventilation with Ventrain until surgical trachestomy was performed. Hemodynamic stability indicated that the active expiration induced by
Ventrain prevented intrapulmonary pressure build-up by air trapping and subsequent barotrauma, which may be observed during traditional jet ventilation in a similar situation. B.M. Wahlen, H. Al-Thani and A. El-Menyar. Ventrain: from theory to practice. Bridging until re-tracheostomy BJM Case Rep 2017 Aug 16; 2017

Dr. Willemsen and colleagues reported cases of ventilation through a small lumen intubating catheter (35 cm long; 1.6 mm I.D.) and an exchange catheter (45 cm long, 1.6 mm I.D) using Ventrain to manage critical paediatric airways in babies of 2.1 kg and 4.3 kg, respectively. M.G. Willemsen, R. Noppe, A.L. Mulder and D. Enk. Ventilation with the Ventrain through a small lumen catheter in the failed paediatric airway: two case reports. Br J Anaest 2014 May;112(5):946-7

Dr. J. Lopez-Torres and colleagues present four case reports of Ventrain use: laryngeal microsurgery, foreign body in the airway emergency, subglottic stenosis and assistance to guide extubation in Pierre-Robin syndrome. They indicate that laryngospasm, edema or anatomical distortion, combined with over-vigorous jet insufflation can result in air trapping with subsequent barotrauma and hemodynamic instability. They state that Ventrain is the only ventilation device that provides full ventilation for these situations. J. Lopez-Torres, F.J. Esciba, J. Alonso, J.V. Cuchillo and P. Argente. Ventrain device for difficult or obstructed airway: 4 case report. Abstracts / Trends in Anesthesia and Critical Care 2017; 12:31

Dr. Krapf demonstrated feasibility of using Ventrain in combination with needle cricothyrotomy in a pre-hospital CICV setting under reanimation conditions. M. Krapf, D. Gäumann, J. Jacquier and S. Graf. Cannot intubate, cannot ventilate: Beatmung über einen 2-mm-Katheter in der Präklinik. Notfallpraxis 2016 8(39); 792-794 (article in German)

Dr. Nellgård underlined the importance of performing an early cricothyrotomy in a situation of CICV. After several failed attempts to intubate a patient with instable angina pectoris scheduled for coronary artery bypass surgery, bag and mask ventilation became unsuccessful. A transtracheal catheter (2 mm I.D.) was placed and ventilation with Ventrain increased saturation from <50% to ~80%. Then, cricothyroidotomy was successfully performed using the Melker Cricothyroidotomy S. Surgery was postponed and percutaneous coronary intervention was performed instead. P. Nellgård. Ventrain in a case of can’t intubate can’t ventilate situation. Orally presented at the European Society of Anaesthesiology 2013

Dr. Kalsi and colleagues reported for the first time the use of Ventrain in combination with a transtracheal catheter (2 mm I.D.) in an emergency scenario. They demonstrated adequate ventilation with saturation levels >98%. A. Kalsi, K. Koniecny and M. Turner. Transtracheal jet ventilation using the Ventrain Device in a patient with severe upper airway obstruction. Poster presented at the Difficult Airway Society 2012
Ventrain - In-vivo studies – Emergency

Prof. Enk’s workgroup demonstrated that Ventrain provided rapid reoxygenation and effective ventilation through a 100 cm long airway exchange catheter (ID 3 mm) in severe hypoxic pigs with an obstructed airway. This study clearly indicates potential clinical applicability and usefulness of Ventrain, not only in combination with short, transtracheal cannulas but also with long small lumen tubes/catheters when (re)intubation is difficult or has failed.


Dr. Paxian and colleagues demonstrated that Ventrain can ensure sufficient oxygenation and ventilation through a small-bore transtracheal catheter in live pigs when the airway is open, partly obstructed, or completely closed. Additionally, the minute ventilation and avoidance of high airway pressures were superior in comparison with traditional hand-triggered jet ventilation, particularly in the event of complete upper airway obstruction.


The workgroup of Prof. Enk showed in severe hypoxic pigs quickly restored oxygenation after ventilation with Expiratory Ventilation Assistance (EVA) in cases of a completely or partially obstructed upper airway. Reoxygenation and ventilation were less efficient when the upper airway was completely unobstructed.

*A.E.W. Hamaekers, T. van der Beek, M. Theunissen and D. Enk Rescue ventilation through a small-bore transtracheal cannula in severe hypoxic pigs using expiratory ventilation assistance. Anesth Analg. 2015 Apr;120(4):890-4*

In post-apnoic sheep, Dr. Berry and colleagues demonstrated that Ventrain provided stable oxygenation and effective ventilation at low airway pressures during emergency percutaneous transtracheal ventilation in critically obstructed airways. Manujet provided effective temporizing oxygenation in this situation with hypoventilation necessary to minimize barotrauma risk.


Dr. Ziebart and colleagues confirmed in a pig model with upper airway obstruction adequate ventilation using Ventrain in combination with a transtracheal catheter. Furthermore, they underline the importance of training and education of users and adherence to the instructions for use in order to use Ventrain safely.

In a small pilot study the workgroup of Prof. Rosenblatt demonstrated that Ventrain rapidly corrected hypoxemia in a large ovine model.


**Technology development**

**Full articles – Technology development**

In a bench study Dr. Wirth and colleagues showed that active expiration assistance (using Ventrain) provided better maintenance of minute ventilation without intrinsic PEEP compared to conventional mechanical ventilation (passive expiration), when using a small endotracheal tube of cricothyrotomy catheter.


In a bench study the workgroup of Prof. Enk tested the efficacy of a prototype of Ventrain. Results of this study suggested that Ventrain is capable of achieving a normal minute volume for an average adult through a 2 mm I.D. transtracheal catheter.


In a bench study Dr. Schmidt and colleagues show that not every oxygen delivery device will generate enough driving pressure to deliver a predictable flow through Ventrain and a 2 mm (I.D.) 75 mm long transtracheal catheter. They confirmed that while using the prescribed oxygen supply system with a pressure compensated flow regulator, flow and tidal volume were predictable enabling adequate ventilation through a small lumen.


Dr. Schmidt and colleagues showed that a Respiration Function Monitor is capable of monitoring ventilation with Ventrain, which could make its use even safer.


A functional model of Ventrain, based on EVA technology was build by Prof. Enk: the DE5. In laboratory tests the workgroup of Prof. Enk showed that the DE 5 is an optimized ventilation ejector suitable for applying expiratory ventilation assistance.

The ineffectiveness and danger of using transtracheal jet ventilation in cases of complete upper airway obstruction motivated Prof. Enk to search for a better solution. Prof. Enk’s workgroup transformed a small, industrial ejector into a simple, manual ventilator providing expiratory ventilation assistance (EVA). They showed that EVA shortened the expiration time and that a minute volume up to 6.6 L/min could be achieved through a 2 mm I.D. transtracheal catheter in a simulated obstructed airway.


The importance of flow and pressure release in jet ventilation devices was demonstrated by Prof. Enk and his co-workers in a bench study where three previously described self-assembled jet devices and the Oxygen Flow Modulator were tested. In case of complete upper airway obstruction the OFM provides sufficient flow and pressure release, whereas the self-assembled jet devices tested are inherently dangerous constructions.


To reduce the risk of air trapping and to increase oxygenation efficacy an emergency transtracheal ventilation device needs to allow both inspiration and expiration. In absence of such a device Prof. Enk and his co-workers determined the capability of two self-assembled, three-way stopcock based jet devices and the Oxygen Flow Modulator to function as a bidirectional airway in conjunction with a small lumen catheter.


Posters – Technology development

Dr. Heerdt and colleagues showed that a prototypical small automated ventilator based upon the EVA principle could be used to generate a controlled period of negative EEP. This resulted in improved hemodynamics relative to positive pressure ventilation (PPV) during experimental hemorrhagic shock.


In a bench study Dr. Calderon and colleagues compared passive expiration with EVA using Ventrain in a Totally Obstructed Airway model. They demonstrated that, in contrast to passive expiration, EVA maintained an acceptable Minute Volume, avoiding auto-PEEP.

The workgroup of Prof. Enk showed in a bench study that Ventrain is capable of achieving adequate minute volume ventilation through a 100 cm long, 3 mm I.D. Airway Exchange Catheter by applying EVA in a simulated completely obstructed airway.

*E.M. Dias, A.E.W. Hamaekers, P.A.J. Borg and D. Enk. Adequate minute volume ventilation through a 100 cm long, 3 mm inner diameter airway exchange catheter by expiratory ventilation assistance (EVA). Poster presented at the European society of Anaesthesiology 2012*

In this bench study Prof. Enk demonstrated that Ventrain in combination with a prototype cuffed jet ventilator catheter should allow adequate minute volume ventilation in adult patients.


**Editorials, Correspondence**

Dr. Ruediger Noppens deliberated Ventrain’s clinical significance:

"*The idea and working principle behind the Ventrain are very promising and have the potential to change the way we look at ventilation through small-bore cannulae, not only in emergency situations.*"

"*For the benefit of patients in critical situations, it will be necessary to train and educate as many anesthetists as possible in this novel ventilation technique, not only to avoid inappropriate use, but to allow its incorporation into routine airway management in the future.*"

This editorial refers to the study of Paxian and colleagues, which elegantly demonstrates that Ventrain ensures sufficient oxygenation and ventilation through a small-bore transtracheal catheter in cases of an open, partly obstructed, or completely closed airway.


Drs. Timmermann, Chrimes and Hagberg responded to the published 2015 Guidelines of the Difficult Airway Society (DAS), which endorse scalpel cricothyroidotomy as the sole method for emergency front-of-neck access:

"*This sole recommendation of a scalpel technique may increase the psychological barriers to successful achievement of front-of-neck access in an appropriate time frame when a CICO situation occurs. Training in both (scalpel-based and cannula-based) techniques remains warranted, and the option to use either technique should continue to be advocated.*"

In addition to airway management techniques, they advised on ventilation techniques to be used after obtaining front-of-neck access. They recommend a.o. Ventrain:

"*These provide, in contrast to a jet ventilator, an affordable, simple mechanism for oxygen insufflation via a cannula that can be connected to a standard oxygen outlet and allows for passive or even active expiration via the cannula between breaths. Techniques have been developed for use of these devices, intended to minimize the risk of complications from volutrauma and barotrauma, even when the upper airway is completely obstructed.*"
This editorial emphasize the multiple options for saving a patient’s life in an emergency CICO situation.


Dr. Scott Lang also responded to the DAS guidelines expressing his concerns that the DAS Plan D amount to ‘wishful thinking’ as it aims to avoid life-threatening consequences of barotrauma:

“It focuses on attaining and then maintaining proficiency using an invasive technique (i.e., surgical cricothyroidotomy) with which many anesthesiologists are not comfortable and do not have an opportunity to practice.”

He underlines that Ventrain is based on concepts and skills familiar to most anesthesia practitioners and that it can be used in routine cases in order to gain clinical experience. As such the technique is trainable. Dr. Scott concludes:

“I also believe, most importantly, that awareness of, familiarity and proficiency with, and dissemination of the device will certainly be easier and quicker to achieve than a cultural shift that would be necessary to ensure maintaining competence with surgical cricothyroidotomy.”


Handbooks

- C. Spies, M. Kastrup, T. Kerner, C. Melzer-Gartzke, H. Zielke and W.J. Kox. SOPs in Anästesiologie und Schmerztherapie. Thieme (publisher); 2013; p.94.