Instructions for use Ventrain®

ventrain

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U.S. patent No. US20100236551

Name	Ventinova Medical B.V.

Product name	ventrain	Single Use	
Product number	REF	Consult instructions for use	
Sterile	STERILE EO		

Caution: US Federal law restricts this device to sale by or on the order of a physician (USA only)

Read these instructions for use prior to using the product. Refer to the product website www.ventinovamedical.com/products/ventrain for further information and training materials related to this product.

Operator

Ventrain is intended to be applied by, or under supervision of, medical personnel trained and experienced in airway management.

Intended use

For emergency ventilation via a small lumen transtracheal catheter, in case conventional ventilation by mask and/or a large-bore endotracheal

tube cannot be performed. Ventilation is accomplished by manual, intermittent ventilation with oxygen through the catheter for subsequentlung inflation and deflation.

Patient group

Adults

Contraindications

Unknown

Potential complications

- barotrauma
- aspiration
- pneumomediastinum
- subcutaneous emphysema

Product description

- Ventrain is a manually controlled, single-use emergency ventilator to be used with a transtracheal catheter with 2 mm inner diameter. It consists of a handheld with tubing for connection to the oxygen supply on one end, a connector for the catheter on the other end.
- Connected to a full 2 liter oxygen cylinder containing 400 liters (uncompressed) of oxygen which is set at a flow of 15 l/min, Ventrain can provide for ventilation for at least 20 minutes.
- With a flow set at 15 l/min the inspiratory flow is about 250 ml per second.

- In a patient with normal healthy lungs Ventrain in combination with the required catheter can reach a respiratory minute volume of at least 6 l/min.
- Ventrain is intended for single use.

Packaging

- The packaging contains Ventrain.
- It is packed in a peel-open package sterilized by use of ethylene oxide.
- Ventrain is sterile as long as the packaging is undamaged and unopened. Do not use Ventrain if any doubt exists on the integrity of the packaging.
- Store the packaged product in a dry place at room temperature.
- Avoid extended exposure to light.

Required additional material

- Oxygen supply (100%):
  - from medical oxygen supply system able to deliver 50 psi/3.5 bar pressure with pressure compensated flow regulator (medical oxygen cylinder or supply system) with a flow range up to at least 15 l/min
  - a full 2 liter medical oxygen cylinder containing at least 400 l oxygen (uncompressed) with a flow regulator ranging up to at least 15 l/min
- A transtracheal catheter with inner diameter between 2.0 and 2.3 mm, a length between 6.5 and 8.0 cm and with female Luer connector.
- Syringe

Warnings and precautions

- During use direct the thumb hole to a paper tissue to collect possible airway debris.
- Severe obstructions may damage the capnometer.
- Do not use $EtCO_2$ values for trend analysis in a (half)-open airway situation.
- Ventrain is not designed for pediatric application.
- The warnings, precautions and user instructions of the catheter used in combination with Ventrain should be taken into account.
- Ventrain is designed for continuous manual control. Holding Ventrain too long in the inspiration, expiration or equilibration position may lead to damage to the lungs and airway of the patient, due to overpressure, negative pressure or lack of ventilation.
- Properties of the patient's lungs influence the ventilation. High bronchial resistance (e.g. 100 cm H_2O/(l/s)) enlarges the time needed for expiration of the same volume as inspired. Low compliance (e.g 10 ml/ cm H_2O) shortens the time needed for expiration of the same volume as inspired.
- Always observe the patients chest and abdomen closely during ventilation and adjust the time for inspiration and expiration where needed or use the equilibration position.
- Use of the equilibration position during the expiration phase (conventional jet ventilation) enlarges the time of expiration compared to ventilation with assisted expiration. This results in fewer breaths per minute and a lower respiratory minute volume.
- Incorrect use of Ventrain can be hazardous to the patient.
- Use of Ventrain and the oxygen supply in a hazardous or explosive atmosphere is dangerous.

- Use of Ventrain nearby flames or smoke is dangerous.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- The system gets pressurized. Tight and pressure-resistant connections are required.
- In case of using a side stream capnometer, the capnogram should only be used to check proper positioning of the catheter and/or to evaluate the relative trend in $EtCO_2$ concentration (applicable for closed or obstructed airways, not for (half)-open airways).
- Be aware that in the expiration phase debris may exit the thumb-hole. Therefore, always point the thumb-hole away from user and bystanders or cover Ventrain during use without obstructing the holes.

Instructions for use

Figure 1 Views on Ventrain
(T) = thumb hole, (S) = index finger hole

Preparation

1 Insert a transtracheal catheter according to the user instructions of the catheter.
2 Connect the oxygen tubing of Ventrain to the oxygen supply.
3 Make sure the cap next to the catheter connection is tightened.
4 Open the oxygen supply and select a flow of 15 l/min.
5 To confirm correct positioning of the catheter connect capnometer to T-Piece of Ventrain (refer to point A11), when using nocapnometer, make sure the cap is tightened.
6 Attach the male Luer connector of Ventrain to the catheter.
7 Hold Ventrain with one hand in the *Equilibration* position, according to Figure 2. In this situation no oxygen is flowing into the lungs and almost no gas is sucked out.

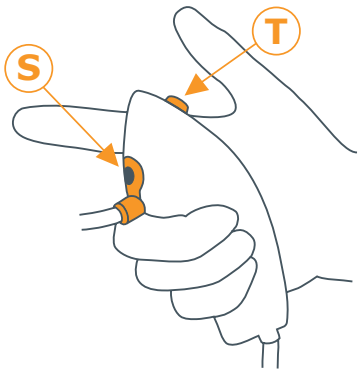
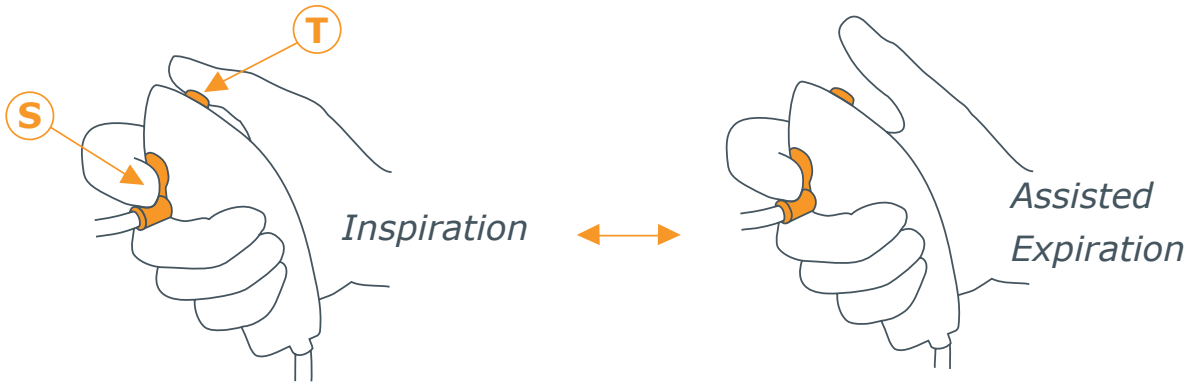


Figure 2
Equilibration

8 Apply ventilation by opening and closing the holes according to one of the following procedures:
A Jet ventilation with Assisted Expiration
B Conventional jet ventilation

A Jet ventilation with Assisted Expiration



A9 Start with simultaneously closing hole (S) with the index finger and hole (T) with the thumb securely, as shown in Figure *Inspiraton*. Oxygen flows into the lungs and inspiration is obtained.

A10 Open hole (T) by removing the thumb from the hole as shown in Figure *Assisted Expiration*. This provides suction of gas from the lungs.

A11 Open and close hole (T) with the thumb repeatedly, while keeping hole (S) closed with the index finger to apply Jet ventilation with Assisted Expiration (Figures *Inspiration* and *Assisted Expiration* alternately). Use an initial inspiration and initial expiration time of 1 to 2 seconds each, exact time depending on aimed Tidal Volume.

A12 To monitor the end tidal CO_2 trend, connect capnometer to T-Piece, inspirate to PEAK and use equilibration phase until the plateau is reached in the capnometer. Disconnect again and close the cap of the T-Piece.

A13 Use the equilibrium position of Ventrain after each 5 ventilation cycles, to equilibrate the thorax excursion avoiding excessive positive or negative pressure in the lungs.

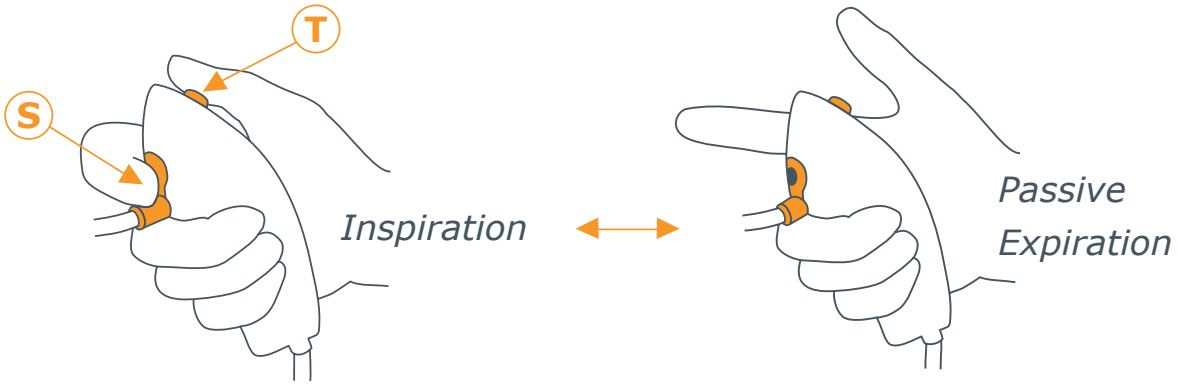
Notes:

- Closely observe the chest and the upper abdomen of the patient for upward and downward movements and adjust the time for inspiration and expiration if needed. The equilibration position can also be used to provide passive expiration.
- Ventrain is designed for application with a transtracheal catheter between 2.0 and 2.3 mm. In the table below the I : E ratio and minute volume are given for Jet ventilation with Assisted Expiration with Ventrain in combination with a 2.0 mm transtracheal catheter in an adult patient with healthy lungs.

catheter ID (mm)	length (mm)	I : E	minute volume (l/min)
2.0	65 - 75	1 : 1.1	7.0 - 7.3

The following test conditions are used:
Flow meter set at: 15 l/min, Compliance: 50 ml/cm H_2O, Resistance: 10 cm H_2O/(l/s) tested with ASL 5000, Ingmar Medical, Ltd.

B Conventional jet ventilation



B9 Start with simultaneously closing hole (S) with the index finger and hole (T) with the thumb as shown in Figure *Inspiration*. Oxygen flows into the lungs and inspiration is obtained.

B10 Simultaneously open hole (S) and (T) as shown in Figure *Passive Expiration*. This enables gas to leave the lungs passively.

B11 Open and close the holes with both fingers simultaneously, to apply Conventional jet ventilation, alternating *Inspiration* and *Passive Expiration*.

Notes:

- In case of upper airway obstruction the expiration time is considerably longer than the inspiration time. Make sure that enough time is given to obtain expiration of the same volume as injected during inspiration.
- Closely observe the chest and the upper abdomen of the patient for upward and downward movements and adjust the time for inspiration and expiration if needed.

Equilibration Position

- The Equilibration Position can be used to let the pressure in the lungs equilibrate with the pressure in the environment. In this situation no oxygen is injected into the lungs and almost no air is sucked out.
- For the Equilibration Position hold Ventrain as shown in Figure *Equilibration*.

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