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Ventrain® **FR** Mode d'emploi de Ventrain® **IT** Istruzioni per l'uso di Ventrain®

Instruction for use Ventrain

Name Dolphys Medical B.V.

Product name > **ventrain** <

Single Use



Productnr.

REF

Phthalates present



Sterile

STERILE EO

Attention,
Read instructions for use**Operator**

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

Intended use

The intended use of Ventrain® is emergency ventilation via a 2mm (inner diameter) transtracheal catheter, in case conventional ventilation by mask and / or a large-bore endotracheal tube cannot be performed.

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 2mm 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 and a connector for capnometry.
- 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.

Instruction for use Ventrain

Required additional material

- Oxygen supply (100%):
 - from medical oxygen supply system 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.
- 10 ml syringe

Optional additional material

Capnometer and tubing with male Luer connector

Warnings and precautions

- 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 to be used in combination with a transtracheal catheter with inner diameter of 2.0 mm and length 7.5 cm and with female Luer connector.
- 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, underpressure or lack of ventilation.
- Properties of the patient's lungs influence the ventilation. High bronchial resistance (e.g. 100 cm H₂O/(l/s)) enlarges the time needed for expiration of the same volume as inspired. Low compliance (e.g 10 ml/cm H₂O) 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 reesterilization 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.

Instructions for use



Figure 1 Views on Ventrain®

Ⓟ = thumb hole, Ⓢ = hole for index finger

Instruction for use Ventrain

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 Attach the male Luer connector of Ventrain® to the catheter.
- 6 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 air is sucked out.

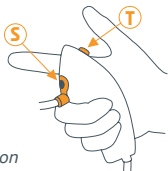
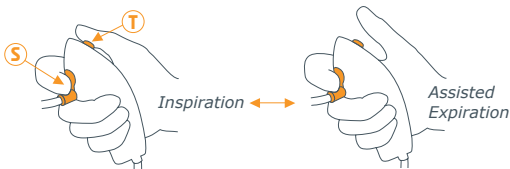


Figure 2
Equilibration

- 7 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

- A8** 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.
- A9** Open hole **(T)** by removing the thumb from the hole as shown in Figure *Assisted Expiration*. This provides suction of gas from the lungs.
- A10** 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).

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 2 mm transtracheal catheter. 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 mm transtracheal catheter in an adult patient with healthy lungs. Additionally, the table gives information about performance of Ventrain® in combination with transtracheal catheters with an inner diameter ranging from 1.8 to 5.0 mm.

catheter ID (mm)	length (mm)	I : E	minute volume (l/min)
1.7 ¹	65	1 : 1.5	5.9 – 6.1
2.0 ²	75	1 : 1.1	7.0 – 7.3
3.0 ³	60	1 : 0.8	8.1 – 8.5
4.0 ⁴	40 - 110	1 : 0.8	8.1 – 8.5
5.0 ⁵	90	1 : 0.8	8.1 – 8.5

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The following test conditions are used:

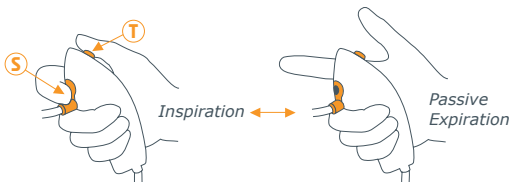
Flow meter set at: 15 l/min, Compliance: 50 ml/cm H₂O, Resistance: 10 cm H₂O/(l/s) tested with ASL 5000, Ingmar Medical, Ltd.

Examples of catheters with given dimensions are:

1 Jet Ventilation Catheter acc. to Ravussin (VBM), 2 Emergency Trans-tracheal Airway Catheter (Cook), 3 Arndt Emergency Cricothyrotomy Catheter (Cook), 4 Portex Minitrach II (Smiths), 5 Melker Emergency Cricothyrotomy Catheter with cuff (Cook)

Cook = Cook Medical, Bloomington, IN, USA, VBM = VBM Medizintechnik, Sulz, Germany, Smiths = Smiths Medical International, Kent, UK.

B Conventional jet ventilation



- B8** 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.
- B9** Simultaneously open hole **(S)** and **(T)** as shown in Figure *Passive Expiration*. This enables gas to leave the lungs passively.
- B10** 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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