

Definition

Exhalation Valves are used to manage exhaled air during the patient's inhalation and exhalation process.

The exhalation valve for the single-limb circuit is integrated into the patient side of the single-line circuit, has a pressure control line above it that connects the valve to the ventilator, and has an opening at the bottom that allows exhaled air to escape.

The pressure control line is a thin tube that transmits air pressure from the ventilator to the exhalation valve. The ventilator uses this air pressure to control the opening and closing of the valve.

As the patient breathes, air pressure is sent through the ventilator control line to the exhalation valve. This air pressure keeps the exhalation portion of the valve in the closed position so that no air escapes through the opening. In this way, all breathing air is transferred from the ventilator to the patient through the single-line breathing circuit and the exhalation valve.

On exhalation, the ventilator cuts off air pressure through the control line to the exhalation valve. This allows the exhalation portion of the valve to open, allowing air to escape through the opening.

Expected Clinical Benefits

Effective Breathing Management: Designed for a single-line breathing circuit, the exhalation valve helps to effectively manage the breathing process of mechanically ventilated patients. Thanks to a pressure-controlled exhalation mechanism, respiratory rate and pressure can be adjusted according to the patient's needs.

Ventilation Control: Through the pressure control line, the ventilator controls the opening and closing of the valve by transmitting the appropriate air pressure. This allows for precise management of breathing.

Intended Use

The exhalation valve is used to regulate the pressure and airflow in the expiratory line of the breathing circuits.

Intended User and Patient Group of the Product

Newborn, pediatric and adult patients who are provided with mechanical respiratory support.

Administrators, Clinicians or Providers

For this medical device, users are defined as all healthcare professionals including medical doctors, nurses, anaesthesia technicians, paramedics. Defined users have necessary expertise, training and knowledge to use, assemble and install this medical device. This medical device should only be used and assembled by defined users.

⚠ WARNING: This product should be implemented by only competent healthcare professionals.

Indications

The exhalation valve is indicated for use in connection with a single and dual line breathing circuit between the patient and the mechanical ventilator. It is used to control ventilation pressure and expiratory airflow to protect the patient's lung against barotrauma during mechanical ventilation.

Contraindications

This product has no known contraindications.

Operation Method

Install the single-line valve on the patient side of the breathing circuit.

Connect one end of the pressure control line to the valve and the other end to the ventilator. Make sure this line is delivering air pressure from the ventilator to the valve.

Make all connections firmly and carefully.

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⚠ WARNING: Do not use the product if the packaging is damaged.

⚠ WARNING: Check that the connections are made correct before and after use.

Device Usage Duration per Patient

The product should be changed in accordance with hospital infection control protocols.

Disposal of Product

After use, the medical device should be disposed of in accordance with applicable hospital, hygiene and medical waste disposal regulations.

⚠ WARNING: Do not reuse this disposable product. Reuse may cause contamination or interruption of treatment, serious harm or death.

⚠ WARNING: Do not immerse, wash, clean, disinfect, or sterilize the product. Reprocessing of disposable medical devices may result in performance degradation or loss of function.

Storage Conditions

Store in a cool and dry place away from direct sunlight. Before use, check the parcels and packages for any damage. Store according to the storage conditions on the label.

Shelf life

If stored under appropriate storage conditions, the product can be used until the expiration date stated on the label.

General Information About the Product

The product does not contain latex and phthalates.

Fire Risk

Do not use in environments with high oxygen concentrations. In such situations, high oxygen levels can be flammable and pose a safety risk.

To protect the patient and the provider, ensure high-oxygen hoses are free from leaks.

To avoid damaging the exhalation valve, maintain a minimum distance of 200 mm (7.9 inches) between hoses carrying oxygen or nitrous oxide and potential sources of ignition (e.g. electrosurgery and laser surgical devices).

Product Shipment

The products are placed in the parcel, in a stretched form; According to the agreement made with the customer, it is shipped on pallets or in bulk.

⚠ WARNING: Reuse of the product or failure to use surgical aseptic techniques may result in biological contamination.




















⚠ WARNING: It should only be used by authorized persons.

⚠ WARNING: Dispose after use according to hospital guidelines.

Label Information

The product label has been prepared with reference to the 2017/745 Medical Device Regulation, EN ISO 15223 and EN ISO 15986 Standard. Explanatory table regarding the symbols on the label is given below.

Symbol Description

 Catalog Number	 Lot Number	 Quantity	 Expiration Date	 Manufacturer Information	 Unique Device Identifier	 Production Date
 Single Use	 Read the IFU	 Do not use if package is damaged	 Keep away from sunlight	 Caution	 Temperature Limits	
 Humidity Limits	 Keep Dry	 Non Sterile	 This product is not made with natural rubber latex	 This product is not made with phthalates	 U.S. Federal law restricts this device to sale by or on the order of a physician	

Manufactured for
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