

## Definition

The catheter mount is used as part of respiratory / anesthetic systems that deliver air and / or anesthetic gas to the patient. The catheter mount is the breathing circuit airway connector used to deliver respiratory gases between the respiratory system and a mechanically ventilated patient. It connects the mechanically ventilated patient and the breathing circuit. This product has been manufactured in accordance with the requirements of the ISO 5356 standard.

## Accessory Description

**Elbow Connector:** As part of the breathing circuit, the elbow connector enables an angled attachment of circuit parts.

**Body Part Cover:** Used to cover the patient side to ensure closure and prevent contamination when the catheter connection is disconnected and not in use.

## Clinical Benefit

Improves positioning and mobility of the breathing/anesthesia circuit by providing a flexible connection between the circuit and the patient interface (endotracheal or tracheostomy tube). Reduces stretching of circuit and facilitates procedures such as gas sampling, aspiration, and bronchoscopy via its ports. Filtered types of catheter connections humidify and filter patient's air.

## Intended Use

The catheter mount connects the breathing / anesthesia circuit and the patient. It contributes to the breathing / anesthesia circuit and patient mobility by reducing the pulling effect. It provides ease of catheterization in procedures such as gas sampling, aspiration and bronchoscopy according to the ports on it.

## The Intended User of the Product

This product is intended for pediatric and adult patients who are mechanically ventilated and breathe in general anesthesia.

## Users

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

**⚠ WARNING: This product should only be implemented by qualified healthcare personnel.**

## Indications

Mechanical ventilation is used by integrating into the breathing circuit in patients undergoing general anesthesia and inhalation anesthesia. It connects the breathing / anesthesia circuits of mechanically ventilated patients. It facilitates procedures such as gas sampling, aspiration or bronchoscopy without interrupting mechanical ventilation thanks to its ports. In addition, the filtered catheter mounts ensure that the air passing through is to be filtered and moistened.

## Contraindications

This product has no known contraindications.

## Operation Method

Install catheter mount by connecting the patient to the breathing circuit. All connections must be checked before use. Conduct a performance test for possible leaks before patient connection.

**⚠ WARNING: Avoid contact with chemicals, cleaning agents or hand sanitizers.**

**⚠ WARNING: Do not use products with damaged packaging.**

**⚠ WARNING: Aspiration and bronchoscopy port should only be used for aspiration and bronchoscopy. If an aspiration or bronchoscopy port is used, this port should be opened just before the aspiration catheter or bronchoscope are inserted due to the high risk of leak and inadequate patient ventilation. For the same reason, the aspiration catheter or bronchoscope should be closed immediately after removal. Check that all connections are tight.**

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**⚠️ WARNING: Regularly check the inside of the medical device for accumulation of fluid or secretion. Liquids or secretions can cause increased resistance or enter the patient's airways. If liquid or solid accumulation is present, replace the device immediately. If this is not done, there is a risk of increased pressure and inadequate patient ventilation.**

**⚠️ WARNING: Apply this disposable product immediately after opening it. The user should change the product regularly in accordance with the hygiene rules. Replace the product as directed by the hospital infection committee and clinical guidelines. This device can be used to deliver a combination of air and / or anesthetic gas and oxygen.**

### Device Usage Duration per Patient

The product should be replaced in accordance with hospital infection control and intensive care/anesthesia protocols. The product must be replaced with a breathing circuit change. The catheter connection product can be used for up to 7 days in intensive care units.

### Disposal of the Product

The medical device should be disposed of in accordance with the applicable hospital hygiene waste disposal regulations after use.

**⚠️ WARNING: Do not reuse this disposable product. Reuse may cause contamination of the infectious agents or disruption of treatment, serious injury or death.**

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

### Risk of Fire

This device is not suitable for use with electrosurgery or laser procedures when used in combination with conductive and easily flammable substances such as oxygen, nitrous oxide (?) or flammable (non-AP/APG) anesthetic gases. In such cases, use of the device may cause a fire hazard.

Before starting electrosurgery and laser surgery, clean the area around the gas carrying components (such as endotracheal tube, mask, Y-piece, hoses, filter and breathing bag) with sufficient air (<25% O2). Clean surgical curtains as well. To avoid damaging the breathing circuit, keep at least 200 mm (7.9 inches) between oxygen and nitrous oxide hoses and potential ignition sources (e.g. electrosurgical or laser devices).

### Storage Conditions

Store in a cool and dry place without exposing to direct sunlight. Check the boxes and packages for any damage before use. Store in accordance with storage instructions on label.

### Shelf life

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

### General Information about the Product

The product does not contain latex and phthalate.




















### Shipment of the Product

The products are placed in a carton/box and stretched. According to the agreement with the customer, it is shipped in pallet or bulk.

### 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

 Stock Code	 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  
Sunset Healthcare Solutions  
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