INSTRUCTIONS FOR USE

CATHETER MOUNT

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

SSIPL/IFU/CM/01. Rev. No.:00, Dt. 01.08.23

PRODUCT DESCRIPTION:

Catheter mounts are adaptors that connect the tracheal tube to the end of the anaesthetic breathing system. Various connectors fit between the distal end and the tracheal tube. The proximal end is of standard 22 mm taper. Connectors are 15 mm in size distally, and they fit to any standardized 15/22 mm equipment.

Catheter Mount (SMD 727):

The catheter mount with double swivel connector and flexible tubing provides mobility and flexibility to the patient end of the circuit. The catheter mount is used as an intermediary connection between the patient and the breathing system. It is manufactured from PP, PVC & K Resin.

INTENDED PURPOSE:

Used as an intermediary connection between the patient and the breathing system for short term use.

INDICATIONS:

Patient in the following condition:

- Surgery & Emergency situations (when a person is unable to breathe on their own)
- Lung disease
- Severe pneumonia
- Respiratory failure
- Other conditions that affect breathing.

Catheter mounts with swivel connectors used to attach the endotracheal tube to the ventilator circuit.

CONTRAINDICATIONS:

None Known

LIMITATION:

None Known

INTENDED USER

Doctors or Trained Healthcare Professional.

INTENDED PATIENT POPULATIONS

All Age Group.

DIRECTIONS FOR USE:

- Used for Anesthesia Breathing Circuits.
- Check and tighten the connection. Avoid leakage when the product be used.
- Test the product, ensure it compatible with the circuit, and not leakage and blocked.
- If without sampling connection, make sure the sampling port is covered by caps and tighten, to prevent leakage.
- Regular inspection the product, if it is contaminated or become no longer suitable for its intended use, please replace immediately.
- The operator for this product must be trained by professional training

WARNING:

- The use of this product is restricted to a qualified Doc tor or Healthcare professional only.

PRECAUTIONS AND CAUTIONS:

- Sterile if package is unopened, undamaged and within shelf life date.
- Do not expose to temperatures above 49°C
- This product must be in a pre-use condition and checked prior to use.
- The operator for this product must be trained by professional training.
- This product is sterilized for single patient use only, please destroy when it was used, please do not repeat sterilization, don't use it once again.
- Should be used immediately when opening the package, please destroy when it was used.
- It is ban to use if the packing damaged, or packing be affected with damp, or the product went moldy.
- This product is for disposable use, after use can not be used again after cleaning.
- Sterile by ETO, Single use only, Latex free.

ADVERSE EFFECTS:

None Known

CLINICAL BENEFITS:

- Increasing the patient comfort.
- Successful SBTs(Spontaneous Breathing Trouble) to evaluate patients' response to zero peep zero end expiratory pressure (ZEEP).
- Decrease extubation failure.
- Reducing the cost burden on patients.
- Prevent air escaping from the nose during treatment.
- Greater maneuverability and the reduced risk of kinking by bending.
- Minimize aerosol generation.
- Disconnection from the ventilator had to be avoided

RESIDUAL RISKS:

- Hypoxia / Lung collapse
- Infection

SUPPLY:

Catheter Mount – SMD 727

MATERIAL USED:

Component	Material	Specification/Grade
22 MM Female Machine End connector (Connected to Ventilator circuit)	K Resin (Styrene Butadine Copolymer)	Medical Grade
15 MM Female 22 MM Male Patient End connector (Connected to Tracheal Tube)	K Resin (Styrene Butadine Copolymer)	Medical Grade
Elbow T Piece	HDPE	Medical Grade
Port Cap	PVC	Medical Grade
Expandable tube	EVA Copolymer + LDPE	Medical Grade
Pigment	Remafin Green	Medical Grade

STERILITY`:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused devices.

STORAGE:

The Device should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.

Store product inside containers or outer boxes in a clean, dry area. Do not expose to direct sunlight or UV light, and its space humidity is not more than 80%.

DEVICE DISPOSAL:

Used Devices may be contaminated with infectious and/or other hazardous materials. Discard used devices in the container meant for infectious waste. Unused expired devices should be disposed of as per local regulations.

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NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

SYMBOLS:

REF	**Catalogue No.**		**See instructions for Use**
	Cautions		**Keep Dry**
	Do not use it if the packaging is damaged.	SBS	**Sterile Barrier System**
	Single-Use		**Do not Re-sterilize**
LOT	**Batch / Lot No.**	STERILE EO	**Ethylene Oxide Sterilized**
	Date of Mfg.	UDI	**Unique Device Identifier**
	Date of Exp.	MD	**Medical Device**
	Avoid Direct Sunlight	45°C 5°C	**Keep in a dry place between 5°C to 45°C**
PHT DEHP	**Phthalate Free**		

Mfd. By: Sterimed Group
Unit No.: 501, Ring Road Mall, 21 Mangalam Place Rohini Sector-3, New Delhi, Delhi-110085 INDIA
Unit-II: Sterimed Surgicals (I) Pvt. Ltd.
E-11, Govt. Industrial Area, Bahadurgarh-124507
Haryana INDIA,PHONE:011-42466396,42466196
Email:info@sterimedgroup.com

EC REP **European Auth. Representative**
OBELIS S.A.
Bd, General Wahis, 53, 1030, Brussels, Belgium
Email:mail@obelis.net