INSTRUCTIONS FOR USE

TRACHEAL TUBE INTRODUCER (ET TUBE STYLETTE)

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

SSIPL/IFU/STY/01. Rev. No.:00, Dt. 12.08.23

PRODUCT DESCRIPTION:

Made of malleable aluminium covered with PVC sheath, which has a lubricated Satin-Slip surface. Helps reduce friction between stylet and tracheal tube to allow for easy insertion and withdrawal. Sheath extends beyond tip to reduce the risk of trauma should stylet extend beyond tip of tracheal tube.

INTENDED PURPOSE:

Used to facilitate tracheal intubation for transit use.

INDICATIONS:

Patient unable to breathe on their own during the following condition:

- Surgery & Emergency situations
- Lung disease
- Severe pneumonia
- Respiratory failure
- Other conditions that affect breathing.

CONTRAINDICATIONS:

- Oropharyngeal tumors
- Infections (epiglottitis)

LIMITATION:

None Known

INTENDED USER

Doctors or Qualified Healthcare Professional

INTENDED PATIENT POPULATIONS

All Age Group

DIRECTIONS FOR USE:

- Lubricate stylet with water soluble gel.
- Insert stylet into ETT
- Bend the stylet into the desired shape.
- Optimal shape for intubation direct laryngoscopy is 'straight-to-the-cuff' with a 'hockey stick' bend at the cuff of no more than 35° degree.
- ETT is inserted from the right side of the patient's mouth to maximize your view and provide optimal control of the position of the tip of the Intubating Stylet.

WARNING:

- The use of this product is restricted to a qualified Doctor 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.

ADVERSE EFFECTS:

- Mucosal Bleeding
- Perforation of the trachea or oesophagus
- Sore Throat

CLINICAL BENEFITS:

- Complication rates are low
- Risk of airway trauma -Reduce
- High success rate (96%)
- Stiffness increased
- Flexibility increased

RESIDUAL RISKS:

- Perforation
- Infection

SUPPLY:

06,10 & 14 FR

Stylette - SMD SS 753

MATERIAL USED:

Item	Material	Specification
PVC Tube	PVC	Medical Grade
Aluminium wire	Aluminium	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.

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:

INSTRUCTIONS FOR USE

TRACHEAL TUBE INTRODUCER (ET TUBE STYLETTE)

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

SSIPL/IFU/STY/01. Rev. No.:00, Dt. 12.08.23

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
	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