INSTRUCTIONS FOR USE

TRACHEAL TUBE INTRODUCER (BOUGIE VENTED & NON VENTED)

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

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

PRODUCT DESCRIPTION:

A thin, flexible angled PVC tube for exploring or dilating a passage of the body.

INTENDED PURPOSE:

Used to aid tracheal intubation in poor laryngoscopic views or after intubation attempts fail and 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:

No absolute contraindications. If the patient has acute inflammation in throat, the doctor should be prudent since the Bougie is likely to diffuse inflammation. If the patient has severe edema in throat, he or she couldn't undergo artificial airway surgery through larynx. For patients who has severe coagulation disorder, the Bougie should be used after recovering. If the patient has a big aneurysm, especially when the aneurysm lies in the arch of aorta, Bougie may break the aneurysm and therefore, when necessary, the intubation needs to be gentle and skilled and the patient should avoid coughing and restless.

COMBINATIONS The medical device used with this product is Endotracheal Tubes and Simple Respirator(for the hollow Bougie only).

LIMITATION:

None Known

INTENDED USER

Doctors or Qualified Healthcare Professional

INTENDED PATIENT POPULATIONS

All Age Group

DIRECTIONS FOR USE:

- Check the expiration date.
- Products exceeding expiration date, packaging damage or packaging containing foreign matter are strictly prohibited to use.
- Select the correct references and sizes of Bougie and place the lubricated Bougie in the pharynx and manipulate into an appropriate position of the larynx and enter into the trachea.
- Ventilate the patient through Hollow Bougie with a 15mm Connector by using a Simple Respirator.(If applicable)
- Apply lubricant to the endotracheal tube and then thread over the Bougie.
- Slide the endotracheal tube through the larynx and enter into the trachea.
- Hold the endotracheal tube in place and gently withdraw the Bougie.
- Follow instructions provided with endotracheal tube to complete safe intubation.
- Once the Bougie has been withdrawn from the patient it must be discarded and do not reuse.

WARNING:

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

PRECAUTIONS AND CAUTIONS:

- Sterile product. Sterilized by Ethylene Oxide.
- Single Use Only. Do not use if the package is damaged or the device is not within shelf life.
- It is forbidden to use in conjunction with nasopharyngeal endotracheal tube.
- Do not re-sterilize. After use, the product should be disposed according to the local law by the hospital.
- Product is not to be exposed to temperatures above 49°C (120°F).
- Should be used immediately when opening the package, please destroy when it was used.
- This product is for disposable use, after use can not be used again after cleaning.

ADVERSE EFFECTS:

- Airway trauma
- Tracheal or bronchial perforation leading to pneumothorax or mediastinal emphysema
- Esophageal perforation

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 & 15 CH

Introducer Bougie (Vented & Non-Vented) - SMD SS 755

MATERIAL USED:

Item	Material	Specification
PVC Tube	PVC	Medical Grade
15 mm Connector	PVC	Medical Grade
Blue Pigment	Blue Pigment	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:

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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		

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