

IFU
Bougie

DESCRIPTION

Bougie is specially used during clinical intubation procedure with Endotracheal Tubes. Especially for difficult airways. Before intubation, the clinicians will insert a Bougie into the patient's trachea through oral cavity. Then the clinicians will intubate the Endotracheal Tube through the Bougie. The Hollow Bougie is supplied with Connectors which can be connected with a breathing device to pre-ventilate patients to ensure that there is sufficient oxygen concentration of the patients and gain more valuable time for clinicians to finish the intubation procedure and achieve artificial ventilation.

Model AND SIZE

Model code	Model name	Size	Remark
47005S	Straight, Paediatric	5ch×470	/
60010S	Straight, Adult	10ch×600	/
60015S		15ch×600	/
80010S		10ch×800	/
80015S		15ch×800	/
60010A		Angled (coudé), Adult	10ch×600
60015A	15ch×600		/
80010A	10ch×800		/
80015A	15ch×800		/
70010HS	Straight, Hollow	10ch×700	Component: 15mm Connector
70015HS		15ch×700	
90010HS		10ch×900	
90015HS		15ch×900	
70010HA	Angled, Hollow	10ch×700	
70015HA		15ch×700	
90010HA		10ch×900	
90015HA		15ch×900	
000946	Pre-lubricated articulating introducer with intuitive colored depth system	15ch×700	/

INTENDED USE

It is a single use product to assist the insertion of endotracheal tubes in the medical department.

PATIENT GROUPS

The Straight and Angled Models are for both Children and adults. The Articulating Model is only for

Adults.

INTENDED USERS

Professionally trained doctors or clinical nurses.

INDICATIONS

Assist the insertion of the Endotracheal Tubes when in difficult airway intubation or replace the Endotracheal Tubes.

CONTRAINDICATIONS

➤ **Straight and Angled Models**

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.

➤ **Articulating Model**

① Do not use if the entrance to the trachea cannot be visualized when performing laryngoscopy, i.e., Grade III or Grade IV Cormack & Lehane laryngoscopy classification.

② Inability to place a laryngoscope into patient's airway.

③ Pediatric patients.

④ Adults with abnormal lower airway anatomy.

⑤ Inability to visualize the color-depth-zone system throughout the procedure.

COMBINATIONS

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

WARNING/PRECAUTIONS

- a. Sterile product. Sterilized by Ethylene Oxide.
- b. Single Use Only. Do not use if the package is damaged or the device is not within shelf life.
- c. It is forbidden to use in conjunction with nasopharyngeal endotracheal tube.

- d. Do not re-sterilize. After use, the product should be disposed according to the local law by the hospital .
- e. Product is not to be exposed to temperatures above 49°C (120°F).
- f. Please immediately contact the doctor if any allergies happen.

PRE-USE CHECKS

- a. Do not use this product unless these checks are fully satisfactory.
- b. Check the expiration date. Products exceeding expiration date, packaging damage or packaging containing foreign matter are strictly prohibited to use.
- c. In the unlikely event of pre-use check failure, do not use but return to supplier for inspection.

DIRECTION FOR USE

These directions are general guidelines intended for use by qualified medical personnel. Any instructions, indications and contraindications given are not exhaustive and it is the clinician's responsibility to ensure the safe, correct use of this product.

➤ Straight and Angled Models

- a. 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.
- b. Ventilate the patient through Hollow Bougie with a 15mm Connector by using a Simple Respirator.(If applicable)
- c. Apply lubricant to the endotracheal tube and then thread over the Bougie.
- d. Slide the endotracheal tube through the larynx and enter into the trachea.
- e. Hold the endotracheal tube in place and gently withdraw the Bougie.
- f. Follow instructions provided with endotracheal tube to complete safe intubation.
- g. Once the Bougie has been withdrawn from the patient it must be discarded and do not reuse.

➤ Articulating Model

- a. Place video laryngoscope (VLS) to visualize cords.
- b. Straighten tip by squeezing trigger.
- c. While inserting into mouth, directly visualize the tip of the introducer until it is no longer directly visible.
- d. Once the tip appears in the laryngoscope view, release the trigger to bring the tip up.

- e. Move tip towards the entrance to the trachea.
- f. Use the trigger and rotate the handle to adjust tip to enter the trachea.
- g. Once the tip is in the trachea, squeeze the trigger to articulate the tip to facilitate passage down the trachea.
- h. If resistance is encountered, do not force the introducer.
- i. Insert the device into the trachea until the green zone of the color-depth-zone system is at the entrance to the trachea.
- j. Remove fingers from the trigger entirely.
- k. Release handle by pushing thumb-release forward until it stops, and then down to open the cover.
- l. Remove the handle from the introducer.
- m. Pass control of the VLS to an assistant to maintain the view of the relationship between introducer shaft and the vocal cords.
- n. While maintaining the green zone of the color-depth-zone system at the vocal cords, pass tube over introducer into the trachea.
- o. While leaving ET tube in place, remove introducer.
- p. Remove VLS.
- q. Inflate the cuff of the ET tube (if present).
- r. Ventilate patient

SHELF LIFE

5 years

DURATION

Less than 1 minute.

STORAGE CONDITIONS




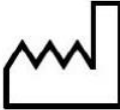














Store product inside containers or outer boxes in a clean, dry area.

Storage should be within a temperature range of 10–30°C.

Do not expose to direct sunlight or UV light.

Made in China

MEANING OF SYMBOLS ON PACKAGE

	Do not re-use		Manufacturer
	Use-by date		Date of manufacture
	Batch code		Authorized representative in the European Community
	Sterilized using ethylene oxide		Keep away from sunlight
	Do not use if package is damaged		Keep dry
	Consult instructions for use		Catalogue number
	Caution		Doesn't contain DEHP
	CE marking of conformity		Latex free
	This way up		Fragile, Handle with care



MR Safe



MR Unsafe

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