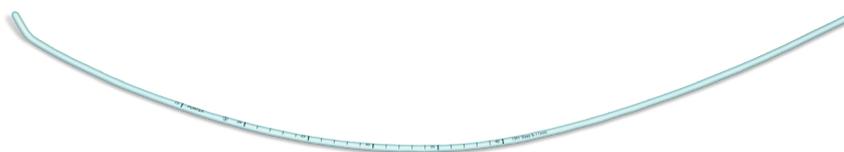


Portex™ Single-Use Bougie Coudé Tip, Size 15 Fr (5 mm)



Device Classification

GMDN: 41829

Classification: Class Is

Device Description

The product is a single-use sterile bougie. The bougie incorporates a smooth angled tip and is suitable for tracheal tube size 6.0 mm ID or greater. The approximate depth of insertion of the bougie can be determined by using the indication marks at 15 cm and at 1 cm intervals between 20 cm and 40 cm from the bougie tip.

Indications

The bougie is designed to give good directional control during routine or difficult oral intubation when the laryngeal inlet cannot be seen completely.

Contraindications

The bougie should not be used for nasal intubation or for changing a tracheal tube. For changing a tracheal tube, it is recommended that a Portex tracheal tube guide be used.

Precautions

Different types of introducers are available, so it is necessary to become familiar with the performance and use of the products before difficult intubations are encountered.

This device should only be used by personnel trained in its use. For training purposes, intubation should be simulated to ensure users are knowledgeable enough to be able to react in an appropriate manner when an unexpected difficult airway requires intubating.

Component Composition

Tube: PVC ivory

- › This device contains plasticiser diethylhexylphthalate (DEHP).
- › This device is not made with natural rubber latex.
- › This device is not manufactured using derivatives of tissues or cells of animal origin.

Legal Manufacturer Name and Address

ICU Medical, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442 USA

Country of Origin

Mexico

Sterilisation Method

Ethylene oxide (EO)

Shelf Life

5 years

Labelling and Packaging

Container Type	Length (mm)	Width (mm)	Height (mm)
Single unit	800	36	–
Shelf carton (10 units)	70	42	836
Transit carton (100 units)	845	225	146

One unit packaged per polybag. Ten units packaged per shelf carton. Ten shelf cartons packaged per transit carton, for a total of one-hundred units. Product is single use, sterile and latex-free. Discard if open, wet or damaged. Product should be kept out of direct sunlight.

The lot number, manufacturing date and expiration date are located on the polybag, shelf carton and transit carton labels.

Product Specifications

Product Code	Description	Recommended Use	Recommended Tube ID (mm)	Size (Fr/mm)	Length (mm)	Units per Case
100/123/515	Single-Use Bougie	SU	6.0–11.0	15/5.0	700	10