

Portex™ Single-Use Exchange Guide, Size 15 Fr (5 mm)



Device Classification

GMDN: 37469

Classification: Class Is

Device Description

The product is a sterile, single-use exchange guide designed for securing access to the patient's airway during an exchanging of tracheal tubes. It is suitable for tracheal tube size 6.0 mm ID or greater. The approximate depth of insertion of the exchange guide can be determined by using the indication marks at 15 cm and 1 cm intervals between 20 cm and 40 cm from the tip.

Contraindications

The exchange guide should not be used for nasal intubation.

Precautions

Different types of exchange guides are available, so it is necessary to become familiar with the performance and use of the products. This device should only be used by personnel trained in its use.

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	36	800	-
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 pack and transit carton labels.

Product Specifications

Portex Single-Use Exchange Guide					
Product Code	Recommended Tube ID (mm)	OD (mm)	Length (mm)	Tip	Units per Case
100/123/015	6.0–11.0	5.0	700	Straight	10

The product complies with current legislation and has the corresponding CE marking (2797).
For additional information, warnings and/or safety precautions, refer to the manufacturer's Instructions for Use.