IFU for Cuff-Safe® Endotracheal Tubes with AccuCuff™ cuff pressure indicator

DESCRIPTION

The Endotracheal Tube with cuff pressure indicator (Cuff-Safe®) is supplied sterile with a standard 15 mm connector. The pressure indicator (AccuCuff) is connected via the inflation line to the Endotracheal Tube, the indicator is used for inflating & deflating the device, it will also indicate the air pressure in the cuff effectively and directly. The Reinforced Endotracheal Tube (Cuff-Safe®) with a stainless steel spring can reduce the risk of kinking or occlusion during use.

- The ET Tube (Cuff-Safe®) consists of tube, cuff, inflation line, pressure indicator and connector;
- The Reinforced ET tube (Cuff-Safe®) consists of tube, cuff, spring, inflation line, pressure indicator and connector.

The Endotracheal Tube (Cuff-Safe®) has the following features:

- Non-toxic, medical grade PVC material
- For use with both oral & nasal intubation
- Atraumatic soft rounded beveled tip
- High volume low pressure cuff provides an effective low pressure seal
- Softer rounded Murphy eye is less traumatic
- Accurate depth marks
- Standard 15 mm ISO connector
- Radio opaque line provided
- Peel pouch pack
- Latex free
- Sterilised by EO, single use
- Pressure indicator for indicating the cuff pressure during use.

TYPE AND SIZE

	Type	Type Code	Size (mm)
Endotracheal Tube (Cuff-Safe®)	Standard, Oral/Nasal with HVLP Cuff	ETT-P32	2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0
	Preformed, South Facing, Oral with HVLP Cuff	ETT-K32	3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0
	Preformed, North Facing,	ETT-B32	3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5

	Nasal with HVLP Cuff		9.0 9.5 10.0
	Reinforced, Oral/Nasal with HVLP Cuff	ETT-J32	3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10.0

INTENDED USE/INDICATIONS

An Endotracheal Tube (Cuff-Safe®) is used in general anaesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs.

CONTRAINDICATIONS

1. Use of Endotracheal Tubes (Cuff-Safe®) in procedures which will involve the use of a laser or an electrosurgical active electrode in the immediate area of the device is contraindicated.
2. Patients who are suffering from the serious throat oedema / inflammation, haemorrhage or neck vertebra trauma are not recommended to use Endotracheal Tubes.
3. Do not use Reinforced Endotracheal Tubes (Cuff-Safe®) during MRI scan.

WARNING/PRECAUTIONS

1. Single Use Only
2. Sterile if package is unopened, undamaged and within its shelf life date
3. Do not re-sterilise
4. Do not expose to temperatures above 49^{o}C
5. This product must be pre-use checked prior to use
6. Various bony anatomical structures (e.g. teeth) during the intubation route, or intubation tools with sharp surfaces, present a threat to maintain cuff integrity. Care must be taken to avoid damaging the thin wall cuff during intubation. **Note:** if a cuff is damaged the tube should not be used
7. Do not over inflate the cuff. Cuff inflation should be made using a syringe until the black piston is set in the green zone of the cuff pressure indicator and an effective seal has been achieved. Over inflation can result in tracheal damage, rupture of the cuff with subsequent deflation, or distortion of the cuff leading to herniation which may cause airway blockage
8. Syringes, 3 way stopcocks or other luer tip devices should not be left inserted in the pressure indicator for extended periods of time.
9. Intubate the trachea following accepted medical guidelines
10. Auscultate both lung fields. If breath sounds are absent or diminished over one or both fields, adjust tube as necessary

11. Use only on equipment with 15mm connectors
12. Fully deflate the cuff prior to repositioning the tube. Any tube displacement should be corrected immediately
    When the patient's position or placement is changed after intubation, it is essential to verify that the tube position remains correct. Any tube displacement should be corrected immediately
13. If the tube is lubricated prior to use, it is essential to check that the lubricant does not enter and block the lumen thereby preventing ventilation
14. Ensure the cuff is fully deflated before attempting to remove the tube. When the device is fully deflated, the black piston line will be below the white line indicating negative pressure and that the cuff is fully deflated
15. Do not use a laser near this airway as this may cause combustion and injury

PRE-USE CHECKS:

Do not use this product unless these checks are fully satisfactory.

1. Product is within its specified shelf life
2. Visually check the whole device for completeness, discolouration, damage and flaws
3. Test inflate cuff prior to use - do not over inflate (the black piston line should not move into the red coloured area of the pressure indicator)
   - Check against leaks and herniation of the cuff and leaks from the inflation line
   - Check that the airway tube is clear with no blockage or occlusion
4. Fully deflate the cuff before removal (when the device is fully deflated the black piston line will be below the white line of the pressure indicator, indicating negative pressure and that the cuff is fully deflated). The airway tube can now be safely removed.
5. If the tube needs to be shortened prior to use, the 15mm connector can be removed on all the airway tubes (with the exception of reinforced versions). The tube can be cut to the desired length remembering to avoid cutting through the inflation line. The 15mm connector can then be replaced with a push and twist action until secure. **Note:** This cannot be carried out on the Reinforced Tubes.

DIRECTION FOR USE

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

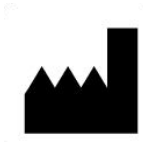
1. Fully deflate the cuff prior to use ensuring the black line of the piston is below the white line of the pressure indicator
2. Lubricate with water soluble lubricant as required
3. Intubate the trachea following current accepted medical guidelines
4. Auscultate both lung fields. if breathing sounds are absent or diminished over one or both fields, adjust tube as necessary
5. Inflate airway cuff using a syringe until the black line of the piston is set within the green zone of the cuff pressure indicator and an effective seal has been achieved. Fully remove the syringe from the cuff pressure indicator
6. Secure the tube and attach the tube to the ventilation equipment

STORAGE CONDITIONS

Store product inside containers or outer boxes in a clean, dry area.
Storage should be within a temperature range of 10–30^{o}C.
Do not expose to direct sunlight or UV light.

MEANING OF SYMBOLS ON PACKAGE

	Do not resterilize		Manufacturer
	Use-by date		Date of manufacture
	Batch code		Authorised representative in the European Community
	Sterilised by ethylene oxide		Keep away from sunlight
	Do not use of package is damaged		Keep dry
	Do not re-use		Latex free



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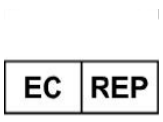

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