IFU for Endotracheal Tubes (all versions, with and without cuff)

DESCRIPTION

The Endotracheal Tube is supplied sterile with a standard 15 mm connector. The tube design incorporates a Magill curve and features a radiopaque line to assist in radiographic visualisation. 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. The Endotracheal Tube is regarded as the most reliable available method for protecting a patient's airway. The Reinforced Endotracheal Tube with a stainless steel spring can reduce the risk of kinking or occluding.

- The cuffed ET Tube consists of tube, cuff, inflation line, valve, pilot balloon, and connector.
- The uncuffed ET Tube consists of tube and connector.
- The cuffed Reinforced ET Tube consists of tube, spring, cuff, inflation line, valve, pilot balloon, and connector.
- The uncuffed Reinforced ET Tube consists of tube, spring and connector.

The Endotracheal Tube has the following features:

- Non-toxic, medical grade PVC material
- For use in both oral & nasal intubation
- Atraumatic soft rounded bevelled tip
- High volume low pressure cuff provides and effective low pressure seal
- Softer rounded Murphy eye is less traumatic
- Accurate depth marks
- Standard 15 mm ISO connector
- Radiopaque line
- Peel pouch pack
- Latex free
- Sterile by EO, single use

TYPE AND SIZE

	Type	Type Code	Size (mm)
Endotracheal Tube (all versions, with and without cuff)	Standard Endotracheal Tube with HVLP cuff	ETT-P22	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
	Endotracheal Tube Oral Preformed with HVLP Cuff	ETT-K22	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
	Endotracheal Tube Nasal Preformed with HVLP Cuff	ETT-B22	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
	Reinforced Endotracheal Tube with HVLP Cuff	ETT-J22	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 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 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 during MRI scan.

WARNING/PRECAUTIONS

1. Single Use Only
2. Sterile if package is unopened, undamaged and within shelf life date
3. Do not re-sterilise.
4. Do not expose to temperatures above 49°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(s) during intubation, which would create the need to subject the patient to trauma of extubation or re-intubation. **Note:** if a cuff is damaged the tube should not be used.
7. Do not overinflate the cuff(s). The cuff(s) should not exceed 25cm H20. Over inflation can result in tracheal or bronchial damage, rupture of cuffs with subsequent deflation or distortion of the cuffs leading to herniation, which may cause airway blockage.
8. Inflation by feel alone or by measured amount of air is not recommended, since resistance is an unreliable guide during inflation. Cuff pressure should continue to be monitored thereafter, and any deviation from the selected seal pressure should be investigated and corrected immediately.
9. Syringes, 3 way stopcocks or other luer tip devices should not be left inserted in the inflation valves for extended periods of time.
10. Deflate the cuff(s) prior to repositioning the tube. Movement of the tube, with cuff(s) inflated could result in patient injury. Verify correct placement of the tube after each repositioning.
    When the patient's position or the placement is changed after intubation, it is essential to verify that the tube position remains correct. Any tube displacement should be corrected immediately.
11. Use only on equipment with 15mm connectors.
12. Intubation and extubation should be performed following current accepted medical techniques.
13. If the tube is lubricated prior to intubation, it is essential to check that the lubricant does not enter and occlude the lumen hereby preventing ventilation
14. 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. If applicable, check product is within its specified sterile shelf life
2. Visually check whole device for completeness, discolouration, damage and flaws.
3. Test inflate cuff prior to use – do not over inflate
    - Check against leaks and herniation of the cuff and leaks from the inflation valve.

- Check that the airway tube is clear with no blockage or occlusion

4. If the Endotracheal Tube needs to be shortened remove the 15mm connector, cut the tube to the desired length then replace the 15mm connector 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.
2. Lubricate with water soluble lubricant as required.
3. Intubate the trachea then inflate cuff using minimum amount of air required to provide an effective seal.
4. Listen for air passing around the cuff to determine if an effective seal has been made.
5. Check for correct intubation and ongoing airway patency adjusting as necessary.
6. Secure the tube (preferably using a device which incorporates a bite block) 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 sun light or UV light.

MEANING OF SYMBOLS ON PACKAGE

	Do not resterilise		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 if package is damaged		Keep dry
	Do not re-use		Latex free

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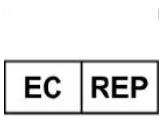

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