IFU for Tracheostomy Tubes with AccuCuff™

TYPE AND SIZE

	Type	Type Code	Size (mm)
Tracheostomy tubes, with AccuCuff™	Standard with AccuCuff	TT-P3	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
	Standard with AccuCuff	TT-J3	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

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. 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.
7. Cuff pressure should continue to be monitored thereafter, and any deviation from the selected seal pressure should be investigated and corrected immediately.
8. The use of Lidocaine topical aerosol has been associated with the formation of pinholes in PVC cuffs. Expert clinical judgement must be used when using this substance, to help prevent cuff leaks.
9. Syringes, 3 way stopcocks or other luer tip devices should not be left inserted in the inflation valves for extended lengths 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.
11. When the patient's position, or the placement is changed after intubation, it essential to verify that the tube position remains correct. Any tube displacement should be corrected immediately.
12. 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。
13. Use only with equipment with 15mm connectors.
14. Tracheostomy Intubation and extubation should be performed following current

accepted medical techniques.

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. 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 (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 valve.
   - 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.

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. Place Tracheostomy Tube then Inflate cuff using a syringe until the black line of the piston is set within the green zone of the cuff pressure indicator 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 and attach the tube to the ventilation equipment as required.

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 resterilise		Manufacturer
	Use-by date		Date of manufacture
	Batch code		Authorised representative in the European Community
	Sterilized 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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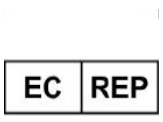

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