




INSTRUCTIONS FOR USE

MATERIAL USED

–PLAIN UNCUFFED Endotracheal Tubes: PVC, Polypropylene

–PLAIN CUFFED Endotracheal Tubes: PVC, Polypropylene, Stainless Steel and Silicone

–RE-INFORCED UNCUFFED Endotracheal Tubes: PVC, Polypropylene, Stainless Steel and Silicone

–RE-INFORCED CUFFED Endotracheal Tubes: PVC, Polypropylene, Stainless Steel and Silicone

INDICATIONS:

The device, 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:

- Product should not be used in patients with known hypersensitivity to any of the materials used.
- 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.
- Patients who are suffering from the serious throat oedema / inflammation, haemorrhage or neck vertebra trauma.
- Do not use Reinforced Endotracheal Tubes during MRI scan.

DIRECTIONS FOR USE:

PRE-USE CHECKS:

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

- Product is within its specified shelf life
- Visually check the whole device for completeness, discoloration, damage and flaws
- Test inflate cuff prior to use - do not over inflate (the black piston line should not move into the red colored 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
- 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
- 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.

STEPS FOR USAGE

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.

INSTRUCTIONS FOR USE

WARNINGS and PRECAUTIONS:
TO BE USED ONLY BY QUALIFIED MEDICAL PRACTITIONERS OR PARAMEDICAL STAFF

–Read instructions before use thoroughly, and use product accordingly.
–The product must be accompanied by its packaging with the lot number and expiration date.
–The product should not be reprocessed.
–Visually inspect the sterile packaging before use, improper transport and handling may cause structural and/or functional damage to device or packaging. Do not use product if packaging is damaged.
–The product should be used immediately after opening the sterile packaging.
–This product must be pre-use checked prior to use.
–Various 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.
–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.
–Syringes, 3 way stopcocks or other luer tip devices should not be left inserted in the pressure indicator for extended periods of time.
–Intubate the trachea following accepted medical guidelines.
–Auscultate both lung fields. If breath sounds are absent or diminished over one or both fields, adjust tube as necessary.
–Use only on equipment with 15mm connectors.
–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.
–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.
–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.
–Do not use a laser near this airway as this may cause combustion and injury.
–The product is guaranteed to be sterile & non-pyrogenic if the package has not been opened or damaged prior to use.
–Sterilised by Ethylene Oxide. Do not resterilize.
–For single use only. Discard after use.
–Store in cool & dry place. Do not expose to heat sources or direct sunlight.
–Intubation beyond 24 hours is not recommended. Replace with a standard ET tube if ventilation is needed beyond this period.
–The use of this product is restricted to a qualified doctor or a paramedic.

HARSORIA HEALTHCARE DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.

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Harsoria

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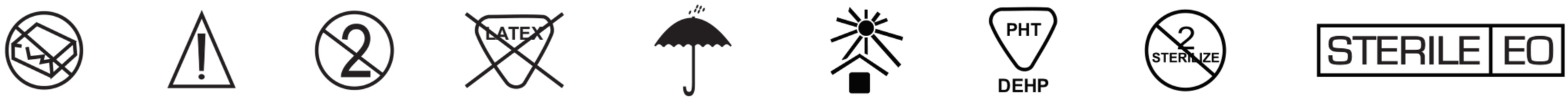

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