

IFU for Pat Tube® endotracheal tube with integrated throat/pharyngeal pack

DESCRIPTION

The PAT Tube is supplied sterile with standard 15 mm connectors. The pharyngeal pack can be positioned above the laryngeal inlet during clinical therapy and surgical operation, which can prevent the blood, secretion and foreign body entering the trachea and oesophagus. A pressure indicator connected with the PAT Tube, as the inflated device, can also indicate the air pressure in the cuff effectively and directly. The Reinforced PAT Tube with a stainless steel spring can reduce the risk of kinking or occluding.

Adult:

- The PAT Tube consists of tube, airway cuff, pharyngeal pack, inflation line, pressure indicator and connector.
- The Reinforced PAT Tube consists of tube, spring, airway cuff, pharyngeal pack, inflation line, pressure indicator and connector.

Paediatric:

- The cuffed Reinforced PAT Tube consists of tube, spring, airway cuff, pharyngeal pack, inflation line, pressure indicator and connector.
- The uncuffed Reinforced PAT Tube consists of tube, spring, pharyngeal pack, inflation line, pressure indicator and connector.

The PAT Tube has the following features:

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

TYPE AND SIZE

Pat Tube® endotracheal tube with	Type	Type Code	Size (mm)					
	Adult, Standard, Oral/Nasal	600	6.0	6.5	7.0	7.5	8.0	8.5

integrated throat/pharyngeal pack	Adult, Preformed, South Facing, Oral	500	6.0	6.5	7.0	7.5	8.0	8.5
	Adult, Preformed, North Facing, Nasal	200	6.0	6.5	7.0	7.5		
	Adult, Reinforced, Oral/Nasal	100	6.0	6.5	7.0	7.5	8.0	8.5
	Paediatric, Reinforced, Oral, Cuffed	300		4.5	5.0	5.5		
	Paediatric, Reinforced, Oral, Uncuffed	400		4.5	5.0	5.5		

WARNING/PRECAUTIONS

PAT Tube® Intubation & Inflation requires specialist training. Only competent trained medical personnel should use this device.

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°C
5. This product must be pre-use checked prior to use
6. Reuse of medical devices intended for single use has associated dangers of cross-infection and may compromise the integrity, functionality or clinical efficiency of the device.
7. Avoid exposure to ultraviolet or direct sunlight.
8. Various bony and anatomical structures (e.g. teeth) during the intubation route or intubation tools with sharp surfaces present a threat to maintain cuff and pack integrity. Care must be taken to avoid damaging the thin wall cuff and pack during intubation. **Note:** if a cuff or pack is damaged the tube should not be used.
9. Additional or alternative equipment may be necessary to aid with difficult intubation.
10. Over- inflation of the airway cuff or pharyngeal pack may result in tracheal or pharyngeal damage. The inflation airway cuff or pharyngeal pack 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 airway cuff or pharyngeal pack with subsequent deflation, or distortion of the airway cuff or pharyngeal pack leading to herniation which may cause airway blockage
11. Syringes, 3 way stopcocks or other luer tip devices should not be left inserted in

the pressure indicator for extended lengths of time.

12. Use only on equipment with 15mm connectors
13. If the PAT 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 airway cuff or pharyngeal pack 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 airway cuff or pharyngeal pack is fully deflated
15. Use of a laser near device may cause combustion with a risk of injury.

PRE-USE CHECKS:

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

1. Device is supplied sterile if packaging is unopened, undamaged and within shelf-life date.
2. Check device for completeness, discolouration, damage & flaws.
3. Ensure all connections are secure.
4. Check that all tubing is clear with no occlusions and free from any foreign bodies.
5. Test airway cuff and pharyngeal pack for leaks and herniation prior to use, ensuring they are fully deflated prior to insertion.
6. In the unlikely event of pre-use check failure, do not use but return to supplier for inspection.

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. Select the appropriately sized device for the patient.
2. Taking care not to occlude airway, lubricate with water soluble lubricant.
3. Intubate the trachea following current accepted medical guidelines.
4. Auscultate both lung fields. If breath sounds are absent or diminished over one or both fields, adjust tube as necessary.
5. Inflate airway cuff (if existing) using a syringe until the indicator is set in the green zone of the cuff pressure indicator and an effective seal has been achieved. Remove syringe from the blue coloured cuff pressure indicator.
6. The PAT Tube placement can be confirmed by viewing position of tube tip with a chest x-ray.
7. Listen for air passing around cuff to determine if an effective seal has been achieved.
8. Secure tube using a device which incorporates a bite block.
9. Promptly connect tube to source ventilation following current accepted medical guidelines.

10. Before surgery, using a syringe, gently inflate the pharyngeal pack, ensuring the pack is positioned above the laryngeal inlet, before inflating the pack to the green zone position of the green pack pressure indicator.
11. Continually monitor airway for adequate seal and pharyngeal pack pressure during the procedure and adjust accordingly.
12. Gentle suction should be applied to prevent any build up of blood or fluid above the level of the pharyngeal pack during surgery.
13. Apply gentle suction to remove any blood or fluid that has gathered above the level of the pharyngeal pack before deflating or removing the PAT Tube.
14. Fully deflate the pharyngeal pack before attempting to deflate the airway cuff prior to removal of the device.













STORAGE CONDITIONS

Store product inside containers or outer boxes in a clean, dry area.

Storage should be within a temperature range of 10–30°C.

Do not expose to direct sunlight or UV light.

MEANING OF SYMBOLS ON PACKAGE

	Do not re-sterilise		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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