BIÇAKCILAR

TR **Endotrakeal Tüp / RAE Endotrakeal Tüp / Spiralli Endotrakeal Tüp** / Kullanma Kılavuzu

ENG **Tracheal Tube/ RAE Tracheal Tube / Reinforced Tracheal Tube** / Instructions For Use

DE **Endotrachealtubus / Rae Endotrachealtubus / Spıralverstärkter Endotrachealtubus** / Gebrauchsanweisungen

ES **Tubo Traqueal / Rae Tubo Traqueal / Tubo Traqueal, Espıral** / Instrucciones de Uso

FR **Tube Trachéal / Rae Tube Trachéal / Sonde Trachéale Armée** / Mode d'emploi

IT **Tubo Tracheale / Rae Tubo Tracheale / Tubo Endotraqueal Con Spıraglıo** / Istruzioni per l'uso

PL **Rurka Dotchawıcza / Rae Rurka Dotchawıcza / Rurka Dotchawıcza, Ze Spıralą** / Instrukcja obsługi

PT **Tubo Endotraqueal / Rae Tubo Endotraqueal / Tubo Endotraqueal-Com Espıral E** / Instruções de Utilização

RU **Эндотрахеальная Трубка / Rae Эндотрахеальная Трубка / Усиленная Эндотрахеальная Трубка Спиральная** / Инструкция По Использованию

SE **Endotrakealtub / Rae Trakeltub / Endotrakealtub Armerad** /Användningsinstruktioner

NL **Endotracheale Tube /Rae Endotracheale Tube / Endotracheale Tube, Gewapend** / Gebruiksinstructies

DA **Trakealtube / Rae Trakealtube / Trakealtube, Spıral** / Brugsanvisning

FI **Intubaatıoputkı / Rae Intubaatıoputkı / Intubaatıoputkı, Spıraalı** / Käyttöohjeet

NO **Trakealtube / Rae Trakealtube / Trakealtube, Med Spıral** / Bruksanvisnin

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550 50XX 1
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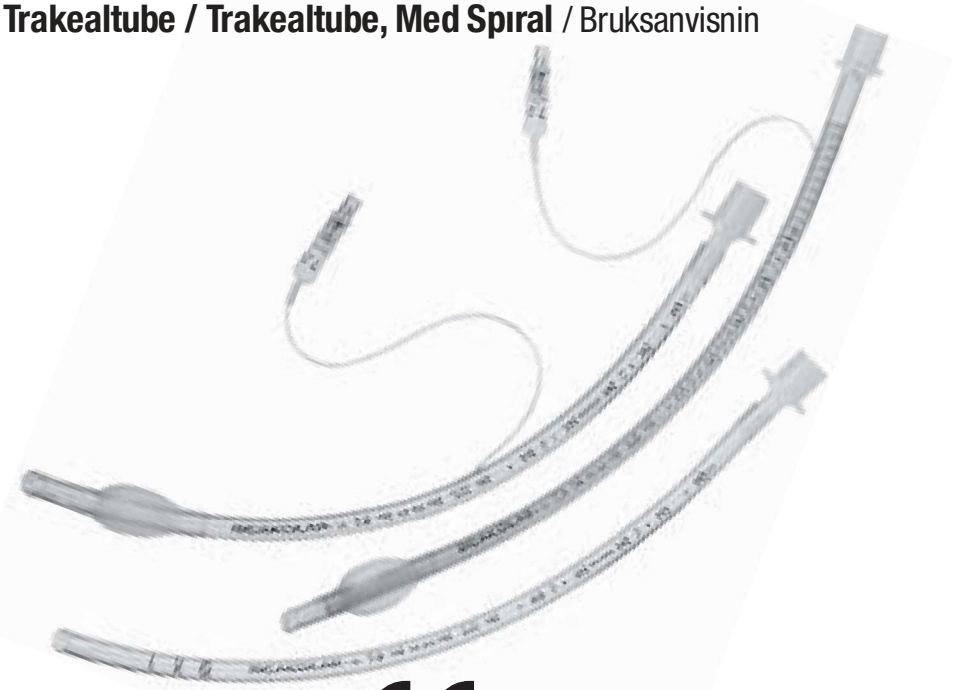

STERILE EO

CE 0044

BIÇAKCILAR TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.
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ENG INSTRUCTIONS FOR USE

1. Intended Use

Tracheal tubes are sterile, single use medical devices made of polyvinyl chloride with cuff, inflation line, pilot balloon and one way check valve, designed for oral or nasal intubation and intended for airway management of the unconscious patients. A radiopaque line is incorporated into the full length of the tracheal tube. Thermosensitive materials with sufficient initial rigidity to facilitate intubation have been selected which by nature conforms to the individual patient's respiratory tract at body temperature ensuring minimum trauma. Each tracheal tube is packed with a loosely assembled 15 mm. connector to enable the user to cut the tube to length.

Warning!
The device is not intended for use other than indicated in the instructions for use. The product is designed for use by trained health personnel.

2. Materials

PVC, PP

Warning!
The product should not be used in patients with known hypersensitivity to any of these components.

3. Warnings

3.1) Inspect the product for damage prior to use. Damage to the product (i.e., kink crimps, distortions or cuts) may result in obstruction or disruption of flow during use and product performance may be affected. Do not use damaged product.

3.2) If the packaging is damaged, do not use as sterility of the device may have been compromised.

3.3) Use aseptic techniques during the procedure.

3.4) A spare product must always be available during operation.

3.5) Carefully check joints for leakage. Change the product if there is a separation/plugging during insertion.

3.6) Use of tracheal tubes in procedures which will involve the use of a LASER or an electrosurgical active electrode in the immedate area of the device is contraindicated. Contact of the beam or electrode with the tracheal tube, especially in the presence of oxygen-enriched or nitrous oxide containing mixtures could result in rapid combustion of the tube with harmful thermal effects and with emmision of corrosive and toxic combustion products including hydrochloric acid.

3.7) When cutting tube length, avoid the joint between the inflation line and the tube to prevent air leak/blockage.

3.8) When cutting the tube to length, the 15mm connector should not be re-inserted so that the distal tip of the connector is in the proximity of the joint between the inflation line and the main body of the tracheal tube. If this occurs then blockage or leakage of the inflation system could result.

3.9) Prior to intubation, the tracheal tube lumen should be checked for patency.

3.10) The user should be alerted for anatomical variations including the length of the airway. Reliance on the cm graduation markers should not, in any case, be substitute for expert clinical judgement. Expert clinical judgement should also be used if cropping occurs below the precut indicator. (Oral; Nasal)

3.11) After intubation, the tracheal tube should be fixed accurately to prevent inadvertent position change.

3.12) When a patient's position or the tube replecement is altered after intubation, it is essential to verify that the tube position remains correct. Should extreme flexing (chin-to-chest) of the head or movement of the patient (e.g. to the lateral or prone position) be anticipated after intubation, it is recommended to check position of the tube.

3.13) Expert clinical judgement should be exercised in the selection of the appropriate size tracheal tube for each individual patient.

3.14) Intubation and extubation should be performed following current accepted medical techniques.

3.15) If the tracheal tube is lubricated prior to intubation, it is essential to verify that lubricant does not enter and occlude the tube lumen, thereby preventing ventilation or cause damage to the cuff.

3.16) Do not use lubricants to ease 15mm insertion as it may contribute to accidental disconnection.

3.17) Adequately humidified air should be used to minimize encrustation of the tracheal tube lumen and prevent tracheal mucosal damage.

3.18) Regular suctioning must be performed to assume tracheal tube lumen patency. Check the tracheal tube routinely and replace as required to maintain a patent airway.

3.19) Duration of product use should be determined according to the standard operating procedures and current local standards. It is generally recommended to replace the product when clinically deemed necessary.

3.20) The user should take the necessary precautions against cross contamination risks.

3.21) The user should take the necessary precautions against risks related with the patient/third parties.

3.22) The product is produced for single use and for single patient use only: the product comes in contact with human blood, body fluids, liquids or gases. Re-sterilization of the product may negatively affect the product performance. Therefore, reuse on other patients may cause cross-contamination, infection and sepsis. Do not resterilize.

Warnings (Cuff related)

3.23) Prior to intubation, tracheal tube cuff inflation system should be checked. The tube should not be used if any defect in this system is observed.

3.24) Inflation of the cuff by "feel" alone or by using a measured amount of air is not recommended, since resistance is an unreliable guide during inflation. Diffusion of the nitrous oxide mixture, oxygen or air may either increase or decrease the cuff volume and pressure. The intracuff pressure should be closely monitored with a pressure measuring device.

3.25) Do not overinflate the cuff. Ordinarily, the cuff pressure should not exceed 25cmH2O. Over inflation can result in tracheal damage, rupture of the cuff with subsequent deflation, or cuff distortion which may lead to airway blockage.

3.26) 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.

3.27) Various bony anatomical structures (e.g. teeth, turbinates) within the intubation routes or any intubation tools with sharp surfaces present a threat to maintaining cuff integrity.

3.28) During intubation, care must be taken to avoid damaging the thin-walled which would create the need to subject the patient to the trauma of extubation and re-intubation. If the cuff is damaged, the tube should not be used.

3.29) Deflate the cuff prior to repositioning the tube. Movement of the tube, with the cuff inflated, could result in patient injury, requiring possible medical intervention or damage to the cuff.

3.30) Syringes, three-way stopcocks or other devices should not be left inserted in the inflation valve for extended periods of time.

3.31) Protect cuff from damage by avoiding sharp edges.

4. Technical Specifications

Normal

Size	ID mm	OD mm
2.0	2.0	3.0
2.5	2.5	3.8
3.0	3.0	4.5
3.5	3.5	5.5
4.0	4.0	6.1
4.5	4.5	6.6
5.0	5.0	7.1
5.5	5.5	7.7
6.0	6.0	8.4
6.5	6.5	9.1
7.0	7.0	9.8
7.5	7.5	10.3
8.0	8.0	10.9
8.5	8.5	11.5
9.0	9.0	12.0
9.5	9.5	12.6
10.0	10.0	13.1

Reinforced

Size	ID mm	OD mm
3.0	3.0	5.3
3.5	3.5	5.5
4.0	4.0	6.1
4.5	4.5	6.6
5.0	5.0	7.1
5.5	5.5	7.7
6.0	6.0	8.4
6.5	6.5	9.1
7.0	7.0	9.8
7.5	7.5	10.3
8.0	8.0	10.9
8.5	8.5	11.5
9.0	9.0	12.0
9.5	9.5	12.6

5. Use

5.1) Remove the sterile tracheal tube from its protective package.

5.2) Check the integrity of the cuff and inflation system. Inflate the cuff with a luer tip syringe. Control for leaks. Reinsert the syringe and completely deflate the cuff.

5.3) Insert the 15mm connector into the tracheal tube firmly and connect to the breathing circuit or accessories tightly, to prevent accidental disconnection during use.

5.4) To cut the tube to length, remove the fitted 15mm connector before the intubation and cut at length.

5.5) Reinsert the 15mm connector into the tracheal tube.

5.6) Use currently accepted intubation technique.

5.7) After intubation, inflate the cuff with the minimum amount of air to provide an effective seal.

5.8) Remove the syringe from the valve.

5.9) Auscultate breath sounds and verify correct placement of the tracheal tube and proper lung ventilation. Control the inflation system for leak. Cuff pressure should be monitored and adjusted routinely.

5.10) Deflate the cuff before extubation.

5.11) Extubate the patient using currently accepted medical techniques.

5.12) For reinforced endotracheal tubes, in cases where the patient may bite down and flatten the tracheal tube's reinforcing spirals, it is recommended to use a bite block.

The following adverse reactions have been reported to be associated with the use of cuffed tracheal tubes during the intubation procedure, during the intubation period and subsequent to extubation. The order of listing is alphabetical and does not indicate frequency or severity; abrasion of the arytenoid cartilage vocal process; cartilage necrosis; cicatrix formation; consequences of failure to ventilate including death; damage to the perichondrium; development of dense or diffuse fibrosis invading the entire glottic area; emphysema; endobronchial aspiration; endobronchial intubation (hypoxemia); endotracheobronchial aspiration; epistaxis; esophageal intubation (stomach distension; excoriated membranes of the pharynx; eye trauma; fibrin deposition; formation of subglottic web; fracture-luxation of cervical column (spinal injury); fragmentation of cartilage; glottic edema (supraglottic, subglottic, retroarytenoidal); granuloma of the inner arytenoid area; infections (laryngitis, sinusitis, abscess, respirtory tract infection); inflammation; intermittent aphonia and recurrent sore throat; laryngeal fibrosis, laryngeal granulomas and polyps; laryngeal obstruction; laryngeal stenosis; laryngeal ulcers; laryngotracheal membranes and webs; membranous glottic congestion; membranous tracheobronchitis; mild edema of the epiglottis; mucosal sloughing; paresis of the hypoglossal and/or lingual nerves; perforation of the trachea; pneumothorax; replacement of the tracheal wall with scar tissue; respiratory obstruction; retrobulbar hemorrhage; retropharyngeal abscess; retropharyngeal dissection; rupture of the trachea; sore throat; dysphagia; stricture of nostril; stridor; subglottic annular cicatrical stenosis; submucosal hemorrhage; submucous puncture of the larynx; superficial epithelial abrasion; swallowed tube; synechia of the vocal cords; teeth trauma; tissue burns; tracheal bleeding; tracheal stenosis; trauma to lips; tongue, pharynx, nose, trachea, glottis, palate, tonsil, etc; traumatic lesions of the larynx and trachea; ulceration of the lips, mouth, pharynx; ulcers of the aryytenoid; vocal cord congestion; vocal cord paralysis and vocal cord ulcerations.

6. Storage

The device should be kept in its original packaging at room temperature until use. Protect from direct exposure to sunlight. Under proper storage conditions, the device may be used up to the expiry date indicated on the label.

7. Disposal of the product

The product should be discarded as a contaminated medical waste.

The product does not contain latex material (natural rubber).