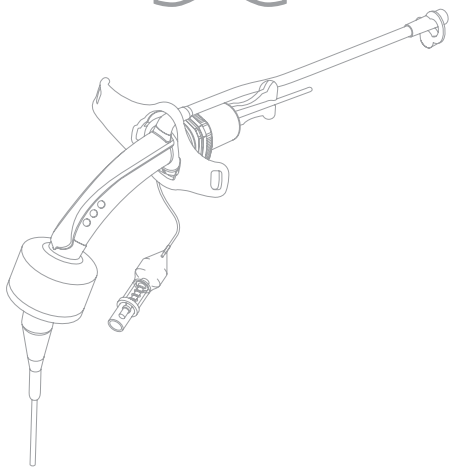


# TRACOE Twist Plus



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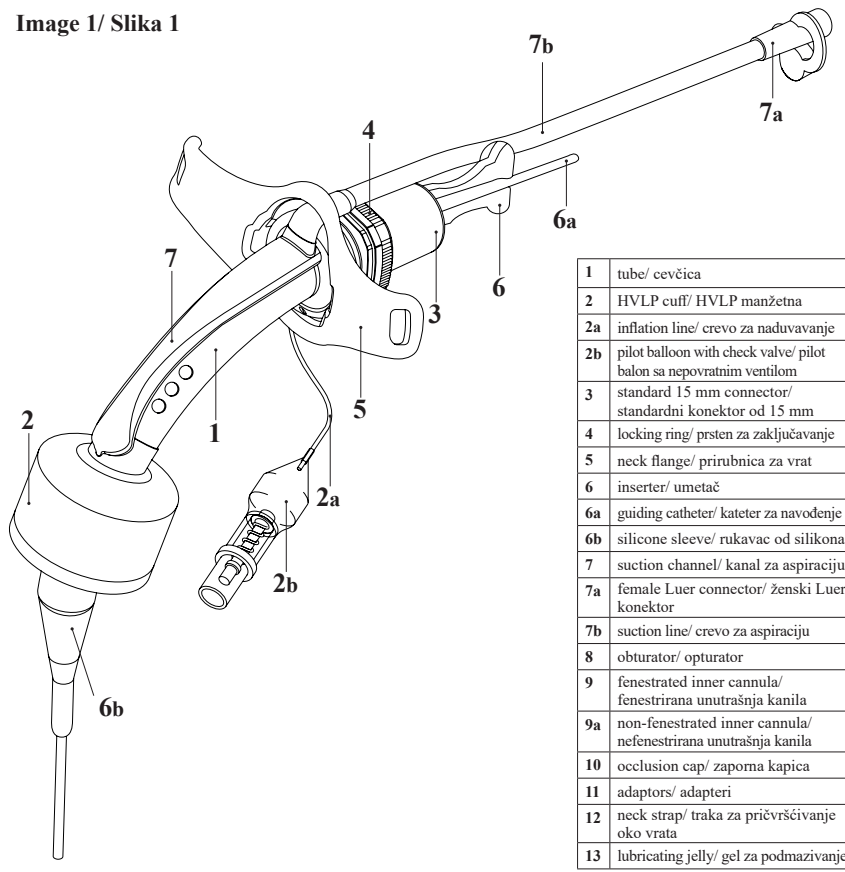
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Image 1/ Slika 1



1	tube/ cevčica
2	HVLP cuff/ HVLP manžetna
2a	inflation line/ crevo za naduvavanje
2b	pilot balloon with check valve/ pilot balon sa nepovratnim ventilom
3	standard 15 mm connector/ standardni konektor od 15 mm
4	locking ring/ prsten za zaključavanje
5	neck flange/ prirubnica za vrat
6	inserter/ umetač
6a	guiding catheter/ kateter za navodjenje
6b	silicone sleeve/ rukavac od silikona
7	suction channel/ kanal za aspiraciju
7a	female Luer connector/ ženski Luer konektor
7b	suction line/ crevo za aspiraciju
8	obturator/ opturator
9	fenestrated inner cannula/ fenestrirana unutrašnja kanila
9a	non-fenestrated inner cannula/ nefenestrirana unutrašnja kanila
10	occlusion cap/ zaporna kapica
11	adaptors/ adapteri
12	neck strap/ traka za pričvršćivanje oko vrata
13	lubricating jelly/ gel za podmazivanje

Image 2/ Slika 2

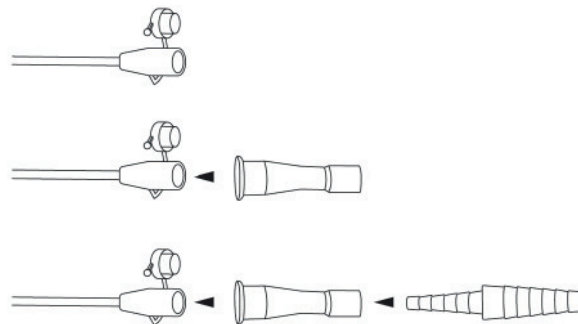


Image 5/ Slika 5

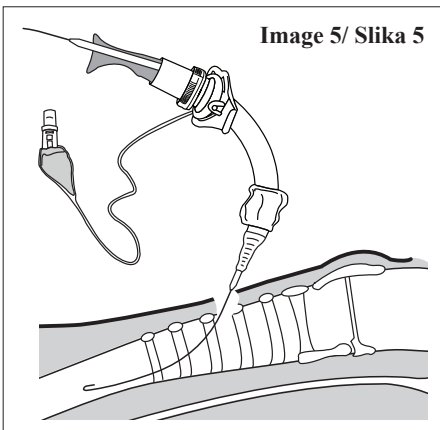


Image 4/ Slika 4

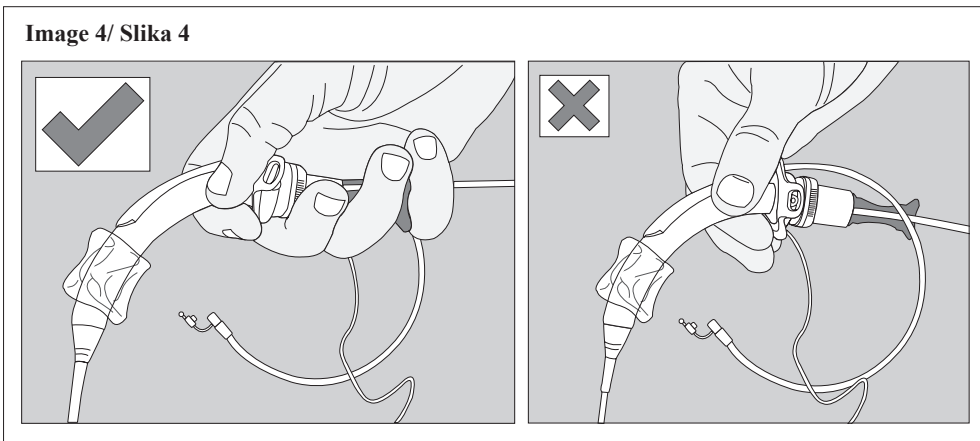
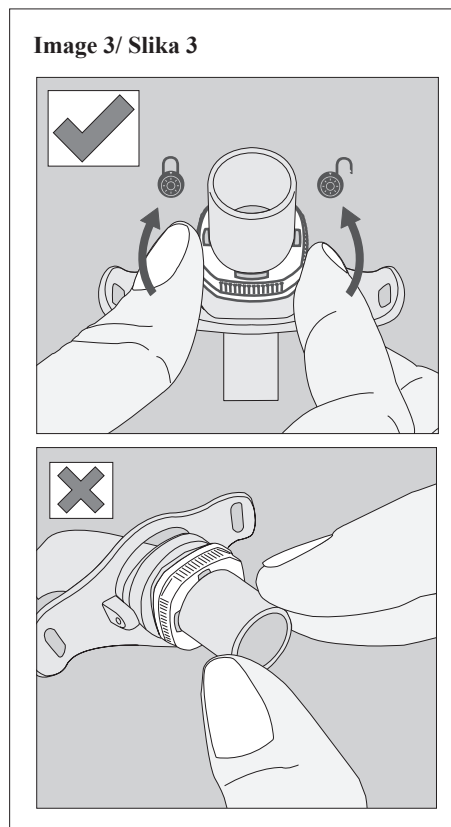
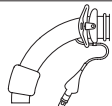
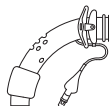
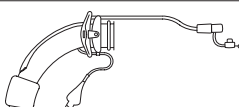
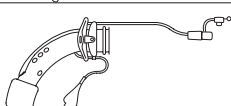
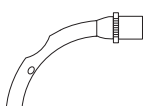
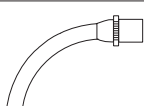
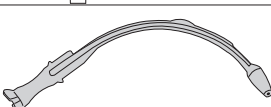
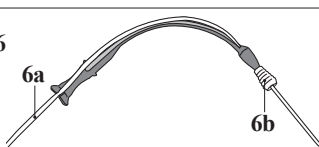




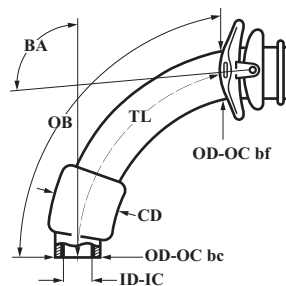


Image 3/ Slika 3



Scope of delivery/ Obim isporuke	REF 311-P	REF 312-P	REF 316-P	REF 888- 316-P
	1	-	-	-
	-	1	-	-
	-	-	1	-
	-	-	-	1
9 	-	1	-	1
9a 	2	2	2	2
8 	1	1	1	1
6  6a 6b	1	1	1	1
10 	-	1	-	1
11 	-	-	1	1
12  13 	1	1	1	1

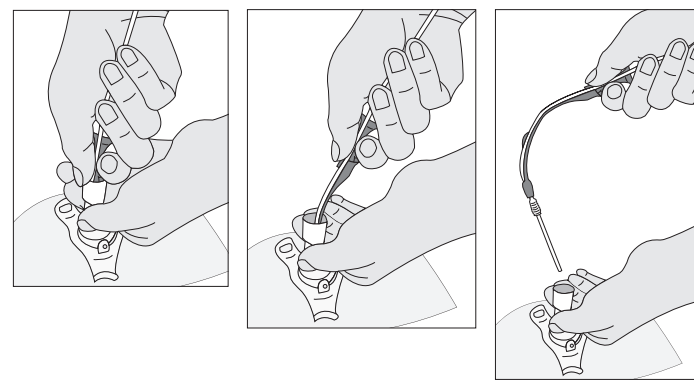
### Size Table/ Tabela veličina



Size	ID-IC mm	OD-OC bc mm	OD-OC bf mm	TL mm	OB mm	BA °	CD mm
07	7.0	9.8	10.1	85	91	100	26
08	8.0	10.8	11.1	88	95	100	28
09	9.0	11.8	12.1	90	99	100	30
10	10.0	12.8	13.1	92	102	100	32

**ID-IC:** inner diameter (clear width) at bottom of inner cannula  
**OD-OC bc:** outer diameter at bottom of outer cannula  
**OD-OC bf:** outer diameter of outer cannula behind the flange  
**TL:** length along center line from start of neck flange to bottom of tube  
**OB:** length along outer bend from start of neck flange to bottom of tube  
**BA:** bending angle **CD:** cuff diameter

### Image 6/ Slika 6



Tracoe Twist Plus tubes are double-lumen tubes. The inner cannula can be removed or exchanged e.g. for cleaning from secretions or obstructions while the outer cannula remains in place. Thus, airway patency can be restored by change of the inner cannula.

The tubes with subglottic suction channel allow to remove the secretions that remain above the inflated cuff.

The fenestrated models permit a proportion of the airflow to be directed towards the upper respiratory tract. If the treatment does not require or allow (e.g. mechanical ventilation) the use of a fenestrated tracheostomy tube, the fenestration can be closed by inserting a non-fenestrated inner cannula.

The 15 mm connector is a standardised component to which other airway management devices (e.g. mechanical ventilator, cough assist, nebuliser etc.) can be connected.

Compared to the usage of an endotracheal tube the anatomical dead space is reduced and there is less need for sedation when using a tracheostomy tube. The risk of long-term complications associated with prolonged endotracheal intubation (e.g. vocal cord injuries, formation of granulation tissue in the laryngeal area etc.) can be prevented when using a tracheostomy tube.

**Patient Population:** The product is intended for adults and adolescents (≥12 - 21 years).

**Clinical Use:** The product is intended for mechanically ventilated and self-breathing patients in hospitals, pre-hospitals (EMS), extended care facilities, or outpatient clinics, or home care.

**Intended User:** The product can be used by medical staff trained in tracheostomy care or individuals trained by professionals.

**Indications for Use:** The tracheostomy tube is indicated for patients where access to the lower respiratory tract is required by means of a tracheostomy to secure the airway. Tracoe Twist Plus tracheostomy tubes are double-lumen tubes. The inner cannula can be removed and replaced in case of encrustation or obstruction by viscous secretions.

The tracheostomy tube with a high-volume-low-pressure (HVLP) cuff seals the trachea to separate the upper airways from the lower respiratory tract. Therefore, it allows efficient ventilation and reduces influx of subglottic secretions into the lung.

The Minimally Traumatic Insertion System is single use only and is indicated for the insertion of the Tracoe Twist Plus tracheostomy tube using the Seldinger technique. It can be used for the first insertion of the tracheostomy tube after percutaneous dilation tracheostomy or when the tube is changed.

The Tracoe Twist Plus extract tracheostomy tubes with subglottic suction channel and cuff (REF 316-P and REF 888-316-P) are predominantly used for patients producing large amounts of secretions and for whom suctioning of the subglottic space is indicated.

## EN - ENGLISH

### Instructions for Use Tracoe Twist Plus Tracheostomy Tubes with the Minimally Traumatic Insertion System

The use of Above Cuff Vocalization (ACV) is CE approved only.

#### NOTE:

• Please read the instructions for use carefully. They are part of the described product and must be available at all times. For your patients' and your own safety, please observe the following safety information.

The illustrations to which the text refers can be found on the illustrated pages at the beginning of these instructions. The numbers indicate product components and refer to the respective illustrations of the product. Symbols and icons used with the product are explained in sections "General Description" and "Functional Description".

#### 1. Intended Use and Indications for Use

Tracoe Twist Plus tracheostomy tubes are indicated for providing tracheal access for airway management. They may be used up to 29 days.

**Clinical Benefit:** Tracoe Twist Plus tracheostomy tubes provide tracheal access to the lower respiratory tract. The cuffed models, when inflated, can be used to seal the airway (e.g. for mechanical ventilation).

The Tracoe Twist Plus extract tracheostomy tubes can be used for Above Cuff Vocalization (ACV).

The double fenestration of the Tracoe Twist Plus models (REF 312-P, REF 888-316-P) allows a proportion of the airflow to be directed towards the upper respiratory tract.

**Single Patient Use and Useful Life:** The Tracoe Twist Plus tracheostomy tube is for single patient use with a useful life of 29 days. The device can be cleaned and reinserted in the same patient during this time period.

The device should not be used for more than 29 days beginning from the initial opening of the sterile barrier. This maximum period of use includes both patient and non-patient (e.g. cleaning) use of the device.

**Caution:**

A prolonged use of the tracheostomy tube for more than 29 days may result in material safety and biocompatibility issues.

**2. General Description**

The Tracoe Twist Plus tracheostomy tube is made of PU and provides an artificial airway to the lower respiratory tract.

The product includes an outer cannula with 2 or 3 inner cannulas with 15 mm connector, a minimally traumatic insertion system (insertor, guiding catheter with silicone sleeve), a perforated obturator, a fabric neck strap, and lubricating jelly which are supplied together within a sterile bag. Adaptors for use with external suctioning devices are only delivered with the subglottic suctioning models (REF 316-P, REF 888-316-P). The fenestrated models (REF 312-P, REF 888-316-P) also contain an occlusion cap.

The Tracoe Twist Plus tracheostomy tubes are available in different diameters and lengths. The tracheostomy tubes, included with the minimally traumatic insertion system, are cuffed models which are provided with the cuff deflated. The appropriate diameter and length of the tube is determined by the physician.

The tracheostomy tube is radiopaque due to its material.

Clinical use of the device in a MR environment is dependent on the product specifications and is described in chapter "MRI Safety Information".

The tracheostomy tube can be used in combination with medical devices that are approved for invasive ventilation through a tracheostoma and are connected via a standard 15 mm connector. The tracheostomy tubes with the subglottic suction channel can be used with medical devices approved for subglottic suction.

This product is supplied with an information card, including two detachable labels, which contain product specific details. These labels will facilitate reordering of the device and its safe use within a MR environment. The labels can be attached to the patient record.

The image 1 represents the most complex tracheostomy tube model.

1	tube	7	suction channel
2	HVLP cuff	7a	female Luer connector
2a	inflation line	7b	suction line
2b	pilot balloon with check valve	8	obturator
3	standard 15 mm connector	9	fenestrated inner cannula
4	locking ring	9a	non-fenestrated inner cannula
5	neck flange	10	occlusion cap
6	insertor	11	adaptors
6a	guiding catheter	12	neck strap
6b	silicone sleeve	13	lubricating jelly

**(1) Tracheostomy Tube:**

- All tubes are curved and tapered towards the distal end and feature a round tip at the distal end (inside the patient)
- All tubes are made of a radiopaque material
- REF 311-P: The tube is cuffed
- REF 312-P: The tube is cuffed and fenestrated
- REF 316-P: The tube is cuffed with subglottic suction channel
- REF 888-316-P: The tube is cuffed, fenestrated, and with subglottic suction channel

**(2) High-Volume-Low-Pressure (HVLP) Cuff:**

- The HVLP cuff (2) is located on the distal end of the tracheostomy tube and directly connected to the inflation line (2a).
- The proximal end of the inflation line includes a pilot balloon (2b), with incorporated self-sealing check valve and a female Luer connector.
- The HVLP-cuff is inflated with air only.
- The pilot balloon (2b) displays the cuff diameter (CD) and size, where appropriate.

**(5) Neck Flange:**

- The neck flange (5) has a curved form.
- Due to its double-swivel the flange is horizontal and vertical movable
- The product code (REF), clinical size (size), inside diameter (ID), outside diameter (OD), length (TL) of the tube and MR Safety symbol are all indicated on the neck flange.

**(6-6b) Minimally Traumatic Insertion System**

- The combination of the insertor (6) and guiding catheter (6a) with silicone sleeve (6b) constitute the minimally traumatic insertion system.
- The silicone sleeve bridges the gap between the conical end of the insertor and the distal end of the tube.
- The minimally traumatic insertion system is used for the placement of the Tracoe Twist Plus tracheostomy tube using the Seldinger technique.

**(7-7b) Subglottic Suction Channel:**

- Tracoe Twist Plus extract tracheostomy tubes (REF 316-P, REF 888-316-P) include a subglottic suction channel (7) on the outside of the tracheostomy tube. The suction opening is placed at the lowest possible position above the cuff.

- The proximal end of the suction channel includes a standard female Luer connector (7a) port for connection to an external accessory device used in subglottic suctioning or for air/oxygen supply for ACV. For subglottic suctioning, additional, adaptors (11) can be used for connection.
- The subglottic suctioning port (7a) can be closed by using the attached cap.

**(8) Obturator:**

- The perforated obturator (8) has a smooth, round, conical tip at the distal end. The obturator is used for re-insertion of the tracheostomy tube for a tracheostoma.
- Due to its perforation the obturator can be used with the Seldinger technique.

**(9-9a) Inner Cannulas:**

- The models REF 311-P and REF 316-P are supplied with 2 inner cannulas, one of which is pre-mounted in the outer cannula.
- The fenestrated models REF 312-P and REF 888-316-P are supplied with 3 inner cannulas, one of which is pre-mounted in the outer cannula.
- Each inner cannula has a 15 mm connector with a locking ring (4). The blue locking ring indicates a fenestrated inner cannula (9), and the white ring indicates a non-fenestrated inner cannula (9a).
- REF 311-P and REF 316-P contain 2 non-fenestrated inner cannulas.
- REF 312-P and REF 888-316-P contain 1 fenestrated and 2 non-fenestrated inner cannulas.
- The standardized 15 mm connector (3) is permanently attached to the inner cannula and is intended for connecting the tracheostomy tube to external devices with a female standardized 15 mm connector e.g., connection to mechanical ventilation, HME, speaking valve.

**(12) Neck Strap:**

- The neck strap (12) is a soft strip of padded fabric that wraps around the patient's neck.
- The ends of the strap include hook-and-loop fasteners that are inserted through the eyelets of the neck flange to secure the tracheostomy tube in position.
- The frequency of change is determined by the physician or healthcare professional.

**(13) Lubricating Jelly**

- The lubricating jelly 13 can be used for the tube insertion with the minimally traumatic insertion system or obturator.

**Supplementary Products:**

- Products, which can be used in combination with the Tracoe Twist Plus tracheostomy tubes are listed in section "Supplementary Products".

**3. MRI Safety Information**

 REF 311-P, REF 312-P, REF 316-P and REF 888-316-P

Nonclinical testing has demonstrated the Tracoe Twist Plus tracheostomy tubes REF 311-P, REF 312-P, REF 316-P and REF 888-316-P are "MR Conditional". A patient with this device can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3.0 T.
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m).
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg (normal operating mode) and a maximum whole head specific absorption rate (SAR) of 3.2W/kg.
- Quadrature driven transmit body coil only.
- The neck flange (5) must be secured in place with the neck strap (12).
- The check valve of the tracheostomy tube cuff (2b) must be secured to the skin with medical tape, away from the area of MR diagnostic interest.
- In non-clinical testing, the image artifact, caused by the check valve, extends (radially) up to 107 mm from the check valve when imaged with a gradient echo pulse sequence and a 1.5 T MR system, and up to 113 mm when imaged with a spin echo pulse sequence in a 3.0 T MR system. Therefore, it is recommended to tape the check valve to the patient's skin away from the area of interest.

**Warning:**

When used in MR imaging:

- Securely fasten the tube, with a metal-free neck strap, to prevent possible movement while in the MR environment.
- Securely affix the check valve away from the area of interest with standard medical tape to prevent movement within the MR environment.
- MR image quality may be compromised if the area of interest is close to the position of the inflation valve.

**4. Contraindications**

Tracheostomy Tubes:

- The tracheostomy tube cannot be used in conjunction with heat emitting devices, e.g. laser. There is a risk of fire, also toxic gases may form, and the tube may get damaged.
- The HVLP cuff must not be inflated, when a speaking valve or an occlusion cap is used and vice versa.
- Neonates, infants, and children (<12 years).

**ACV use:**

- Patients with a new tracheostoma (less than 7-10 days after surgical incision).
- Obstructions in the upper airways that can inhibit the airflow and therefore phonation capabilities.
- Obstructions may lead to pressure increase in the trachea and therefore cause a risk of subcutaneous emphysema.
- Patients with surgical emphysema or infections of the tracheal tissue.
- Patients with unilateral or bilateral paralysis of the vocal cords in median position.

**5. General Precautions**

- When the product is used together with other medical devices, follow their respective instructions for use. Contact the manufacturer if there are any questions, or if assistance is required.
- Safety precautions must be taken in case of complications during the described procedures, in order to provide immediate ventilation through alternative airways, (e.g. trans laryngeal intubation, laryngeal mask). This is recommended to be based on the respective applicable guidelines and standards for patients with difficult airways, e.g. Practice Guidelines for Management of the Difficult Airway (American Society of Anesthesiologists, 2013).
- Optimum oxygen levels must be established in the patient before cannulation or recannulation.
- It is strongly recommended that a ready-to-use spare tube and several inner cannulas are kept at the patient's bedside. Store the spare devices under clean and dry conditions.
- It is also recommended keeping an emergency spare device at the bedside in case of an unplanned tracheostomy tube change, e.g. due to complications, a collapsed tracheostoma or similar. The emergency spare device should be one or two sizes smaller than the device in use.
- The product should be inspected for integrity and function prior to use/insertion. Verify that the tube is free of obstruction and the cuff material is not brittle or torn and can be inflated/deflated,

that there is an absence of kinks, tears or cuts, and there is a stable connection between the tube and the neck flange, etc. If the product is damaged, it should be replaced with a new product.

- The sterile packaging and the outer packaging should be inspected for damage prior to opening. If the packaging is damaged or has been unintentionally opened, the device should not be used.
- While in placement, use or removal of the tracheostomy tube do not use excessive forces.
- Do not use unnecessary force on the tracheostomy tube when connecting to or disconnecting from external devices. This may result in damage of the tracheostomy tube and/or displacement / decannulation.
- Always hold the tracheostomy tube at the base of the 15 mm connector when connecting to or disconnecting from external devices.
- The position of the fenestration should be checked via endoscopy.
- The cuff pressure can change if nitrous oxide (laughing gas) is used as an anesthetic.
- All parts of the cuff inflation system must be free from strain and kinking during measurement of the cuff pressure, otherwise the manometer may show incorrect pressure values.
- Ensure that all allowed objects (e.g. hand-held manometer) used to inflate the cuff are clean (free of dust, visible particles, and contaminants). Any obstruction of the cuff filling system may result in deflation of the cuff which will reduce efficiency of ventilation or protection from aspiration.
- To avoid damage to the cuff and improve ease of insertion, always ensure that the cuff is deflated prior to insertion with the deflated cuff towards the neck flange.
- When a manometer and/or a connection tube is attached to the filling line of an inflated cuff, there will always be pressure compensation between cuff and connected device. This will result in a slight pressure loss in the cuff. If necessary, re-adjust the pressure until it is within the optimal range.
- Water inside the cuff: All HVLVP cuffs have a certain degree of permeability to water vapor. Therefore, condensed water vapor may accumulate inside the cuff. If larger quantities of water inadvertently enter the inflation line, it may lead to improper cuff pressure measurement, cuff pressure adjustment, and cuff deflation. In this case, the tracheostomy tube must be replaced.
- When changing the inner cannula, always ensure that the inflation line of the cuff is not positioned between the inner and outer cannulas as it may get trapped and damaged.
- During mechanical ventilation and frequent changes of the patient's position or manipulation of the tube, the inner cannula may become separated from the outer cannula. Therefore, check the connection of the inner cannula regularly.
- During subglottic suctioning, ensure that negative pressure is not excessive and not applied for an extended period in order to avoid drying out of the subglottic area. Intermittent suction is recommended. Closing the cap of the suction line port after suctioning may reduce the drying-out effect. The suction line may be blocked due to accumulated and/or dried secretions inside the suction line or during suctioning of excessive fluid. If the suction line becomes blocked, follow the instructions in chapter "Subglottic Suction".
- Improper storage conditions may result in product or sterile barrier damage.
- The vital parameters should be monitored regularly by professionals.

## 6. Warnings

- Do not use this product if the sterile packaging or the outer packaging have been compromised/damaged, e.g. open edges, holes in packaging etc.
- Reprocessing (including re-sterilisation) is not allowed, this may influence the material and function of the product. The products are single use only.
- Modifications of Tracoe products are not allowed. Tracoe will not be responsible for modified products.
- After removing the insertion system, ensure that the silicone sleeve is still located on the guiding catheter. If not, the silicone sleeve (radiopaque) must immediately be removed from the tube or airway.
- During initial placement of a tracheostomy tube immediately stop the ventilation through the upper airways when the cuff of the inserted tracheostomy tube is inflated. This reduces the risk of barotrauma.
- Ensure that the cuff is not punctured by instruments or sharp tracheal cartilage ridges.
- Use only water-soluble lubricating jelly for tracheostomy applications, as oil-based jelly may damage the tube.
- Ensure that the tube does not become obstructed when applying lubricating jelly to the obturator tip.
- Check the position and function of the tube following insertion. Incorrect placement may result e.g. in permanent damage to the tracheal mucosa or minor bleeding.
- Do not move or shift the tube once it is in position, as this may damage the stoma / trachea or lead to insufficient ventilation.
- Do not turn the 15 mm connector, as this may cause the rotation of the inner cannula inside the outer cannula. It may lead to interruption of the air supply or dislocation of the tracheostomy tube. Use the locking ring to loosen and re-lock the inner cannula.
- Never use fenestrated inner cannulas for ventilation.
- To avoid damage to the cuff material it should not be in contact with local anesthetics containing aerosols or any ointments, i.e. dexpanthenol.
- Long-term and excessive cuff pressure above 30 cmH<sub>2</sub>O (≈ 22 mmHg) poses a risk of permanent damage to the trachea.
- Only fill the cuff with air. Do not fill the cuff with liquids as this would lead to cuff pressure peaks above 30 cmH<sub>2</sub>O.
- Insufficient filling (below 20 cmH<sub>2</sub>O) of the cuff could result in insufficient ventilation and/or an increased risk of aspiration, which may result in the worst case in VAP (ventilator associated pneumonia) or aspiration pneumonia.
- When repositioning the patient, while in bed, ensure that the patient does not lie on the pilot balloon, as this could increase the cuff pressure and potentially damage the trachea.
- To prevent damage to the stoma or trachea, ensure that the cuff is deflated (empty) prior to insertion or removal of the tube. If it is not possible to deflate the cuff, cut the inflation line with a pair of scissors and remove the air. In this event, the product is defective and must be replaced.
- During air travel alteration of the cuff pressure may occur. Therefore, ensure permanent cuff pressure control.
- Before deflating the cuff ensure that the patient's upper respiratory tract is unobstructed. When applicable, clear the upper respiratory tract of any secretions through suction or patient coughing.
- Make sure that the correct Luer connectors are used for filling the cuff (transparent) and suctioning (white).
- Make sure that the correct Luer connector (white) is used for ACV.
- Ensure that the tracheostomy tube is free of obstructions which may lead to reduction of the delivered airflow. Therefore, regular suctioning of the secretion inside the tube depending on individual patient's needs (e.g. amount of secretions) is recommended.
- Excessive viscous secretion may lead to dislocation of the tracheostomy tube. Ensure the correct placement of the tube by regularly checking of the tube position and reduce the risk of dislocation by subglottic suctioning of the secretion.
- Use only suction catheters to clear the secretions from the patient's respiratory tract and the tracheostomy tube. Instruments may wedge in the tube and restrict ventilation.
- Regularly check that all connections are secure to prevent an inadvertent disconnection of the tube from external equipment and ensure efficient ventilation.
- Keep the 15 mm connector clean and dry.
- Do not use non-authorized tools to disconnect external equipment from the 15 mm connector, as this might deform the 15 mm connector.

- Occlusion caps/speaking valves must only be used with a deflated cuff to avoid the risk of suffocation.
- During insertion and removal of the tube a need to cough or bleeding may occur.

## 7. Side Effects

Typical side effects of tracheostomy tubes use include bleeding, pressure points, pain, stenosis, and skin irritation (e.g. due to moisture), granulation tissue, tracheomalacia, tracheoesophageal fistula, increased secretion, and swallowing difficulties. In case of an adverse event please contact a medical professional immediately.

When using ACV, typical side effects include increased secretion, discomfort, hoarseness, coughing, nausea, or laryngeal drying out due to restoring upper respiratory tract (cleaning / tasting / speaking) functionality.

During cuff deflation trials, increased secretion, discomfort, hoarseness, coughing, or nausea may be present.

## 8. Functional Description

### Caution:

- It is strongly recommended that a ready-to-use spare tube and several inner cannulas are kept at the patient's bedside. Store the spare devices under clean and dry conditions.
- It is also recommended keeping an emergency spare device at the bedside in case of an unplanned tracheostomy tube change, e.g. due to complications, a collapsed tracheostoma or similar. The emergency spare device should be one or two sizes smaller than the device in use.
- Safety precautions must be taken in case of complications during the described procedures, in order to provide immediate ventilation through alternative airways, (e.g. trans laryngeal intubation, laryngeal mask). This is recommended to be based on the respective applicable guidelines and standards for patients with difficult airways, e.g. Practice Guidelines for Management of the Difficult Airway (American Society of Anesthesiologists, 2013).

### 8.1 Preparing the Tube

This is a sterile device, which allows usage within a sterile environment.

The size of the tube and appropriate length is determined by a physician.

The following functions must be checked immediately prior to use: functionality of the cuff, completeness of the device. If the device fails the initial inspection, repeat the procedure with a new device. Do not discard the device and follow instructions provided in section "Returns and Complaints".

### A. When using the Minimally Traumatic Insertion System

1. Inspect the sterile packaging to ensure it is undamaged and all components are present.
2. Open the package and visually inspect the device for damages.
3. Check if the tube is free of obstruction, the material is not brittle or torn, the cuff is intact, the inflating or suction lines are not kinked, there are no tears or cuts, the connection between the tube and the neck flange is stable.
4. Check the HVLVP cuff for leakage by inflating with a hand-held manometer, to a pressure of 50 cmH<sub>2</sub>O (≈ 36.78 mmHg). Watch the filled cuff for 1 minute to detect leakage by pressure decrease / cuff deflation. If the cuff is tight, remove the air with a syringe. Do not pull any further, e.g. into a vacuum.
5. Verify that the locking ring of the pre-mounted inner cannula can be opened and re-locked without resistance. To open the locking ring of the inner cannula, turn it counterclockwise. To lock the locking ring of the inner cannula, turn it clockwise. Afterwards, make sure that the locking ring is locked properly, and the inner cannula is secured within the outer cannula. Do not remove the inner cannula from the outer cannula.

### Caution:

- Make sure to not shift the silicone sleeve when checking the locking mechanism of the inner cannula to prevent a gap in diameter between distal tube end and inserter. In case of a shift the connection can be tightened by carefully pulling back the inserter or the guiding catheter.

6. Check if the pre-assembled silicone sleeve smoothly bridges the gap between the conical end of the inserter and the distal end of the tube. If a gap is visible, the connection can be tightened by carefully pulling back the inserter or the guiding catheter.

### Caution:

- **Do not disassemble the pre-assembled tracheostomy tube consisting of insertion system with guiding catheter, tracheostomy tube, and inner cannula.**
- **Do not pull on the tip of the guiding catheter or silicone sleeve. Ensure to take hold of the complete insertion system (inserter, guiding catheter).**
- 7. The silicone sleeve and the end of the tracheostomy tube are then lubricated with a pea-sized amount of the lubricating jelly supplied.
- 8. If appropriate, the neck strap can be attached to the neck flange wings for fixation after insertion of the tube. If a neck strap is to be used, it should be placed below the patient's neck prior to the procedure.

### B. When using the obturator for re-insertion

Follow steps 1-5 as described above and proceed as follows:

6. Ensure the obturator inside the tracheostomy tube can be easily moved in and out of the tube.
7. Place the obturator inside the tracheostomy tube.
8. Apply a thin film of lubricating jelly to the protruding part of the obturator at the lower part of the tube including the cuff.
9. If appropriate, the neck strap can be attached to the neck flange wings for fixation after insertion of the tube. If a neck strap is to be used, it should be placed below the patient's neck prior to the procedure.

## 8.2 Preparing the Patient

Ensure that the patient is optimally pre-oxygenated immediately before insertion or re-insertion. To facilitate insertion, place the patient in a flat supine position with overextended neck, if possible.

### 8.3 Inserting the Tube

#### A. When using the Minimally Traumatic Insertion System

The minimally traumatic insertion system is intended for use with the Seldinger technique.

1. The tracheotomized patient has been prepared for cannulation and a Seldinger wire (included in Tracoe expere Sets, not included in P tubes) has been inserted into the stoma canal.
2. Place the tracheostomy tube with insertion system (inserter, guiding catheter) over the Seldinger wire in situ (see Image 5). If using the Tracoe Seldinger wire make sure to stop when the marking on the wire is visible outside of the tube at the end of the guiding catheter outside of the patient.
3. Insert the tube together with the inserter and guiding catheter along the Seldinger wire through the tracheostoma into the trachea. Take care that the tube, inserter handle, guiding catheter, and Seldinger wire remain aligned and fixed with one hand. Any displacement may result in a gap between the silicone sleeve and the tube leading to a difficult or aborted insertion.
4. Gently push the tube forward until the neck flange is in contact with the skin surface.

5. Once in place, secure the tube with one hand and withdraw the inserter and guiding catheter together with the Seldinger wire while the tracheostomy tube remains in position within the trachea (see Image 6).

If the inserter is too difficult to be removed, it can also be removed together with the inner cannula. Therefore, loosen the inner cannula by turning the locking ring counterclockwise. If the inner cannula is removed when removing the inserter, make sure that an inner cannula is then reinserted and locked into place by turning the locking ring clockwise. This can be either the inner cannula from which the insertion system has been removed or a spare inner cannula.

#### Caution:

- **Do not pull on the guiding catheter separately while the inserter is still inside the tracheostomy tube.** Pull out the inserter always together with the guiding catheter and Seldinger wire or remove the inserter first before pulling on the guiding catheter leaving the tracheostomy tube in place within the trachea.
- After removing the inserter, ensure that the silicone sleeve is still located on the guiding catheter. If the silicone sleeve detaches from the guiding catheter, proceed as follows:
  - o Immediate inspection of the lumen of the tracheostomy tube. If the sleeve remains in the tube, the inner cannula must be replaced with the spare device immediately.
  - o If the silicone sleeve is not visually detectable, it is recommended taking a chest X-ray with the precise localization immediately. Since the silicone sleeve is radiopaque, the X-ray serves as preparation for bronchoscopic removal.

#### B. With the Obturator

The obturator is perforated and can be used in combination with a Seldinger wire.

1. Prepare the tube and the patient as described in chapter "Preparing the Tube" and "Preparing the Patient".
2. When inserting the tube (with the obturator inside) into the tracheostoma, hold the tube at the neck flange and press the obturator firmly against the 15 mm connector.
3. Gently push the tube forward until the neck flange is in contact with the skin surface.
4. Secure the tube with one hand and remove immediately the obturator after insertion.

#### 8.4 Following Tube Insertion

1. Check if the airway through the tube is unobstructed and if necessary, adjust the position of the tracheostomy tube (e.g. using a bronchoscope).
2. Connect the 15 mm connector of the inner cannula with the respiratory system if ventilation is required.
3. If appropriate: Inflate the cuff of the tracheostomy tube with air through the Luer connector located at the pilot balloon.
4. To prevent tube dislocation, secure the tube in place with the neck strap.
5. It is recommended that a dressing is placed between the tracheostoma and the neck flange to prevent irritation of the skin underneath the flange.
6. Re-check the cuff pressure to make sure that the cuff has not been damaged during the insertion.

#### 8.5 Inflating the Cuff

**Option 1:** In place of a standard syringe for inflating the cuff, we recommend the use of a hand-held manometer. Adjust the cuff pressure to the individual ventilation therapy and check it at regular intervals. Typically, the pressure should be between 20 cmH<sub>2</sub>O (≈ 15 mmHg) and 30 cmH<sub>2</sub>O (≈ 22 mmHg).

**Option 2:** Use a Tracoe Smart Cuff Manager to maintain the cuff pressure within the range of 20 to 30 cmH<sub>2</sub>O through passive control. Attach the male Luer of the Tracoe Smart Cuff Manager to the female Luer of the check valve of the tracheostomy tube. Inflate the Tracoe Smart Cuff Manager using a standard syringe according to the respective IFU.

#### Caution:

- When repositioning the patient, while in bed, ensure that the patient does not lie on the pilot balloon, as this could increase the cuff pressure and potentially damage the trachea.

#### 8.6 Connecting/Disconnecting External Equipment

To connect to external equipment or accessories (e.g. ventilator) firmly hold the base of the 15 mm connector and gently push the connection end of the external device until it is securely attached to the tracheostomy tube. If in doubt, twist the connection end on and off several times, in order to confirm the amount of force needed to ensure the connection is secure and the external device can be easily disconnected at a later time.

If disconnection is difficult, use a standardized disconnect wedge (not supplied) to uncouple the tracheostomy tube from external equipment or accessories by sliding the opening of the disconnect wedge between the 15 mm connector and external device until the two devices are separated, see chapter "Supplementary Products".

#### Caution:

- Do not use unnecessary force on the tracheostomy tube when connecting to or disconnecting from external devices. This may result in damage of the tracheostomy tube and/or displacement/decannulation.

#### 8.7 Subglottic Suction

1. To perform intermittent suctioning, remove the cap of the subglottic suction line Luer connector.
- 2a. Manual suctioning can be carried out using a syringe.
- 2b. An active suction device can be connected using the adaptors (see Image 2).
3. Following subglottic suctioning, reseal the suction line Luer connector with the cap.

#### Caution:

- If the suction channel is obstructed, it can be cleared by inflation of air/ oxygen (recommended 3-6 l/min; max. 12l/min) or it can be rinsed with saline solution (recommended 2-3 ml). Do not exceed the recommended limits and take care of the patient's individual tolerability. The following side-effects could occur: Accumulation of potentially contaminated secretions, discomfort, nausea and retching, excessive secretions.
- Before rinsing the suction channel, make sure that the cuff is sufficiently inflated.
- Remove the applied saline immediately after rinsing the suction channel.
- If the suction channel does not get cleared, the tube must be changed.

#### 8.8 Above Cuff Vocalisation

##### Caution:

- ACV must be performed by professional personnel.

ACV is used to provide phonation capabilities for the patient. Therefore, it must be adjusted to the individual patient's needs and abilities. It is essential that the patient is instructed and involved in every step of ACV to ensure cooperation and good results during the application. Before using ACV ensure that the patient is wearing a tracheostomy tube with permanently inflated cuff and does not tolerate cuff deflation. If needed, air can be humidified before inflation through the subglottic suction line which may prevent the laryngeal mucosa from drying out.

1. Explain the planned procedure to the patient. Indicate possible adverse reactions and clarify patient's questions.
2. Verify that the upper airways are not obstructed.
3. Clear the subglottic space from secretions using subglottic suctioning.
4. Verify that the suction channel is not obstructed.
5. Connect the adjustable air or oxygen supply via a fingertip connector to the female Luer connector of the subglottic suction line. Alternatively, other devices for interruption of the permanent airflow may be used (e.g. Y-connector).
6. Inflate air slowly into the upper airways of the patient starting with 1 l/min and slowly rising to a typical flow rate of 3-6 l/min depending on the patients' requirements. To may reduce laryngeal mucosa from drying out, flow rates must not exceed 12 l/min. Use the fingertip connector to limit the air flow time. This timeframe should be adapted to the patient's exhaling rhythm. Adjust airflow and time within the comfort zone of the patient.
7. Monitor the patient's reaction and adjust parameters (flow and time of airflow) as necessary.
8. When the session is finished, turn off the air flow and disconnect the equipment from the subglottic suction line connector and replace the cap.

#### Caution:

- The airflow through the upper airways may irritate the patient or may lead to increased secretion, coughing, nausea, or retching.
- If the voice sounds gruff, repeat subglottic suction to clear the airway.
- Adjust the duration of a single ACV session to the capabilities/endurance of the patient.
- Use short sessions of ACV to prevent drying of the laryngeal mucosa.
- Regularly monitor patients with tracheostoma by medically trained staff.

#### 8.9 Deflating the Cuff

Before deflating the cuff, ensure that as little secretions as possible enter the lower respiratory tract, e.g. by subglottic suctioning and/or suctioning through the tube. To deflate the cuff, attach a syringe (with the plunger pushed in) to the female Luer connector of the pilot check valve. Pull the plunger back until air is removed from the cuff. Do not pull any further, e.g. into a vacuum. The cuff must be deflated (empty) prior to removal of the tracheostomy tube.

#### Caution:

- When removing the air from the cuff, pay attention to the volume of the air removed. This serves as a reference for the integrity of the system for further cuff inflation.

#### 8.10 Changing the Inner Cannula

If viscous secretion collects in the inner cannula and cannot be suctioned, thus impeding the airflow, replace the inner cannula with a new or cleaned inner cannula.

1. Loosen the inner cannula by turning the locking ring counterclockwise and remove it.
2. If the product is damaged, do not further use the inner cannula, do not discard the inner cannula and follow instructions in chapter "Returns and Complaints".
3. Once a new inner cannula has been inserted into the outer cannula, lock in place by turning the locking ring clockwise until it clicks into place.

#### Caution:

- When inserting the inner cannula, ensure that the inflation line of the cuff is not lying between the inner and outer cannulas, otherwise it may get trapped and damaged.

#### 8.11 Removing the Tube

In case of a tube change, prepare the replacement tube as described in chapter "Preparing the Tube". Before removing the tube, prepare the patient as described in chapter "Preparing the Patient".

1. Deflate the cuff (see chapter "Deflating the Cuff").
2. Secure the neck flange, while loosening the neck strap.
3. Firmly hold the neck flange and gently pull the tracheostomy tube from the stoma. If necessary, suctioning of secretions through the tube may be helpful to prevent infiltration into the lower respiratory tract.
4. Following removal, the tube should be cleaned as soon as possible to prevent encrustation of fluids.
5. If the product is damaged, do not further use the tube, do not discard the tube and follow instructions in chapter "Returns and Complaints". In case of a tube change, follow the instructions described in chapters "Inserting the Tube", "Following Tube Insertion", "Inflating the Cuff" and "Connecting/Disconnecting External Equipment" after removing the tube.

#### 9. Care and Cleaning

##### Caution:

- The device should not be used for more than 29 days beginning from the initial opening of the sterile barrier.
- The minimally traumatic inserter and guiding catheter are single-use and not allowed to be cleaned and reused.
- This maximum period of use includes both patient and non-patient (e. g. cleaning) use of the device.
- For reasons of hygiene and to avoid a mix-up when reassembling the tube afterwards only one outer cannula together with the corresponding inner cannula must be cleaned together.
- The product should be inspected for integrity and function prior to re-insertion

Cleaning of the tracheostomy tube and obturator is intended to remove any bodily fluids or encrustation that may inhibit its clinical use.

Please take care to hold the outer cannula after cleaning at its neck flange, the inner cannula at the 15 mm connector and the obturator at its handle.

The following instruction for manual cleaning applies to all Tracoe Twist Plus models and sizes:

1. Loosen the inner cannula from the outer cannula
2. To clean the tube (outer and inner cannula) and obturator, rinse the devices separately under lukewarm (max. 40 °C/104 °F) potable water until they are visibly clean and free of encrustations.
3. Particular attention should be taken to ensure the inside of the tube and as appropriate, the subglottic suction are thoroughly rinsed.
4. For removal of residual debris brushes or swabs offered by Tracoe can be used, see "Supplementary Products".
5. Alternatively, the Tracoe cleaning products (see "Supplementary Products") can be used in accordance with their respective instructions for use.
6. After cleaning, rinse the tube with potable or distilled water.
7. If the tube is not visually clean after rinsing then:
  - repeat rinsing until it is visibly clean, or
  - repeat the cleaning using the Tracoe cleaning products, or
  - safely dispose of the tracheostomy tube.

8. All areas of the tube and obturator should be inspected, in adequate light, to ensure the device is free of contaminants and encrustations.

9. Following the cleaning process, place the tube and obturator on a clean lint-free dry towel and air dry in an area free of airborne contaminants.

10. The outer cannula, the inner cannula and the obturator are considered dry when there is no visual evidence of residual water. Please check, that the inner of the cuff is dry.

11. Finally, a visual and functional inspection prior to re-insertion should be performed to verify that the tube and obturator are not damaged (also see chapter "Preparing the Tube").

#### Caution:

- The tracheostomy tube (outer and inner cannulas) and obturator should be cleaned immediately after removal from the stoma to prevent drying of soil and contaminants.
- When cleaning, take care not to damage the cuff or the inflating line.
- When immersing a cuffed tube in a cleaning reagent solution, it is recommended to not submerge the pilot balloon in the solution.
- The frequency of cleaning must be defined by the physician but must not exceed the allowed frequency.
- It is recommended to clean the tracheostomy tube on a daily basis. Maximum allowed cleaning cycles within 29 days are 29 for the outer cannula and 35 for the inner cannula, otherwise biocompatibility and material stability could be impaired.
- The tubes must never be cleaned using agents or procedures which are not specified in this instruction.
- The tracheostomy tube is single patient use. Therefore, it must be returned to the same patient.
- Failure to clean the device properly can result in damage to the tube, an increase in air resistance due to obstructions, or irritation/inflammation of the tracheal stoma.
- Since the upper respiratory tract is never free from microorganisms, even in healthy individuals, we do not recommend the use of disinfectants.

#### 10. Storage

a) Store the Tracoe products in their original packaging according to the conditions displayed on the packaging. Do not heat the products to a temperature above 60°C.

b) Store cleaned tracheostomy tubes in a clean covered container, within a clean and dry location, and away from sunlight. Re-insert the tracheostomy tube as soon as possible. Improper storage conditions may result in tube damage or contamination. Do not store the cleaned devices for more than 29 days from first use.

#### 11. Packaging

The product is provided sterile (with ethylene oxide) which allows application under sterile conditions. Tracoe tracheostomy tubes do not require a sterile environment during normal use or cleaning.

#### 12. Disposal

Used products are to be disposed of in accordance with national regulations, waste management plans, or clinical procedures governing biohazardous waste materials, e.g. the direct disposal in a tear and moisture-resistant and secure bag or container, which is routed to the local waste disposal system for contaminated medical products.

For further recommendations, contact your hygiene officer in health facilities, or the local waste management for homecare use.

#### 13. Returns and Complaints

If you have a complaint about the device, please contact [complaint.se@atosmedical.com](mailto:complaint.se@atosmedical.com).

If it is involved in a reportable incident, as defined in local medical device legislation, additionally contact the appropriate regulatory body in the country of use.

#### 14. Supplementary Products

Tracoe Twist Plus Tracheostomy Tubes with Minimally Traumatic Insertion System are also available as Tracoe Experc Set in combination with Tracoe Experc Dilation Set.

The Tracoe Seldinger Guide Wire is part of the above-mentioned sets. It is also available separately with or without guiding catheter.

#### 14.1 Recommended Products:

- Tracoe Twist Plus Spare inner cannulas
- Syringes with standard male Luer connector
- Cuff pressure monitors for HVLV cuffs with standard male Luer connector
- Tracoe Smart Cuff Manager
- Sterile water-soluble lubricating jellies for tracheostomy applications
- Neck straps
- Disconnecting wedges for tracheostomy / endotracheal tubes with 15 mm connectors
- Humid Moist Exchangers (HME) with a standard male 15 mm connector

#### 14.2 Optional Products:

- Speaking valves and occlusion caps with a standard male 15 mm connector
- Cleaning agents offered by Tracoe
- Cleaning accessories (e.g. swabs, brushes, tub) offered by Tracoe
- Tracoe Shower Guard
- Dressings and compresses
- Protective textiles (e.g. bibs, scarves, roll-necks)

#### 15. General Terms and Conditions

The sale, delivery and return of all Tracoe products shall be affected exclusively on the basis of the valid General Terms and Conditions (GTC), which are available either from Tracoe Medical GmbH or on our website at [www.tracoe.com](http://www.tracoe.com).

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#### Uputstvo za upotrebu Cevčice za traheostomiju Tracoe Twist Plus sa minimalno traumatičnim sistemom za umetanje

Upotreba funkcije Above Cuff Vocalization (ACV) je odobrena samo CE oznakom.

#### NAPOMENA:

- Pažljivo pročitajte uputstvo za upotrebu. Ono predstavlja sastavni deo opisanog proizvoda i mora da bude dostupno u svakom trenutku. Radi vaše i bezbednosti pacijenta, poštujujte sledeće bezbednosne informacije.

Ilustracija na koje se odnosi tekst nalaze se na ilustrovanim stranicama na početku ovog uputstva. Brojevi označavaju komponente proizvoda i odnose se na odgovarajuće ilustracije proizvoda. Simboli i ikone koji se koriste sa proizvodom objašnjeni su u odeljcima „Opšti opis“ i „Funkcionalni opis“.

#### 1. Predviđena upotreba i indikacije za upotrebu

Cevčice za traheostomiju Tracoe Twist Plus su namenjene za obezbeđivanje pristupa preko dušnika radi regulacije disajnog puta. Mogu da se koriste najduže 29 dana.

**Klinička korist:** Tracoe Twist Plus cevčice za traheostomiju obezbeđuju pristup donjem respiratornom traktu preko dušnika. Modeli sa manžetnama, kada su one naduvane, mogu da se koriste za zatvaranje disajnog puta (npr. za mehaničku ventilaciju). Tracoe Twist Plus cevčice su cevčice sa dvostrukim lumenom. Unutrašnja kanila može da se ukloni ili zameni npr. radi čišćenja od sekreta ili začepljenja, dok spoljna kanila ostaje na mestu. Stoga prohodnost disajnog puta može da se povrti zamenom unutrašnje kanile. Cevčice sa kanalom za subglotičku aspiraciju omogućavaju uklanjanje sekreta koji se zadržava iznad naduvane manžete. Fenestrirani modeli omogućavaju da se deo protoka vazduha usmeri ka gornjem respiratornom traktu. Ako terapija ne zahteva ili ne dozvoljava (npr. mehanička ventilacija) upotrebu fenestrirane cevčice za traheostomiju, fenestracija može da se zatvori umetanjem nefenestrirane unutrašnje kanile. Konektor od 15 mm je standardizovana komponenta na koju mogu da se povežu druga sredstva za održavanje disajnog puta (npr. mehanički ventilator, uređaj za potpomognuto kašljanje, nebulizator i slično).

U poređenju sa upotrebom endotrahealne cevčice, kada se koristi cevčica za traheostomiju anatomske mrtvi prostor je smanjen i postoji manja potreba za sedacijom. Rizik od dugoročnih komplikacija povezanih sa produženom endotrahealnom intubacijom (npr. povrede glasnica, formiranje granulacionog tkiva u oblasti grkljana itd.) može se sprečiti upotrebom cevčice za traheostomiju.

**Populacija pacijenata:** Proizvod je namenjen odraslima i adolescentima (≥12–21 godina).

**Klinička upotreba:** Proizvod je namenjen pacijentima na mehaničkoj ventilaciji i pacijentima koji samostalno dišu u bolnicama, vanbolničkoj hitnoj medicinskoj službi (EMS), ustanovama za produženu negu, ambulancama ili na kućnoj nezi.

**Predviđeni korisnik:** Proizvod može da koristi medicinsko osoblje obučeno za negu traheostome ili pojedinci obučeni od strane stručnjaka.

**Indikacije za upotrebu:** Cevčica za traheostomiju je indikovana za pacijente kod kojih je potreban pristup donjem respiratornom traktu putem traheostomije kako bi se osigurao disajni put. Tracoe Twist Plus cevčice za traheostomiju su cevčice sa dvostrukim lumenom. Unutrašnja kanila može da se ukloni i zameni u slučaju stvaranja kraste ili opstrukcije usled naslaga viskozno sekreta.

Cevčica za traheostomiju sa manžetnom velike zapremine i niskog pritiska (HVLV) zaptiva traheju kako bi se gornji disajni putevi odvojili od donjeg respiratornog trakta. Ona stoga omogućava efikasnu ventilaciju i smanjuje dotok subglotičkog sekreta u pluća.

Minimalno traumatični sistem za umetanje indikovano je isključivo za jednokratnu upotrebu i namenjen je za umetanje cevčice za traheostomiju Tracoe Twist Plus primenom tehnike po Seldingeru. Može se koristiti za prvo umetanje cevčice za traheostomiju nakon perkutane dilatativne traheostomije ili kada se cevčica promeni.

Tracoe Twist Plus Extract cevčice za traheostomiju sa kanalom za subglotičku aspiraciju i manžetnom (REF 316-P i REF 888-316-P) se prevashodno koriste za pacijente sa velikim količinama sekreta i one za koje je indikovana aspiracija subglotičkog prostora.

The Tracoe Twist Plus Extract cevčice za traheostomiju mogu da se koriste za vokalizaciju iznad manžete (ACV).

Dupla fenestracija na Tracoe Twist Plus modelima (REF 312-P, REF 888-316-P) omogućava da se deo protoka vazduha usmeri ka gornjem respiratornom traktu.

**Upotreba na jednom pacijentu i rok trajanja:** Tracoe Twist Plus cevčica za traheostomiju je za upotrebu na jednom pacijentu sa radnim vekom od 29 dana. Tokom ovog perioda medicinsko sredstvo može da se očisti i ponovo implantira u istog pacijenta.

Medicinsko sredstvo ne sme da se koristi duže od 29 dana od inicijalnog otvaranja sterilne barijere. Ovaj maksimalni period upotrebe uključuje i upotrebu sredstva na pacijentu i njegovu upotrebu van tela pacijenta (npr. čišćenje).

#### Oprez:

Produžena upotreba cevčice za traheostomiju duže od 29 dana može da dovede do problema sa bezbednošću materijala i biokompatibilnošću.

#### 2. Opšti opis

Tracoe Twist Plus cevčica za traheostomiju je napravljena od poliuretana i obezbeđuje veštački disajni put do donjeg respiratornog trakta.

Proizvod uključuje spoljnu kanilu sa 2 ili 3 unutrašnje kanile sa konektorom od 15 mm, minimalno traumatični sistem za umetanje (umetač, kateter za navođenje sa rukavcem od silikona), opturator, platnenu traku za pričvršćivanje oko vrata i gel za podmazivanje, koji se isporučuju zajedno u sterilnoj kesici. Adapteri za upotrebu sa spoljnim uređajima za aspiraciju isporučuju se samo sa modelima za subglotičku aspiraciju (REF 316-P, REF 888-316-P). Fenestrirani modeli (REF 312-P, REF 888-316-P) imaju i zapornu kapicu.

Tracoe Twist Plus cevčice za traheostomiju dostupne su u različitim prečnicima i dužinama. Cevčice za traheostomiju iz minimalno traumatičnog sistema za umetanje su modeli sa manžetnom koji se isporučuju sa izduvanom manžetnom. Odgovarajući prečnik i dužinu cevčice određuje lekar.

Cevčica za traheostomiju je radionepropusna zbog materijala od kog je napravljena.

Klinička upotreba sredstva u MR okruženju zavisi od specifikacija proizvoda i opisana je u poglavlju „Bezbednosne informacije o MR“.

Cevčica za traheostomiju može da se koristi u kombinaciji sa medicinskim sredstvima koja su odobrena za invazivnu ventilaciju kroz traheostomu i povezana preko standardnog konektora od 15 mm. Cevčice za traheostomiju sa kanalom za subglotičku aspiraciju mogu da se koriste sa medicinskim sredstvima odobrenim za subglotičku aspiraciju.

Ovaj proizvod se isporučuje sa karticom sa informacijama, uključujući dve odvojive nalepnice, koje sadrže pojednosti specifične za proizvod. Ove nalepnice će olakšati ponovno naručivanje sredstva i njegovu bezbednu upotrebu u MR okruženju. Nalepnice mogu da se zalepe na zdravstveni karton pacijenta.









### 13. Povraćaji i reklamacije

Ako imate reklamaciju na sredstvo, obratite se na adresu [complaint.se@atosmedical.com](mailto:complaint.se@atosmedical.com). Ukoliko je došlo do incidenta koji se mora prijaviti, kao što definišu propisi za medicinska sredstva, možete se obratiti nadležnom regulatornom telu u zemlji korišćenja.

### 14. Dopunski proizvodi

Cevčice za traheostomiju Tracoe Twist Plus sa minimalno traumatičnim sistemom za umetanje dostupne su i kao Tracoe Experc Set u kombinaciji sa Tracoe Experc Dilation Set.

Tracoe Seldinger žica vodilica je deo gore navedenih kompleta. Takođe je dostupna zasebno sa kateterom za navođenje ili bez njega.

#### 14.1 Preporučeni proizvodi:

- Tracoe Twist Plus rezervne unutrašnje kanile
- Špricevi sa standardnim muškim Luer konektorom
- Merači pritiska za HVLP manžetne sa standardnim muškim Luer konektorom
- Tracoe Smart Cuff Manager
- Sterilni gelovi za podmazivanje rastvorljivi u vodi za primene u traheostomiji
- Trake za pričvršćivanje oko vrata
- Klinovi za razdvajanje cevčica za traheostomiju / endotrahealnih cevčica i konektora od 15 mm
- Izmenjivači toplote i vlage (HME) sa standardnim muškim konektorom od 15 mm





























#### 14.2 Opcioni proizvodi:

- Valvule za govor i zaporne kapice sa standardnim muškim konektorom od 15 mm
- Sredstva za čišćenje koja nudi kompanija Tracoe
- Dodatna oprema za čišćenje (npr. štapići, četke, kada) koji nudi kompanija Tracoe
- Zaštita za tuširanje kompanije Tracoe
- Zavoji i komprese
- Zaštitni tekstil (npr. podbradnici, šalovi, okovratnici)

### 15. Opšti uslovi i odredbe

Prodaja, isporuka i povraćaj svih Tracoe proizvoda regulisani su isključivo važećim Opštim uslovima i odredbama (OUO), koji su dostupni kod kompanije Tracoe Medical GmbH ili na našoj veb-lokaciji na adresi [www.tracoe.com](http://www.tracoe.com).

### Symbols

	Manufacturer; Proizvođač
	Country of manufacture with date of manufacture; Zemlja proizvodnje sa datumom proizvodnje
	Use-by date; Rok upotrebe
	Batch Code; Šifra serije
	Medical Device; Медицинско средство
	Instructions for use; Uputstvo za upotrebu
	Caution, consult instructions for use; Oprez, konsultovati uputstvo za upotrebu
	Federal (USA) law restricts this device to the sale by or on the order of a physician
	Single Patient - multiple use; Један пацијент – вишеструка употреба
	Sterilized using ethylene oxide; Sterilisano etilen-oksikom
	Do not resterilize; Ne sterilisati ponovo
	Do not use if package is damaged; Ne koristiti ako je pakovanje oštećeno
	Peel here; Odlepi ovde
	Keep away from sunlight and keep dry; Držati dalje od sunčeve svetlosti i čuvati na suvom
	Storage temperature limit; Ograničenje temperature skladištenja
	Single sterile barrier system; Sistem jedne sterilne barijere
	Single sterile barrier system with protective packaging outside; Sistem jedne sterilne barijere sa zaštitnom spoljašnjom ambalažom
	Not made with phthalates (e.g. DEHP); Ne sadrži ftalate (npr. DEHP)
	Not made with Natural Rubber latex; Ne sadrži prirodni gumeni lateks
	Packaging Content; Sadržaj pakovanja
	MR conditional; Uslovno bezbedno za korišćenje u MR okruženju
	Triman symbol and Infotri for France; Simboli Triman i Infotri za Francusku
	Packaging is recyclable; Pakovanje može da se reciklira
	Recycling guidelines; Smernice za reciklažu
	Fenestration; Fenestracija
	Low-pressure cuff; Manžetna sa malim pritiskom
	Suction line; Crevo za aspiraciju
	Minimally-traumatic inserter; Minimalno traumatični umetač