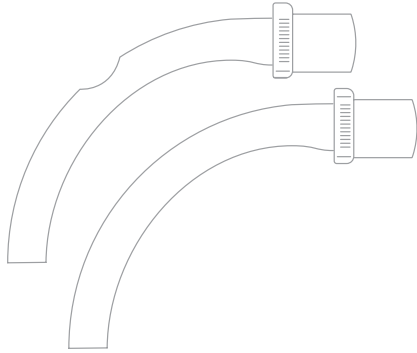


TRACOE Twist Plus



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EN - ENGLISH

Instructions for Use for

Tracoe Twist Plus Spare Inner Cannulas

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

Tracoe Twist Plus spare inner cannulas must only be used in combination with the corresponding Tracoe Twist Plus tracheostomy tubes. Please read the corresponding instructions for use carefully. They are part of the described product and must be available at all times.

1. Intended Use & Indications for Use

Tracoe Twist Plus spare inner cannulas are indicated for use only in combination with Tracoe Twist Plus tracheostomy tube. They may be used up to 29 days.

The product is intended to be used only in combination with Tracoe Twist Plus outer cannulas of the corresponding size. For the application refer to the instructions for use for the Tracoe Twist Plus tracheostomy tubes.

For information on Clinical Benefit, Patient Population, Clinical Use, Intended User and Indications for Use please refer to the instructions for use of the respective Tracoe Twist Plus tracheostomy tube.

Single Patient Use and Useful Life: The Tracoe Twist Plus inner cannula 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.

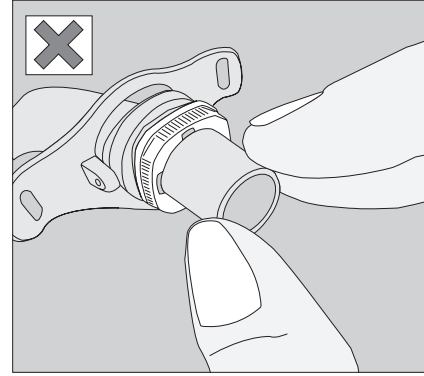
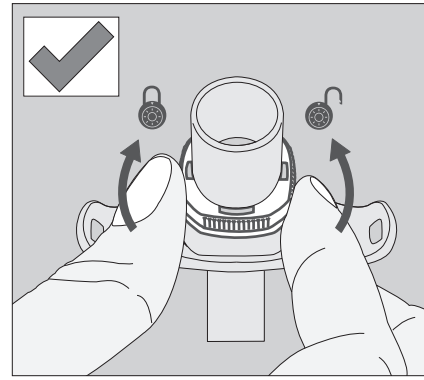
Caution:

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

2. General Description

The Tracoe Twist Plus spare inner cannulas are made of polypropylene. The standardized 15 mm connector is permanently attached to the proximal end of the inner cannulas.

Image 1/ 1. attēls.



The non-fenestrated models have a white locking ring and are available in packs of 3 (REF 521), 10 (REF 521-X) or 30 (REF 521-XXX) units.

The fenestrated models have a blue locking ring and are available in packs of 3 (REF 523) or 10 (REF 523-X) units.

The inner cannulas are radiopaque due to material specifications and are categorized as MR Safe.

Supplementary Products:

• Products, which can be used in combination with the Twist Plus tracheostomy tubes are listed in section "Supplementary Products" of the IFU for the respective tracheostomy tube.

3. MRI Safety Information

MR All Tracoe inner cannulas are classified as "MR Safe"

Caution: Before using the Tracoe Twist Plus inner cannula in MRI, check the MR capability of the respective Tracoe Twist Plus tracheostomy tube.

4. Contraindications

For the application refer to the instructions for use for the Tracoe Twist Plus tracheostomy tubes.

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).
- 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. 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.
- 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.
- 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.
- Improper storage conditions may result in product or sterile barrier damage.

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.
- 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.
- 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.

7. Side Effects

For typical side effects of tracheostomy tubes, ACV and cuff deflation trials refer to the instructions for use of the Tracoe Twist Plus tracheostomy tubes.

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 Inner Cannula

This is a sterile device, which enables use within a sterile environment.

The following functions must be checked immediately prior to use: 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".

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 prior to use.
3. Verify that the inner cannula is free of obstruction and the material is not brittle or torn.

8.2 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 (see Image 1).

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.

9. Care and Cleaning

Caution:

- The inner cannula should not be used 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.
- 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 inner cannula is intended to remove any bodily fluids or encrustation that may inhibit its clinical use.

Please take care to hold the inner cannula after cleaning at the 15 mm connector.

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

1. To clean the inner cannula, rinse the devices under lukewarm (max. 40 °C/104 °F) potable water until it is visibly clean and free of encrustations.
2. Particular attention should be taken to ensure the inside of the cannula is thoroughly rinsed.
3. For removal of residual debris brushes or swabs offered by Tracoe can be used, see "Supplementary Products".
4. Alternatively, the Tracoe cleaning products (see "Supplementary Products") can be used in accordance with their respective instructions for use.
5. After cleaning, rinse the inner cannula with potable or distilled water.
6. If the inner cannula 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 inner cannula.
7. All areas of the inner cannula should be inspected, in adequate light, to ensure the device is free of contaminants and encrustations.
8. Following the cleaning process, place the inner cannula on a clean lint-free dry towel and air dry in an area free of airborne contaminants.
9. The inner cannula is considered dry when there is no visual evidence of residual water.
10. Finally, a visual and functional inspection prior to re-insertion should be performed to verify that the inner cannula is not damaged (also see chapter "Preparing the Inner Cannula").

Caution:

- The inner cannula should be cleaned immediately after removal from the stoma to prevent drying of soil and contaminants.
- The frequency of cleaning must be defined by the physician but must not exceed the allowed frequency.
- A maximum of 35 cleaning cycles are possible within the period of use of 29 days for the inner cannula, otherwise biocompatibility and material stability could be impaired. For information on cleaning frequency of the outer cannula, please refer to the instructions for use of the Tracoe Twist Plus tracheostomy tubes.
- The inner cannula must never be cleaned using agents or procedures which are not specified in this instruction.
- The inner cannula 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 cannula, 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 inner cannulas in a clean covered container, within a clean and dry location, and away from sunlight. Re-insert the inner cannula as soon as possible. Improper storage conditions

may result in cannula 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 Twist Plus spare inner cannulas 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.

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. 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.

LV — LATVIEŠU VALODĀ

Lietošanas instrukcija

Tracoe Twist Plus rezerves iekšējās kanulas

Piezīme. Lūdzu, uzmanīgi izlasiet lietošanas instrukciju. Tā ir uzskatāma par aprakstītā izstrādājuma daļu, un tai vienmēr jābūt pieejamai. Lai gādātu par savu un pacientu drošību, ievērojiet tālāk sniegto drošības informāciju.

Tracoe Twist Plus rezerves iekšējās kanulas drīkst izmantot tikai kopā ar atbilstošajām Tracoe Twist Plus traheostomijas caurulītēm. Uzmanīgi izlasiet attiecīgo lietošanas instrukciju. Tā ir uzskatāma par aprakstītā izstrādājuma daļu, un tai vienmēr jābūt pieejamai.

1. Paredzētais lietojums un lietošanas indikācijas

Tracoe Twist Plus rezerves iekšējās kanulas ir paredzētas lietošanai tikai kopā ar Tracoe Twist Plus traheostomijas caurulīti. Tās var lietot līdz 29 dienām.

Izstrādājums ir paredzēts lietošanai tikai kopā ar atbilstoša izmēra Tracoe Twist Plus ārējām kanulām. Informāciju par lietošanu skatiet Tracoe Twist Plus traheostomijas caurulīšu lietošanas instrukcijā. Informāciju par klīniskajiem ieguvumiem, mērķa pacientiem, klīnisko lietojumu, paredzēto lietojumu un lietošanas indikācijām skatiet attiecīgās Tracoe Twist Plus traheostomijas caurulītes lietošanas instrukcijā.

Lietošana vienam pacientam un lietderīgās lietošanas laiks. Tracoe Twist Plus iekšējā kanula ir paredzēta vienreizējai lietošanai vienam pacientam, un tās lietderīgās lietošanas laiks ir 29 dienas. Šajā laikā ierīci var izīrēt un atkārtoti ievietot tam pašam pacientam.

Ierīci nedrīkst lietot ilgāk par 29 dienām kopš sterilā iepakojuma pirmreizējās atvēršanas. Šis maksimālais lietošanas laiks ietver gan ar pacientu saistītu, gan ar pacientu nesaitītu ierīces lietošanu (piem., tīrīšanu).

Uzmanību!

Iekšējās kanulas ilgstoša lietošana ilgāk par 29 dienām var radīt materiālu drošuma un bioloģiskās saderības problēmas.

2. Vispārīgs apraksts

Tracoe Twist Plus rezerves iekšējās kanulas ir izgatavotas no polipropilēna. Standartizētais 15 mm savienotājs ir pastāvīgi piestiprināts iekšējo kanulu tuvākajam galam.

Modeļiem bez daudzām atverēm ir balts slēdzējgredzens, un tie ir pieejami iepakojumos pa 3 (REF 521), 10 (REF 521-X) vai 30 (REF 521-XXX) vienībām.

Modeļiem ar daudzām atverēm ir zils slēdzējgredzens, un tie ir pieejami iepakojumos pa 3 (REF 523) vai 10 (REF 523-X) vienībām.

Materiāla raksturlielumu dēļ iekšējās kanulas ir rentgenstarojumu neaurlaidīgas un tiek klasificētas kā drošas MR vidē.

Papildu izstrādājumi:

- Izstrādājumi, kurus var izmantot kopā ar Twist Plus traheostomijas caurulītēm, ir uzskaitīti attiecīgās traheostomijas caurulītes lietošanas instrukcijas sadaļā „Papildu izstrādājumi”.

3. MRA drošuma informācija

MR Visas Tracoe iekšējās kanulas ir klasificētas kā „drošas MR vidē”.









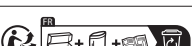


Uzmanību! Pirms Tracoe Twist Plus iekšējās kanulas izmantošanas MRA vidē pārbaudiet attiecīgās Tracoe Twist Plus traheostomijas caurulītes darbību MR vidē.

4. Kontrindikācijas

Informāciju par lietošanu skatiet Tracoe Twist Plus traheostomijas caurulīšu lietošanas instrukcijā.

5. Vispārīgie piesardzības pasākumi

- Ja izstrādājums tiek lietots kopā ar citām medicīniskajām ierīcēm, jāievēro to lietošanas instrukcijas. Ja rodas jautājumi vai ir vajadzīga palīdzība, sazinieties ar ražotāju.
- Ja aprakstīto procedūru laikā rodas komplikācijas, ir jāveic drošības pasākumi, lai varētu nodrošināt tūlītēju ventilāciju, izmantojot alternatīvus elpceļus (piem., laringeālo intubāciju, laringeālo masku). To ieteicams darīt, pamatojoties uz attiecīgajām piemērojamo vadlīnijām un standartiem pacientiem ar apgrūtinātiem elpceļiem, piemēram, dokumentam „Practice Guidelines for Management of the Difficult Airway” (Praktiskās vadlīnijas apgrūtinātu elpceļu kontrolei) (American Society of Anesthesiologists, 2013).

	Keep away from sunlight and keep dry; Sargāt no saules stariem un mitruma
	Storage temperature limit; Uzglabāšanas temperatūras ierobežojums
	Single sterile barrier system; Vienas sterilās barjeras sistēma
	Single sterile barrier system with protective packaging outside; Vienas sterilās barjeras sistēma ar ārējo aizsargiepakojumu
	Not made with phthalates (e.g. DEHP); Izgatavošanā nav izmantoti ftalāti (piem., DEHP)
	Not made with Natural Rubber latex; Izgatavošanā nav izmantots dabiskā kaučuka latekss
	Packaging Content; Iepakojuma saturs
	MR safe; Drošs MR vidē
	Triman symbol and Infotri for France; Triman simbols un Infotri Francijai
	Packaging is recyclable; Iepakojums ir reciklējams
	Recycling guidelines; Reciklēšanas vadlīnijas