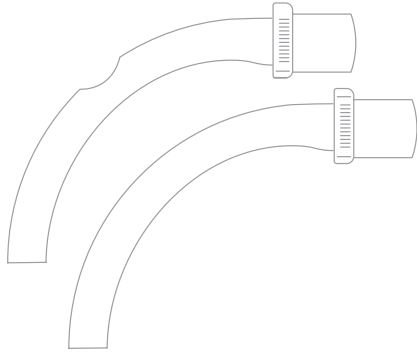


# TRACOE Twist Plus



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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.

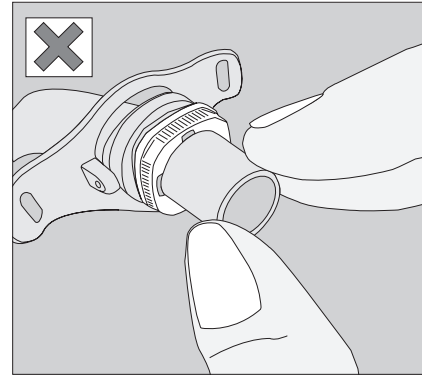
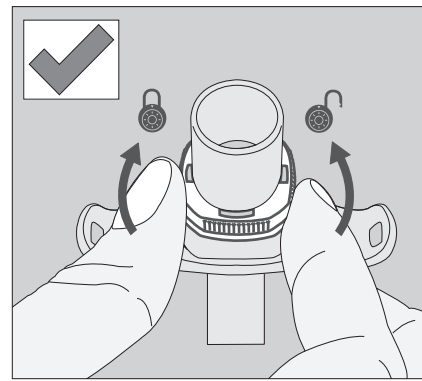
#### Caution:

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



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".

- Inspect the sterile packaging to ensure it is undamaged and all components are present.
- Open the package and visually inspect the device for damages prior to use.
- 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.

- Loosen the inner cannula by turning the locking ring counterclockwise and remove it.
- 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".
- 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:

- 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.
- Particular attention should be taken to ensure the inside of the cannula is thoroughly rinsed.
- For removal of residual debris brushes or swabs offered by Tracoe can be used, see "Supplementary Products".
- Alternatively, the Tracoe cleaning products (see "Supplementary Products") can be used in accordance with their respective instructions for use.
- After cleaning, rinse the inner cannula with potable or distilled water.
- 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.
- All areas of the inner cannula should be inspected, in adequate light, to ensure the device is free of contaminants and encrustations.
- 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.
- The inner cannula is considered dry when there is no visual evidence of residual water.
- 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

- 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.
- 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](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. 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).

## ZHTW - 繁體中文

### 使用說明

#### Tracoe Twist Plus 備用內管

**備註：**請仔細閱讀使用說明。使用說明所描述產品的一部分，必須隨時可取得。為了您自身和患者的安全，請遵守以下安全資訊。

Tracoe Twist Plus 備用內管只能與相應的 Tracoe Twist Plus 氣切套管搭配使用。請仔細閱讀相應的使用說明。使用說明所描述產品的一部分，必須隨時可取得。

#### 1. 預期用途和使用適應症

Tracoe Twist Plus 備用內管僅與 Tracoe Twist Plus 氣切套管搭配使用。最多可使用 29 天。

本產品僅與相應尺寸的 Tracoe Twist Plus 外管搭配使用。有關應用，請參閱 Tracoe Twist Plus 氣切套管的使用說明。有關臨床益處、患者群體、臨床使用、預期使用者和使用適應症的資訊，請參閱各 Tracoe Twist Plus 氣切套管的使用說明。

**單一患者使用和使用壽命：**Tracoe Twist Plus 內管適用於單一患者，使用壽命為 29 天。在此期間，可清潔本裝置並重新插入同一位患者體內。

從最初打開無菌屏障開始，本裝置的使用時間不應超過 29 天。此最長使用期間包括患者和非患者（例如清潔）使用本裝置。

#### 注意：

使用內管超過 29 天可能導致材料安全性和生物相容性問題。

#### 2. 概述

Tracoe Twist Plus 備用內管由聚丙烯製成。標準化的 15 mm 連接器永久地連接到內管的近端。

非開窗式型號具有白色鎖環，並且在有 3 個 (REF 521)、10 個 (REF 521-X) 或 30 個 (REF 521-XXX) 單位的包裝中提供。

開窗式型號帶有藍色鎖環，並且在有 3 個 (REF 523) 或 10 個 (REF 523-X) 單位的包裝中提供。

內管由於材料規格而具有放射線不透性，並被歸類為 MR 安全。

#### 補充產品：

可以與 Twist Plus 氣切套管搭配使用的產品列在使用說明的「補充產品」部分，適用於各個氣切套管。

#### 3. 磁共振 (MRI) 安全資訊

**MR** 所有 Tracoe 內管均被歸類為「MR 安全」

**注意：**在磁共振 (MRI) 影像檢查中使用 Tracoe Twist Plus 內管之前，請檢查各自 Tracoe Twist Plus 氣切套管的磁共振功能。

#### 4. 禁忌症

有關應用，請參閱 Tracoe Twist Plus 氣切套管的使用說明。

#### 5. 一般注意事項

- 產品與其他醫療器械一起使用時，請遵循各自的使用說明。如有任何問題或需要協助，請聯絡製造商。
- 在所述程序中出現併發症時，必須採取安全預防措施，以便透過替代氣道（如經喉插套管、喉罩）提供即時通氣。建議根據困難氣道患者的相應適用指南和標準，例如《困難氣道管理實務指南》(American Society of Anesthesiologists, 2013 年)。
- 強烈建議在患者床邊放置一個可隨時使用的備用套管和幾個內管。將備用裝置存放在乾淨和乾燥的條件下。

- 還建議在床邊放置緊急備用裝置，以防發生意外氣切套管變化，例如由於併發症、氣管造口塌陷或類似原因造成的變化。緊急備用裝置應比使用中的裝置小一到兩號。在使用/插入之前，應檢查產品的完整性和功能。如果產品損壞，應更換為新產品。
- 開啟前應檢查無菌包裝和外包裝是否有損壞。如果包裝損壞或無意中打開，則不應使用本器材。
- 在機械通氣、頻繁調整患者位置或操縱套管過程中，內管可能會與外管分離。因此，定期檢查內管的連接。
- 更換內管時，始終確保氣囊的充盈管線未位於內管和外管之間，因為它可能會被卡住並受損。
- 存放條件不當可能會導致產品或無菌屏障損壞。

## 6. 警告

- 如果無菌包裝或外包裝已被破壞/損壞，例如邊緣裂開、包裝上有孔等，請勿使用本產品。
- 不允許重複處理（包括再消毒），這可能會影響產品的材料和功能。本產品僅供一次性使用。
- 不允許調整 Tracoe 產品。Tracoe 對調整後的產品概不負責。
- 請勿轉動 15 mm 連接器，因為這可能會導致內管在外管內旋轉。這可能會導致供氣中斷或氣切套管脫位。使用鎖環鬆開並重新鎖定內管。
- 切勿使用開窗式內管通氣。
- 定期檢查所有連接是否牢固，以防止套管與外部裝置意外斷開，確保有效通氣。
- 保持 15 mm 連接器清潔乾燥。
- 請勿使用未經授權的工具將外部裝置與 15 mm 連接器斷開，因為這可能會讓 15 mm 連接器變形。

## 7. 副作用

關於氣切套管、ACV 和氣囊放氣試驗的典型副作用請參閱 Tracoe Twist Plus 氣切套管的使用說明。

## 8. 功能描述

### 注意：

- 強烈建議在患者床邊放置一個可隨時使用的備用套管和幾個內管。將備用裝置存放在乾淨和乾燥的條件下。
- 還建議在床邊放置緊急備用裝置，以防發生意外氣切套管變化，例如由於併發症、氣管造口塌陷或類似原因造成的變化。緊急備用裝置應比使用中的裝置小一到兩號。
- 在所述程序中出現併發症時，必須採取安全預防措施，以便透過替代氣道（如喉嚨插管、喉罩）提供即時通氣。建議根據困難氣道患者的相應適用指南和標準，例如《困難氣道管理實務指南》（American Society of Anesthesiologists，2013 年）。

### 8.1 準備內管

這是一種無菌裝置，可以在無菌環境中使用。使用前必須立即檢查以下功能：器材的完整性。如果裝置未能通過初步檢查，請使用新裝置重複此程序。請勿丟棄裝置，並按照「退貨和投訴」一節中的說明操作。

1. 檢查無菌包裝，確保其完好無損且所有組件齊全。
2. 打開包裝，在使用前目視檢查裝置是否有損壞。
3. 檢查內管是否沒有障礙物，材料是否有脆裂或破損。

### 8.2 更換內管

如果黏稠的分泌物聚集在內管中且無法吸出，從而阻礙氣流，請用新的或清潔的內管替換原內管。

1. 逆時針旋轉鎖環，鬆開內管，然後將其取出。
2. 如果產品損壞，請勿進一步使用內管，請勿丟棄內管，並按照「退貨和投訴」章節中的說明進行操作。
3. 一旦新的內管插入外管，順時針旋轉鎖環，直到卡入到位將其鎖定（見圖 1）。

**注意：**插入內管時，始終確保氣囊的充盈管線未位於內管和外管之間，因為它可能會被卡住並受損。

## 9. 保養和清潔

### 注意：

- 從最初打開無菌屏障開始，內管的使用時間不應超過 29 天。
- 此最長使用期間包括患者和非患者（例如清潔）使用本裝置。
- 為了衛生起見，並且為了避免在事後重新組裝套管時發生混淆，必須將外管與相應的內管一起清潔。
- 在重新插入之前，應檢查產品的完整性和功能。

清潔內管的目的是清除可能影響其臨床使用的任何體液或結垢。請注意清潔後在 15 mm 連接器處握住內管。

以下手動清潔指南適用於所有 Tracoe Twist Plus 內管型號和尺寸：

1. 要清潔內管，將其放在溫水（最高 40°C/104°F）中沖洗，直到目視明顯乾淨且無結垢。
2. 應特別注意確保徹底沖洗插管內部。
3. Tracoe 提供的刷子或棉花棒可用於去除殘留的碎屑，請參閱「補充產品」。
4. 或者，可以按照各自的使用說明使用 Tracoe 清潔產品（見「補充產品」）。
5. 清潔後，用飲用水或蒸餾水沖洗內管。
6. 如果沖洗後，目視內管仍不乾淨，則：
  - 重複沖洗，直至明顯清潔，或
  - 使用 Tracoe 清潔產品重複清潔，或
  - 安全地丟棄內管。
7. 應在光線充足的情況下檢查內管的所有區域，以確保裝置沒有污染物和結垢。
8. 在清潔過程完成後，將內管放在乾淨、無絨毛的乾毛巾上，並在沒有空氣污染的区域風乾。
9. 目視內管沒有殘留水時即視為已乾燥。
10. 最後，在重新插入之前應進行目視和功能檢查，以驗證內管沒有損壞（另請參閱「準備內管」章節）。

### 注意：

- 從造口取出後，應立即清潔內管，以防止泥污和污染物的乾燥。
- 清潔頻率必須由醫生確定，但不得超過允許的頻率。
- 內管在使用 29 天內最多可進行 35 次清潔，否則可能會損害生物相容性和材料穩定性。有關外管的清潔頻率，請參閱 Tracoe Twist Plus 氣切套管的使用說明。
- 切勿使用本說明書中未指定的藥劑或程序清潔內管。
- 內管僅供一位患者使用。因此，必須將其送回給同一位患者。
- 未正確清潔器材可能會導致套管損壞，由於阻塞而增加空氣阻力，或氣管造口的刺激/炎症。
- 由於上呼吸道從來沒有微生物，即使是健康人，我們也不建議使用消毒劑。

## 10. 存放

- a) 根據包裝上顯示的條件將 Tracoe 產品存放在其原包裝中。不要將產品加熱到 60°C 以上的溫度。
- b) 將清潔的內管存放在乾淨的容器中並蓋上蓋子，將容器儲存在乾淨且乾燥的地方，並避免陽光照射。盡快重新插入內管。存放條件不當可能會導致插管損壞或污染。自首次使用起，清潔過的裝置的存放時間不得超過 29 天。

## 11. 包裝

本產品提供無菌（環氧乙烷滅菌），可在無菌條件下使用。Tracoe Twist Plus 備用內管在正常使用或清潔期間不需要無菌環境。

## 12. 處置

使用過的產品應根據國家法規、廢棄物管理計劃或生物危害性廢棄物材料的臨床程序進行處置，例如直接丟棄在防銹裂和防潮的安全袋或容器中，並將其送往當地可處理受污染醫療產品的廢棄物處理系統。

如需進一步建議，請聯絡您所在醫療機構的衛生主管，或者聯絡當地的家庭護理廢棄物管理部門。

## 13. 退貨和投訴

如果您想對本器材提出投訴，請聯絡 [complaint.se@atosmedical.com](mailto:complaint.se@atosmedical.com)。

如果涉及當地醫療器械法律中定義的可通報事件，請與使用國家/地區的相關監管機構聯絡。

## 14. 一般條款和條件

所有 Tracoe 產品的銷售、交付和退貨應僅根據有效的一般條款和條件 (GTC) 進行，這些條款和條件可從 Tracoe Medical GmbH 或網站 [www.tracoe.com](http://www.tracoe.com) 取得。

## Symbols

	Manufacturer; 製造商
	Country of manufacture with date of manufacture; 製造國家/地區和製造日期
	Use-by date; 使用截止日期
	Batch Code; 批次代碼
	Medical Device; 醫療裝置
	Instructions for use; 使用說明
	Caution, consult instructions for use; 注意事項，參閱使用說明
	Federal (USA) law restricts this device to the sale by or on the order of a physician
	Single Patient - multiple use; 單一患者：多次使用
	Sterilized using ethylene oxide; 使用環氧乙烷滅菌
	Do not resterilize; 禁止反復滅菌
	Do not use if package is damaged; 若包裝受損，請勿使用
	Peel here; 從此處撕開
	Keep away from sunlight and keep dry; 避免日照並保持乾燥
	Storage temperature limit; 儲存溫度限制
	Single sterile barrier system; 單一無菌屏障系統
	Single sterile barrier system with protective packaging outside; 具有外部保護包裝的單一無菌屏障系統
	Not made with phthalates (e.g. DEHP); 非由鄰苯二甲酸酯（例如 DEHP）製成

	Not made with Natural Rubber latex; 非天然橡膠乳膠製品
	Packaging Content; 包裝內容
	MR safe; MR 安全
	Triman symbol and Infotri for France; 法國 Triman 標誌和分類中心
	Packaging is recyclable; 包裝可回收
	Recycling guidelines; 回收指引