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TRACOE medical GmbH

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Dr. Christian Zischek

Magistrate's Court, HRB 44548
Tax No.: 08/658/71878

Your Reference

Our Reference

Date

24. October 2022

URGENT Field Safety Notification

FSCA 2022-10

Specific attention to details in the Instruction for Use of TRACOE Tracheostomy Tubes:

TRACOE *vario* P-Tracheostomy Tube, TRACOE *experc Set vario*,

TRACOE *twist plus* P-Tracheostomy Tube, TRACOE *experc Set twist plus*

Dear Customer,

TRACOE medical GmbH has issued a voluntary Field Safety Corrective Action by sending this Field Safety Notification to emphasize details in the Instruction for Use of the products listed below.

Our records indicate that you have received some of the products listed in the following:

TRACOE <i>vario</i> P-Tracheostomy Tube with minimally traumatic insertion system with REF numbers:	TRACOE <i>experc Set vario</i> with REF numbers:
• REF 450-08-P / -09-P	• REF 420-08 / -09
• REF 451-08-P / -09-P	• REF 421-08 / -09
• REF 460-08-P / -09-P	• REF 422-08 / -09
• REF 461-08-P / -09-P	• REF 423-08 / -09
• REF 470-08-P / -09-P	• REF 424-08 / -09
• REF 471-08-P / -09-P	• REF 425-08 / -09

TRACOE <i>twist plus</i> P-Tracheostomy Tube with minimally traumatic insertion system with REF numbers:	TRACOE <i>experc Set twist plus</i> with REF numbers
• REF 311-08-P / -09-P	• REF 330-08 / -09
• REF 312-08-P / -09-P	• REF 331-08 / -09
• REF 316-08-P / -09-P	• REF 332-08 / -09
• REF 888-316-08-P / -09-P	• REF 888-332-08 / -09

Mitglied im



AKTIONSBÜNDNIS
PATIENTENSICHERHEIT



Commerzbank Hanau
IBAN DE63 5064 0015 0240 0604 00
BIC COBADEFF

Frankfurter Volksbank
IBAN DE48 5019 0000 6100 0113 00
BIC FFBVDEFF

Deutsche Bank Frankfurt
IBAN DE83 5007 0010 0469 4006 00
BIC DEUTDEFF

Description of the problem and immediate action required

TRACOE medical GmbH is issuing a Field Safety Notice for the above products as the application bears a very low risk of tearing off the silicone sleeve when removing the insertion system. The incidence rate is 0.016 % and may be further minimized if the application is performed as described in the IFU.

Despite general measures in production and in-process control to improve the strength of adhesion of the silicone sleeve to the guiding catheter, a small residual risk remains during use, as in all areas of medicine.

To reduce these risks even further, please pay close **attention to the instructions in the user manual** and in particular to the following points:

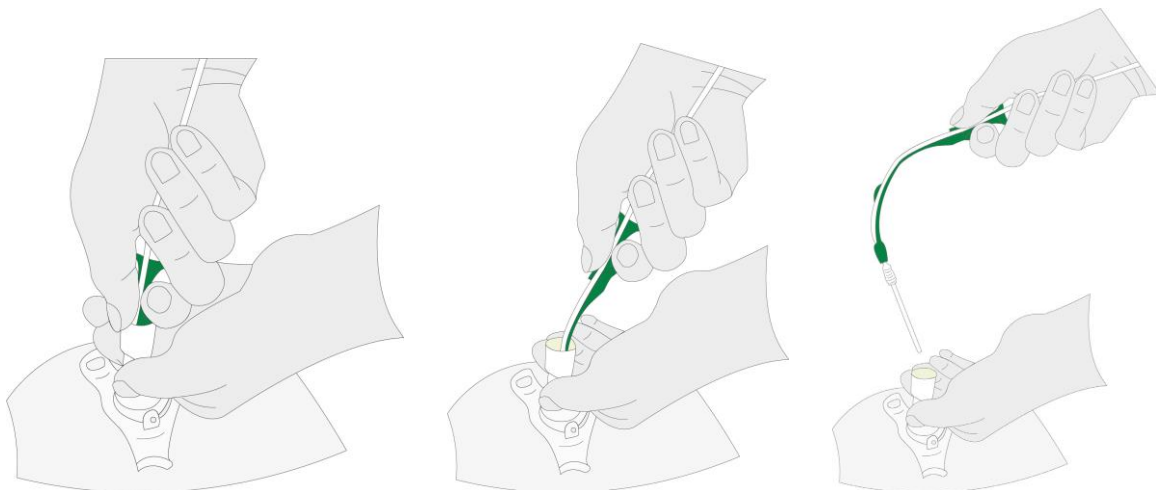
Before Use:

- Keep a ready-to-use **spare tube, several spare inner cannulas, and an identical *twist plus* or *vario expirc set*** of the same size at the patient's bedside as a replacement.
- Tubes with **1 – 2 sizes smaller diameter** should be at hand for emergency use.
- **Take appropriate safety measures** that allow the user to carry out short-term ventilation using translaryngeal intubation or a laryngeal mask.
- Check the **tube for integrity and correct function** and make sure that the inserter / insertion system is **correctly assembled**.
- **Do not disassemble the pre-assembled tracheostomy tube** consisting of inserter / insertion system with guiding catheter and cannula.
- **Do not pull on** the tip of the guiding catheter or silicone sleeve.

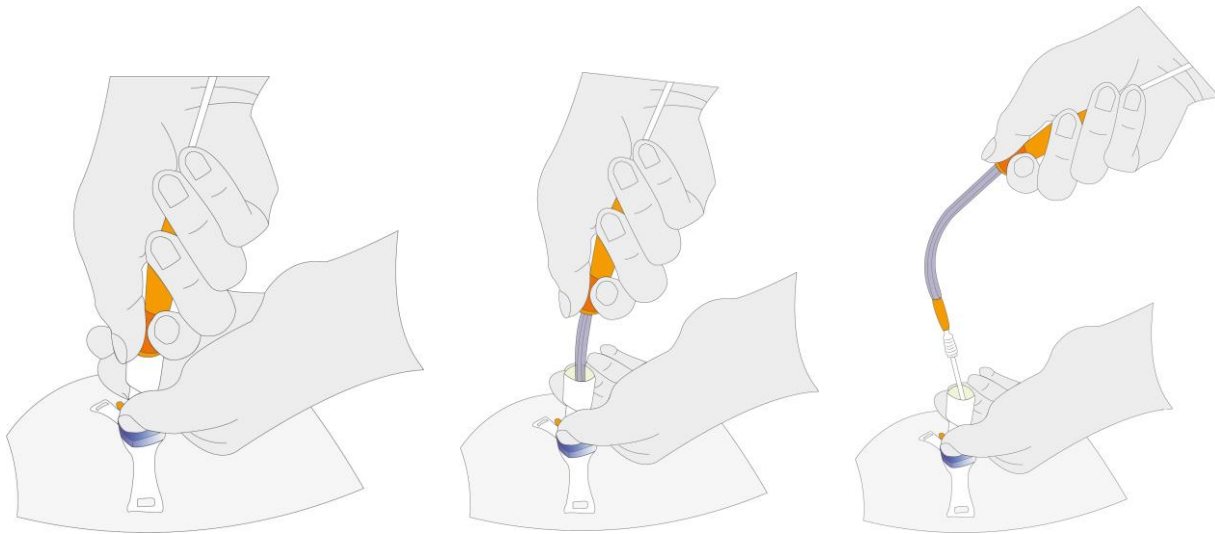
During use:

- Apply a pea-sized amount of the enclosed **lubricating gel** on the tip of the inserter / insertion system and the tracheostomy tube.
- Do not pull on the guiding catheter separately while the inserter is still inside the tube. **Pull out the inserter / insertion system 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 in the trachea.
- Ensure that the silicone sleeve is still on the guiding catheter when the guiding catheter is pulled out.

Pic. Correct pulling out the inserter / insertion system together with the guiding catheter for TRACOE *twist plus*



Pic. Correct pulling out the inserter / insertion system together with the guiding catheter for TRACOE vario



- If the silicone sleeve detaches from the guide catheter, proceed as follows:
 - Immediate inspection of the lumen of the tracheostomy tube. If the sleeve remains in the tube, the inner cannula must be removed immediately for TRACOE *twist plus*. In case of a single-lumen tracheostomy tube (TRACOE *vario*) it must be replaced with the spare device immediately.
 - If the silicone sleeve is not visually detectable in the lumen of the tube, we recommend taking a chest X-ray for the precise localization immediately. Since the silicone sleeve is radiopaque, the X-ray serves as preparation for bronchoscopic removal.
- **Only for TRACOE *twist plus*:** If the inserter is too difficult to be remove, it can also be removed together with the inner cannula. Therefore, loosen the inner cannula by turning the locking ring. If the inner cannula is removed when removing the inserter, it must be reinserted into the tracheostomy tube without the insertion system and locked into place by turning the locking ring.

Forwarding of this Field Safety Notice

This notification should be forwarded to all persons who need to be informed within your institution or in another company to which the products concerned have been transferred.

If applicable, include end users, doctors, nurses, risk managers, supply chain/distribution centres, etc. in the distribution list for this Field Safety Notice.

If you are not a direct end-user, please ask your end-users to complete the feedback form and return it either to you or to TRACOE medical.

Please confirm receipt of this notification by returning the feedback form attached by e-mail or fax no later than **07. November 2022**.

Contact

Should you require further information or assistance regarding this measure, please contact

Customer Service of TRACOE medical GmbH:

Phone (DE): +49-6136-9169-310
Phone (internat.): +49-6136-9169-320
Fax: +49-6136-9169-288
E-mail: customerservice@tracoe.com

TRACOE medical GmbH is committed to providing high quality, safe and effective products.

We expressly apologise for any inconvenience this may cause you.

If you have any further questions, please contact your local sales representative or customer service.

Yours sincerely,



Dr. Christian Zischek

Managing Director TRACOE medical GmbH

Confirmation Form

Field Safety Notice FSCA 2022-10

TRACOE *vario* P-Tracheostomy tube and TRACOE *experc Set vario*
TRACOE *twist plus* P-Tracheostomy tube and TRACOE *experc Set twist plus*

Name of the customer. <Kd Name>
 <Kd Straße> <Hausnr.>
 <PLZ> <Ort>

Customer number: <Kd Nummer>

Please fill out this form and send it by fax to +49-6136-9169-288 or by e-mail to customerservice@tracoe.com

For Medical Facility:

We acknowledge receipt of this Field Safety Notification.

For Distributor:

We acknowledge receipt of this Field Safety Notification and have forwarded the Field Safety Notification to our customers.

Name, First name: _____

E-mail: _____

Date, Signature: _____