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TRACOE medical GmbH

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Geschäftsführer:

Dr. Hans-Marcus Kränzler

Amtsgericht Mainz, HRB 44548

Steuer-Nr.: 08/658/71878

Ihr Zeichen

Unser Zeichen

Datum

25. Juli 2025

URGENT Field Safety Notification, FSCA 2025-07

**Risk of Use of the Obturator of Tracoe Vario Tracheostomy Tube REF 470-08:
The Tip of the Obturator may detach when pulling the Obturator out of the tube.**

Dear Customer,

Tracoe medical GmbH has issued a voluntary Field Safety Corrective Action by sending this Field Safety Notification to point out the risk of the obturator tip separation and to initiate countermeasures.

Based on the current knowledge this defect only occurs with the obturator of one model of the Tracoe Vario Tube with article number: **REF 470-08**, and with a limited number of the following batches:

1100030590
1100037007
1100037008
1100037332
1100039718
1100041006
1100041739
1100041740
1100043524

Our records indicate that you have received some of the affected products mentioned here.

Description of the problem and immediate action required

With the tubes of the listed batches, a fault may occur with the obturator when pulling out the obturator after inserting of the tube, causing the tip of the obturator to detach and remain in the tube or the airways. The tracheostomy tube itself is not defective.

Atos

Commerzbank Hanau
IBAN DE63 5064 0015 0240 0604 00
BIC COBADEFF

Frankfurter Volksbank
IBAN DE48 5019 0000 6100 0113 00
BIC FFVBDEFF

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

The root cause of this error is a faulty manufacturing process of the obturators. This error has already been corrected by the end of 2024, meaning that all current products no longer have this error.

Potential Harm

The tip of the obturator can either displace the lumen of the tube, causing it to become blocked and requiring replacement, or enter the trachea, requiring medical intervention to remove it. In both cases, there is a risk of insufficient air supply of the patient.

However, the error can be detected immediately during use, allowing immediate action to be taken.

Immediate Measures for Users

Please check your stock of Tracoe Vario Tubes for the batch numbers listed above. If the batch numbers listed are not in your inventory, you do not need to take any further action. If you have products from these batches in stock and need to use them promptly, you can take the following **safety measures**:

- Unpack the tube right before use.
- **Remove the obturator from the tube and dispose of it.**
- **Use the tube without the obturator.**

If it is necessary to use the Tracoe Vario Tube with an obturator, please let us know the number of affected products you still have in stock by entering the number on the Confirmation Form and confirm the destruction of these tubes. This will enable us to send you the necessary number of replacement products as soon as possible.

Forwarding of this Field Safety Notification

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

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 confirmation and return it to you so that you can collect them and forward them to us.

Please confirm receipt of this Safety Notification by returning the confirmation form attached by e-mail or fax no later than **29. August 2025**.

Contact

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

FSCA Service of Tracoe Medical GmbH

Phone (DE): +49-6136-9169-145

Fax: +49-6136-9169-200

E-mail: FSCA@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 representative or FSCA service.

Yours sincerely,

Dr. Hans-Marcus Kränzler

Site Director Tracoe Medical GmbH

Mitglied im



Confirmation Form

Field Safety Notification FSCA 2025-07

**Risiko of Use of the Obturator of Tracoe Vario Tubes REF 470-08:
The Tip of the Obturator may detach when pulling the Obturator out of the Tube.**

Name of the customer. <Kd Name> <No>
 <Kd Straße> <Hausnr.>
 <PLZ> <Ort>
Customer number: <Kd Nummer>

Please fill out this form and send it by fax to +49-6136-9169-200 or by e-mail to FSCA@tracoe.com

For Medical Facility:

☐ We acknowledge receipt of this Field Safety Notification and following the Instruction.

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: _____

Order of Replacement Tracoe Vario Tubes REF 470-08

Please enter here all products that are still in your inventory and will be destroyed and replaced.

REF	LOT	Number existing tubes	Number destroyed tubes

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