



Your Reference

Our Reference

Date

3. November 2020

Field Safety Notification

FSCA 2020-02

Dear Customer,

f

TRACOE medical GmbH have issued a voluntary Field Safety Notice for the products listed below.

All TRACOE *twist* plus tubes and TRACOE *experc* Set *twist* plus in sizes 07 and 08 with the REF numbers listed below are affected (Full list of affected batches / LOT numbers in Appendix):

TRACOE *twist* plus Tracheostomy Tubes

- REF 316-07, REF 316-08
- REF 316-07-P, REF 316-08-P
- REF 888-316-07, REF 888-316-08
- REF 888-316-07-P, REF 888-316-08-P

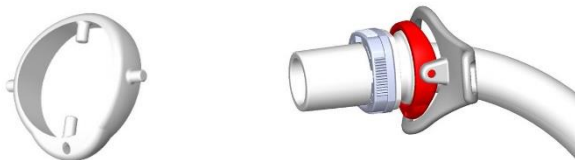
TRACOE *experc* Set *twist* plus

- REF 332-07, REF 332-08
- REF 888-332-07, REF 888-332-08

Description of the problem and immediate action required

TRACOE medical GmbH are issuing a field safety notice in relation to the above-mentioned products after it became known that the ring of the joint which attaches the flange may break.

To better recognize the ring, we have inserted the pictures here:



The ring breakage occurs very rarely, so treatment with an affected lot number tube can still be carried out without the defect occurring in most cases. However, the tube should be checked more frequently and more precisely during use, so that the first sign of a ring breakage initiates an immediate change of the tube.

If the ring breakage occurs with a tracheal tube that is already in place, the secure attachment of the tube via the flange and neck strap is no longer guaranteed. The tube could come loose from its position in the tracheostoma and trachea and thus the airway could no longer be secured. If the fault occurs, the tube must be replaced immediately.

An early change of the tube, especially in freshly tracheostomised patients, without the occurrence of the error is not recommended, as this represents a higher risk. We recommend not to use tubes with these lot numbers in freshly tracheostomised patients.

Forwarding of this safety information

Our records show that you have received the products listed in the Appendix which are affected by this safety information.

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.

Please confirm receipt of this letter by returning the Confirmation Form by e-mail or fax.

Contact

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

Customer Service of TRACOE medical GmbH:

Phone (D):	06136-9169-310
Phone (internat.):	+49-6136-9169-320
Fax:	+49-6136-9169-288
E-mail:	complaints@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,

.....

.....

Confirmation Form

Safety Information FSCA 2020-02

concerning

TRACOE *twist plus* Tracheostomy tube and TRACOE *experc Set twist plus*

Name of the customer. _____

Customer number: _____

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

For Medical Facility:

We acknowledge receipt of this safety information.

For Distributor:

We acknowledge receipt of this safety information and have forwarded the safety information to our customers.

Name, First name: _____

E-mail: _____

Date/Signature: _____

Appendix

List of affected products	
LOT No.	REF