TRACOE®

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Your Reference	Our Reference	Date
		19 November 2015

URGENT FIELD SAFETY NOTICE - RECALL

Affected Devices:	TRACOE *larynx* stoma button REF 612-09 TRACOE *larynx* grid button REF 603-08
Type of Action:	Field Safety Corrective Action - Recall
Date:	19 November 2015
Attention	Risk/Safety Managers, Clinicians, Nurses and other users of the device
Details on affected devices:	**Product Code:** REF 612-09 REF 603-08 **Lot number:** 1000097162 1000098480

Dear valued customer,

TRACOE medical GmbH is providing this Urgent Field Safety Notice to advice its customers of a voluntary recall for TRACOE *larynx* stoma button REF 612-09 and TRACOE larynx grid button REF 603-08. TRACOE medical GmbH is voluntary taking this recall with the knowledge of the relevant Regulatory Agencies.

The products with the above mentioned Lot number do not contain the product labelled on the packaging.
The by mistake packed products have not the inner diameter which is mentioned on the packaging.

Until now we have not received any reports about an impairment of patients due to this issue.

Advice on action to be taken by the user:
Subject to this Field Safety Corrective Action, TRACOE medical is requiring its customers to:

1. Inspect your inventory and segregate any unused affected products; and
2. Complete and please return the Confirmation Form (Attachment 1), either by fax at +49-6136-9169-218 or by e-mail to: [redacted]@tracoe.com within five (5) days of receipt of this notice.

Upon receipt of the completed Confirmation Form, a customer service representative will contact you to arrange for exchange of your unused affected inventory for credit or replacement with an alternative TRACOE *vario* Tracheostomy Tube with Atraumatic Insertion System.

Transmission of this Urgent Field Safety Notice:
This notice shall be passed on to all personnel who need to be aware within your organization, including points of use or to any organization where the potentially affected devices have been transferred. If you or your facility have distributed these affected products to other persons or facilities, please promptly forward a copy of this Urgent Field Safety Notice to the recipients.

Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this recall.

TRACOE medical GmbH is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may have caused.

Sincerely,

[redacted]
General Director

[redacted]
General Director

Enclosures: Attachment 1 – Field Safety Notice Confirmation Form

ATTACHMENT 1

FIELD SAFETY NOTICE CONFIRMATION FORM
For TRACOE *larynx* stoma button and grid button

Customer Name _____
Customer Number _____

Please complete and return this form by fax to +49-6136-9169-218 or by email to [redacted]@tracoe.com

☐ **YES** – We have affected products in our inventory. Please contact me using the details provided below to provide me with the instructions on returning my unused products.	Total number of affected products: _____
☐ We no longer have any of the affected products. We transferred them to the following location: (Please provide name, address, and phone number):	
☐ We did have affected products; however, they were already used/have been disposed of.	

Date/Signature:_____