TRACOE®

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Your Reference	Our Reference	Date
		08 May 2015

URGENT FIELD SAFETY NOTICE - RECALL

Affected Devices:	TRACOE *vario* Tracheostomy Tube with Atraumatic Insertion System REF 460-07-P, which is also a part of TRACOE experc Set *vario* REF 423-07.
Type of Action:	Field Safety Corrective Action - Recall
Date:	05 November 2014
Attention	Risk/Safety Managers, Clinicians, Nurses and other users of the device
Details on affected devices:	**Product Code:** REF 460-07-P and REF 423-07 **Lot number:** 0002-1000092168 and 0004-1000092080

Dear valued customer,

TRACOE medical GmbH is providing this Urgent Field Safety Notice to advice its customers of a recall for TRACOE *vario* Tracheostomy Tube with Atraumatic Insertion System REF 460-07-P and REF 423-07. TRACOE medical GmbH is voluntary taking this recall with the knowledge of the relevant Regulatory Agencies.

The products with the above mentioned Lot numbers were packed in a wrong secondary packaging by mistake. However the secondary packaging as well as the sterile bag is labelled correctly. Until now we have not received any reports about an impairment of patients due to this issue. Our risk evaluation showed that the safety of our products is not affected by the wrong secondary packaging.

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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 General Director

Enclosures: Attachment 1 – Field Safety Notice Confirmation Form