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TRACOE medical GmbH

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Amtsgericht Mainz HRB 44548
Tax no.: 26 668 001 33

Your Reference

Our Reference

Date

05 November 2014

URGENT FIELD SAFETY NOTICE - RECALL

Affected Devices: TRACOE softpad tracheostomy stoma pads REF 969

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 969
Lot number: F1466063

Dear valued customer,

TRACOE medical GmbH is providing this Urgent Field Safety Notice to advise its customers of a recall for TRACOE softpads tracheostomy stoma pads REF 969. TRACOE medical GmbH is voluntary taking this recall with the knowledge of the relevant Regulatory Agencies.

TRACOE medical GmbH has become aware that the above listed lot number has not been sterilized. TRACOE medical GmbH has received no reports of patient injury to this issue until now.

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: a.renier@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 softpad.

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,



S. Köhler
General Director



Dr. T. Jurisch
General Director

Enclosures: Attachment 1 – Field Safety Notice Confirmation Form





FIELD SAFETY NOTICE CONFIRMATION FORM
For TRACOE softpad tracheostomy stoma pads REF 969

Customer Name _____
Customer Number _____

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

<input type="checkbox"/> 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: _____
<input type="checkbox"/> We no longer have any of the affected products. We transferred them to the following location: (Please provide name, address, and phone number): 	
<input type="checkbox"/> We did have affected products; however, they were already used/have been disposed of.	

Date/Signature: _____