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Managing Directors:
Stephan Köhler, Dr. Thomas Jurisch

Amtsgericht Mainz, HRB 44548
Tax No: 26 668 001 33

Your Reference	Our Reference	Date
	4916532	3 January 2017

Urgent Field Safety Notice

Corrective Action

TRACOE *vario* REF 464, Tracheostomy Tube, Fenestrated with Adjustable Neck Flange

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Reference Number: 4916532

Sender:
TRACOE medical GmbH
Managing Directors:
Stephan Köhler, Dr. Thomas Jurisch
Reichelsheimer Straße 1 / 3
55268 Nieder-Olm
GERMANY

Addressee:
User, distributor, patients

Details of affected devices:
Tracheostomy Tube, Fenestrated with Adjustable Neck Flange
Product group: TRACOE *vario*
Reference number: REF 464
LOT: 1000104004, 1000103495, 1000103496, 1000104002

Description of the Problem:
TRACOE medical GmbH has decided to organize a corrective action since it has been determined that 4 individual batches of the fenestrated TRACOE *vario* REF 464 tubes have been packaged and placed on the market with an incorrect version (version 3.0) of the instructions for use. This version does not contain complete information on the mentioned fenestrated cannula.

The cause of this fault is currently determined.

Due to the incorrectly packaged version of the instruction for use, there is the risk that the user will use the fenestrated tracheostomy tube contrary to its regulations / instructions due to the lack of information. The general handling of the tube (insertion, cleaning, etc.) is covered by the enclosed instructions for use.

Since TRACOE *vario* tracheostomy tubes are life-sustaining / life-supporting medical devices, it is assumed that the tubes are handled by trained users who are familiar with the treatment of tracheostomy tubes. Therefore, the probability of occurrence of the risks described below is considered to be low. This risk assessment is supported by the fact that the affected cannulas have been on the market since March 2016 and no patient injuries / incidents have been reported as a result of the affected batches.

The following theoretical risks were identified as a result of the incorrect version of the instruction for use:

- In the instruction for use following caution is missing: Never use fenestrated cannulas for ventilation. This can lead to inadequate ventilation, since air can escape through the fenestration. However, since the TRACOE *vario* REF 464 is a non-cuffed tracheostomy tube, it is considered highly unlikely that it will be used for ventilation. Therefore the risk is estimated to be very low.
- There is no reference to select the tube in such way that the fenestration is positioned with a sufficient distance to the stoma canal. If this warning is not observed, there is a risk of emphysema if the tube is incorrectly used for ventilated patients. Also, granulation tissue may form. Since it is very unlikely that the uncuffed REF 464 is used for ventilation, the risk is classified as very low. The formation of granulation tissue does not represent a life-threatening situation for the patient and therefore the severity and thus the risk for the patient is considered to be low.
- There is no reference that the fenestration must always be unobstructed in the trachea. Otherwise the patient cannot use the cannula for speaking. This does not constitute a safety risk for the patient.
- There is no reference that the speaking valves may only be attached when the patient is awake and who can breathe spontaneously after cuff has been deflated. As the TRACOE *vario* REF 464 is an uncuffed tracheostomy tube and the instructions for use of the corresponding speaking valves, which also contain this type of caution, needs to be observed,the risk of incorrect application is estimated to be low.

If the tube was already used on the patient and there were no complications / no risks, no risks are to be expected afterwards of the use.

What kind of measures need to be taken by the addressee?
Please check if you have tubes of the affected batches in stock or if a affected tube is currently in use. If this is the case, we ask you to replace the enclosed instruction for use, version number 3.0 (see on the back of the instructions), by version 4.0.
We also ask you to check whether the affected tubes in use are inserted and used according to the specifications in the instructions for use version 4.0.

Please complete and return the Confirmation Form (Attachment 1), either by fax to +49-6136-9169-218 or by e-mail to: a.renier@tracoe.com within five (5) days of receipt of this notice.

The corrective action is thus implemented.

All other TRACOE *vario* REF 464 products on the market contain the correct instructions for use.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:
If you have any further questions please contact Mrs. Adeline Renier
Tel: 06136 9169 – 118
Fax: 06136 9169 – 218
E-Mail: a.renier@tracoe.com

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,

03. JAN. 2017

M. Keidl
Authorized Representative

S. Köhler
Managing Partner

Dr. T. Jurisch
Managing Director

Enclosures: Attachment 1 – Field Safety Notice Confirmation Form
Attachment 2 – IFU V4.0

ATTACHMENT 1

FIELD SAFETY NOTICE CONFIRMATION FORM
TRACOE *vario* REF 464, tracheostomy tube, fenestrated with adjustable neck flange

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

☐ **YES** – We have affected products in our inventory and replace the Instructions for Use.	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 as well as the number of the transferred product):	
☐ We did have affected products; however, they were already used/have been disposed of.	Total number of affected products: _____

Date/Signature:_____