FIELD SAFTEY NOTICE - Field Safety Corrective Action

Hamburg, 11.12.2017

URGENT - FIELD SAFETY NOTICE

Type of Action	**Recall**
Product	Blood Transfusion Set, for single use
Commercial Name	TRO-DONORSET Ref.No. **93000**
Report No.	M17-034
Lot No.	11731-01; 12143-01; 12537-01; 13137-01; 13228-01; 13231-01; 13536-01; 13732-01; 14067-01; 14082-01; 14470-01; 14516-01; 14705-01; 14780-01; 15024-01; 15255-01

Dear Customer,

Troge Medical is initiating a voluntary Field Safety Corrective Action for one of our Transfusion set models, as per above listed product code.

Description of the problem

Troge Medical Medical is recalling the product referenced above on a voluntary basis, because a missing information in the labelling was identified.
The injection site of this product Ref. No. contains natural latex, which may cause allergic reactions in patients or users.

The symbol or other relevant information indicating the presence of latex is missing on the pouch of this product. Although, this product was correctly supplied according to your order as a “latex containing product”, there is a risk, that the final user (e.g. nurse, doctor, paramedic) might not be aware of it.

All products supplied and used until now, have not led to reporting of any adverse effect or reaction.

Our records indicate that you have received a product that is subject to this recall. We are now notifying our customers to take the following actions:

INSTRUCTIONS TO BE TAKEN BY MEDICAL STAFF

1. We request that you check your stocks for a.m. product Ref. No. and LOT nos. Users should cease use and distribution of stock of the affected product lot and quarantine immediately.
2. If you do not have stock of the product referred to in above table, kindly tick the respective checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail- address mentioned below.
3. If you have stock of the affected product referred to in above table, kindly tick the respective checkbox on the Acknowledgement form (Appendix 1).
4. Complete ‘Appendix 1’ for all products in your possession and under your control. Return this form immediately to our Customer Service.
5. Troge Medical will co-ordinate all further steps closely with you. In some cases it might not be possible to send the goods back, but they should be discarded according to the local regulations in place.

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INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

- If you are a distributor, provide this field safety notice to all of your customers who have received the affected product. Your customer is then required to complete the acknowledgement form and return this to you.
- As a distributor, you are required to confirm to Troge Medical that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to our Customer Service.
- If you are a distributor and/or have a reporting responsibility within or outside the EEA area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Troge Medical.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service:

Contact: Kathleen Schoop
Telephone: +49 40 441844-0
FAX:+49 40 4107303
Email: vigilance@trogemedical.de

The undersigned confirms that this notice has been submitted to all respective Regulatory persons and authorities. We sincerely apologize for any inconvenience this action may cause to you. If you have any other questions, kindly feel free to contact our Customer Service at any time.

Troge Medical GmbH

[redacted]

[redacted]

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Appendix 1

ACKNOWLEDGEMENT FORM

FIELD SAFETY CORRECTIVE ACTION BY TROGE MEDICAL - IMMEDIATE ATTENTION REQUIRED

Report No. M17-034
RETURN COMPLETED FORM IMMEDIATELY TO:

FAX:+49 40 4107303 **Email:** vigilance@trogemedical.de

☐ We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our stock does **NOT** include products affected by this Field Action.	☐ We confirm receipt of this FSN and completed the required actions contained therein. We confirm our stock **DOES** include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are blocked /quarantined and the amount below will be returned or destroyed, if applicable.

PLEASE PRINT DETAILS CLEARLY !

Commercial Name: TRO-DONORSET Ref. No. 93000	
LOT NUMBER(S)	**QUANTITY (Returning)**

Customer / Institution details:

INSTITUTION NAME (e.g. Name of hospital, health care organisation)	
ADDRESS	**Phone / Fax**
FORM COMPLETED BY:	**Stamp / Date**
PRINT NAME: **SIGNATURE:**_____	