Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

01.04.2011

URGENT
FIELD SAFETY NOTICE

Commercial Name of Affected Product:	CrystalClear Tracheostomy Tube Cuffed, Sterile Pack CrystalClear Tracheostomy Tube Cuffed, Sterile Pack CrystalClear PDT, Sterile Percutwist Set With CrystalClear Sterile
Type of action:	Product Removal
Affected Part and Lot Numbers: Refer to Appendix 2	

Dear Customer,

1. Details of affected devices

Teleflex Medical has issued a voluntary Field Action for products as detailed in Appendix 2.

2. Description of the problem

Teleflex Medical has received complaints for air leakage from the main ventilation lumen through air passageway between the nexkplate and the open end of the inflation lumen for the above referenced Crystal Clear Tube. This may result in potential injury and the need for possible medical intervention.

3. FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

Advice on action to be taken by Medical Staff

1. We request that you check stock for product within the scope of this field action. Users should cease use and distribution of stock from the affected lot number and quarantine all products from the affected lot number immediately.

2. If you have no stock from the affected lot number, please indicate so on the 'field safety corrective action acknowledgement and stock status form' and fax to your local Teleflex Medical Customer Service/Sales Rep as indicated on the 'field safety corrective action acknowledgement and stock status form' (Appendix 1)

3. If you do have stock from the affected lot number, please contact your local Teleflex Medical Customer Service/Sales Rep (or Distributor) as indicated on the attached 'field safety corrective action acknowledgement and stock status form' for a Return Authorization Number. Once you have received the Return Authorization Number, please enter it in the space provided on the enclosed 'field safety corrective action acknowledgement and stock status form'

4. Complete the enclosed 'field safety corrective action acknowledgement and stock status form' providing detail on stock from the affected lot number under your control within the scope of this Field Safety Action and immediately email the completed form to **orders.intl@teleflexmedical.com** This will allow us to document your receipt of this letter and the amount of product you have on hand for return.

5. Your local Teleflex Medical Customer Service/Sales Rep (or Distributor) will coordinate the product return with you.

6. Teleflex Medical Customer Service can credit your account when the product is returned.

Instruction for Distributors of affected product

If you are a distributor, Teleflex Medical requires that you communicate this field safety corrective action notice to your customers who received product within the scope of this field safety corrective action by providing:

- A copy of this Field Safety Notice to them.
- A copy of the 'field safety corrective action acknowledgement and stock status form' (Appendix 1)

The 'field safety corrective action acknowledgement and stock status form' is required to be completed in its entirety, signed and returned to you (the Distributor).

As a Distributor, it is your responsibility to provide Teleflex Medical with confirmation that all of your consignees have been contacted under this field safety corrective action. Please forward the completed Acknowledgement Form to **orders.intl@teleflexmedical.com or by fax on +353 1 437 0773**

Please be advised that all affected European Economic Area/Switzerland (EEA/CH) Member State Competent Authorities will be notified by Teleflex Medical where we have distributed product directly. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH area please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex Medical.

4. Teleflex Medical

Teleflex Medical is notifying any potentially affected Customers, Teleflex Medical employees and Distributors of this Field Safety Notice.

5. Transmission of this Field Safety Notice

This notice should be passed on all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

6. Contact reference person

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

For Customer Service
Raychel Murtagh
Email: orders.intl@teleflexmedical.com
Fax: +353 1 437 0773
Phone: +353 906 460 838

For Product Specific Queries:
Vladamir Vasseck on
Phone: +420 602 791 683
Email: vvasek@teleflexmedical.com

This field safety corrective action is voluntary and all affected competent authorities have been advised of this Field Safety Corrective Action.

Teleflex Medical is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service at orders.intl@teleflexmedical.com

Signed by:

[redacted]
VP Quality Assurance & Regulatory Affairs, EMEA

Attachments as follows: Appendix 1 :'field safety corrective action acknowledgement and stock status form'

Appendix 1

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT AND STOCK STATUS FORM

Medical Device Field Safety Corrective Action Concerning Teleflex MedicalProducts

Customer No _____

Immediate Attention Required

Return Authorisation No _____

RETURN COMPLETED FORM IMMEDIATELY TO:
Email: orders.intl@teleflexmedical.com ; Fax: +353 1 437 0773

☐ We have no inventory of stock from the affected lot number within the scope of this Field Action.	☐ We have the following stock from the affected lot numbers at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities. ☐ Please credit our account once you have received the returns

Please print product numbers clearly.

Product	CrystalClear Tracheostomy Tube Cuffed, Sterile Pack CrystalClear Tracheostomy Tube Cuffed, Sterile Pack CrystalClear PDT, Sterile Percutwist Set With CrystalClear Sterile
Product Number	**Lot Number/Quantity (unit)**
121610	
858510	
121502	
121556	

Print Name/Title _____ Date _____

Signature _____ Telephone Number _____

Institution Name _____

Address _____

City, State, Zip Code _____