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

31st March 2016

URGENT - FIELD SAFETY ADVISORY NOTICE

Type of Action	Field Safety Advisory Notice	
Teleflex Reference:	EIF-000037	
Commercial Name	**Material**	**Batch**
PE ATS BAG LF 6/CS	A-1500-08LF	Refer to Appendix 1
PE PNEUMONECTOMY LF 6/CS	A-4301-08LF	
PE ADULT-PED DRY/ WET LF 6/CS	A-6000-08LF	
PE DRY/WET DUAL COLL LF 6/CS	A-6002-08LF	
PE INFANT DRY/WET LF 6/CS	A-6020-08LF	
PE ADULT-PED WET LF 6/CS	A-7000-08LF	
PE ADULT-PED WET LF 6/CS	A-8000-08LF	
PE ADULT-PED WET DUAL COLL LF 6/CS	A-8002-08LF	
PE MINI SAHARA 6/BX LATEX FREE	S-0500	
PE SAHARA ATS BAG LF 6/CS	S-100-08LF	
PE SAHARA DRY SUCT/DRY SEAL LF 6/CS	S-1100-08LF	
PE SAHARA DRY SUCT/DRY SEAL DUAL LF 6	S-1102-08LF	

Dear Customer,

Details of affected devices
Teleflex has initiated a voluntary Field Safety **Advisory Notice** for the above listed products.

Description of the problem
Teleflex is issuing an advisory notification to our customers due to an error in labelling. The label on the Tyvek bag, which is used by customers to identify material code, lot number, and expiration date once the product has been removed from the shipper box, is missing (see image 1, Appendix 2). As a result it is not possible to clearly identify the product without breaking the sterile barrier to access the individual unit label. Outside a possible delay in the procedure, this defect would have little if any clinical impact as the issue would be immediately noted by the user.

The Pleur-Evac product is a sterile, single-use, chest drainage system intended for post-operative use. The system consists of a suction control chamber to control patient applied suction, a patient seal chamber to provide the patient isolation from ambient air and pressure, and a fluid collection chamber for collection of fluids drained from the chest cavity or mediastinum.

- No chest drain tubing is provided as part of this device
- The device itself does not have direct contact with the patient.
- The Pleur-Evac product acts as a drainage collection container.
- The Actual device (Image 2, Appendix 2) and the Shipping carton (Image 3, Appendix 2) labelling is correct.
- IFU placement within the Tyvek bag (SECONDARY packaging) will allow the user to identify the product as a Pleur-Evac device.
- The user will be able to identify the unique product information upon opening of this sterile packaging.

INSTRUCTIONS FOR USE:

The Pleur-Evac device can be used as normal per IFU. The user can readily identify the Pleur-Evac device within the packaging and can also identify the product information upon opening of the sterile packaging.

FIELD SAFETY ADVISORY NOTICE ACTION INSTRUCTIONS

Advice on action to be taken by Healthcare Institution and Medical Staff

- Our records indicate your facility has received product in scope of this advisory notice.
- Please provide this Field Safety Advisory Notice to all those who need to be aware of it within your organisation and place a copy prominently with affected product.
- Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice. There is no further action required.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

- If you are a distributor, provide this Field Safety Advisory Notice to all of your customers who have received product in scope of this Field Action.
- As a Distributor you are required to confirm to Teleflex that you have completed the field activity outlined above.
- Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
- If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

TELEFLEX

Teleflex informs all direct customers, employees of Teleflex and distributors on this Field Safety Advisory Notice.

TRANSMISSION OF THIS FIELD SAFETY ADVISORY 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.

Maintain awareness of this notice until all required actions have been completed in your organisation

Please be advised that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex.

Teleflex 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.

Contact reference person

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

Customer Service:
Contact: Shane Kenny
FAX: +353 (0)1 4370773
Telephone: +353 (0)90 6460869
E-mail: Recalls.intl@teleflex.com

For and on behalf of Teleflex,

[redacted]

Karen Boylan
VP, Global RA/QA

Teleflex MEDICAL

Appendix 1

Product Code	Description	Lot/Batch Numbers
A-1500-08LF	PE ATS BAG LF 6/CS	74J1501715
A-1500-08LF	PE ATS BAG LF 6/CS	74K1501006
A-1500-08LF	PE ATS BAG LF 6/CS	74L1500163
A-4301-08LF	PE PNEUMONECTOMY LF 6/CS	74K1500975
A-4301-08LF	PE PNEUMONECTOMY LF 6/CS	74K1502313
A-4301-08LF	PE PNEUMONECTOMY LF 6/CS	74L1500164
A-4301-08LF	PE PNEUMONECTOMY LF 6/CS	74L1500165
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1500364
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1500365
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1500367
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1500907
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1500908
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1501007
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1501008
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1501010
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1501014
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74K1502274
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74L1502302
A-6000-08LF	PE ADULT-PED DRY/ WET LF 6/CS	74L1502304
A-6002-08LF	PE DRY/WET DUAL COLL LF 6/CS	74K1500391
A-6002-08LF	PE DRY/WET DUAL COLL LF 6/CS	74K1500909
A-6002-08LF	PE DRY/WET DUAL COLL LF 6/CS	74K1500910
A-6002-08LF	PE DRY/WET DUAL COLL LF 6/CS	74K1503003
A-6002-08LF	PE DRY/WET DUAL COLL LF 6/CS	74L1500179
A-6020-08LF	PE INFANT DRY/WET LF 6/CS	74L1500180
A-7000-08LF	PE ADULT-PED WET LF 6/CS	74K1500372
A-7000-08LF	PE ADULT-PED WET LF 6/CS	74K1500913
A-7000-08LF	PE ADULT-PED WET LF 6/CS	74K1501021
A-7000-08LF	PE ADULT-PED WET LF 6/CS	74K1502277
A-8000-08LF	PE ADULT-PED WET LF 6/CS	74K1500369
A-8000-08LF	PE ADULT-PED WET LF 6/CS	74K1500915
A-8000-08LF	PE ADULT-PED WET LF 6/CS	74K1501025
A-8000-08LF	PE ADULT-PED WET LF 6/CS	74K1501026
A-8000-08LF	PE ADULT-PED WET LF 6/CS	74K1501028
A-8000-08LF	PE ADULT-PED WET LF 6/CS	74K1502263
A-8000-08LF	PE ADULT-PED WET LF 6/CS	74K1502264
A-8000-08LF	PE ADULT-PED WET LF 6/CS	74L1500190
A-8002-08LF	PE ADULT-PED WET DUAL COLL LF 6/CS	74K1500376
A-8002-08LF	PE ADULT-PED WET DUAL COLL LF 6/CS	74K1501032
S-0500	PE MINI SAHARA 6/BX LATEX FREE	74K1500379
S-100-08LF	PE SAHARA ATS BAG LF 6/CS	74K1501039
S-1100-08LF	PE SAHARA DRY SUCT/DRY SEAL LF 6/CS	74K1500381
S-1100-08LF	PE SAHARA DRY SUCT/DRY SEAL LF 6/CS	74K1501041
S-1100-08LF	PE SAHARA DRY SUCT/DRY SEAL LF 6/CS	74K1502267
S-1100-08LF	PE SAHARA DRY SUCT/DRY SEAL LF 6/CS	74L1500208
S-1100-08LF	PE SAHARA DRY SUCT/DRY SEAL LF 6/CS	74L1500209
S-1100-08LF	PE SAHARA DRY SUCT/DRY SEAL LF 6/CS	74L1500210
S-1102-08LF	PE SAHARA DRY SUCT/DRY SEAL DUAL LF 6	74K1500382
S-1102-08LF	PE SAHARA DRY SUCT/DRY SEAL DUAL LF 6	74K1500383
S-1130-08LF	PE INFANT SAHARA DRY SUC/ SEAL LF 6/CS	74K1500922
S-1150-08LF	PE SAHARA DRY SUC/SEAL CONT REINF LF 6	74J1501725
S-1200-08LF	PE SAHARA DRY SUC/SEAL LF W/ATS 3/CS	74K1500385
S-1200-08LF	PE SAHARA DRY SUC/SEAL LF W/ATS 3/CS	74K1501043

Appendix 2

Image 1:

Tyvek bag (Secondary) labeling and IFU placement example

Image of how device IS presently labelled

Image of how device SHOULD be labelled (label in red is missing)

Image 2:

Actual Device labeling example:

Image of how ACTUAL device IS presently labelled

Image 3:

Shipping Carton labeling example

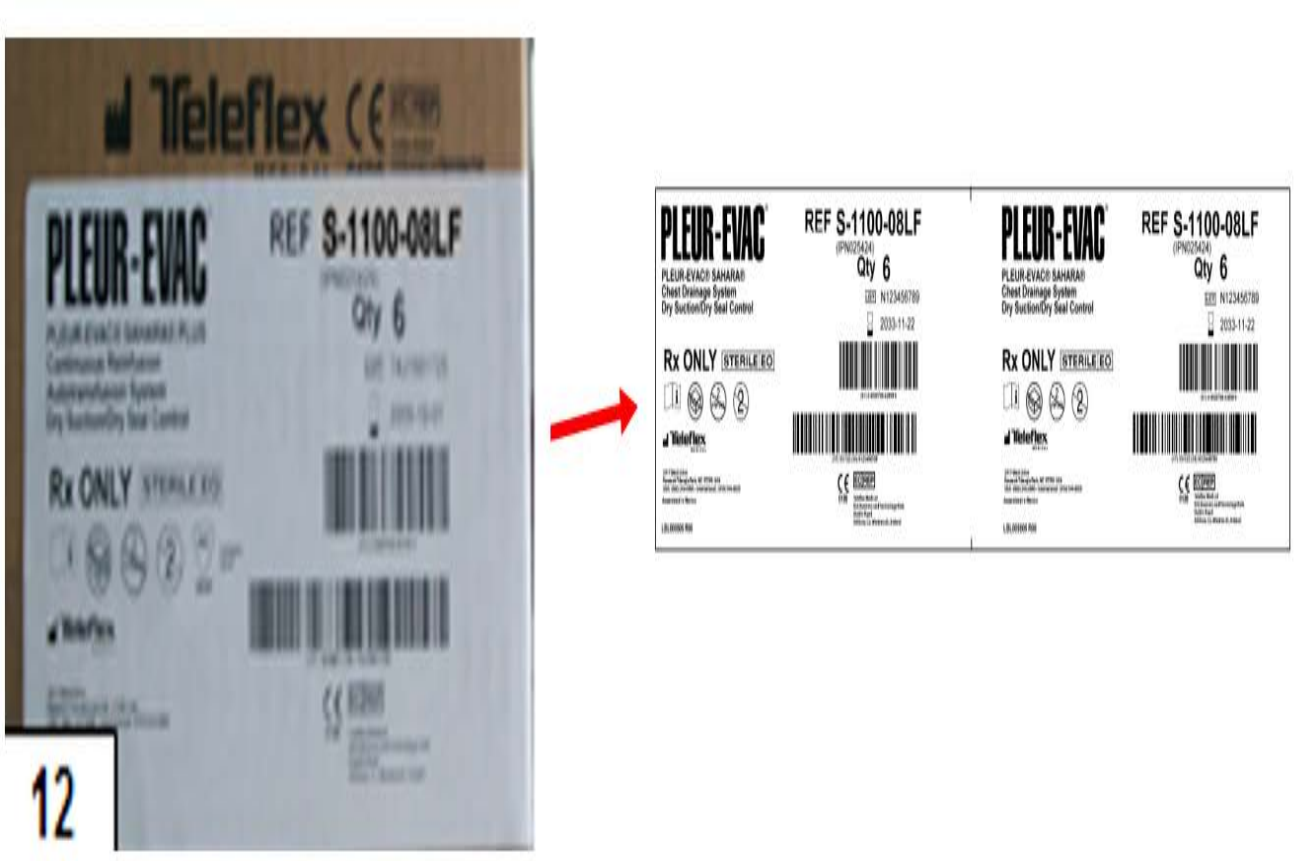

Image of how ACTUAL Shipping Carton IS presently labelled