

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

02 July 2020

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall
Teleflex Reference	EIF-000432
Commercial Name	Pleur-evac® Chest Drainage Systems
Product Code/Lot Number	Refer to Appendix 2

Dear Customer

Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action (FSCA) for the above listed product, refer to Appendix 2 for a list of product codes and lots impacted.

Description of the problem & immediate actions required

Teleflex is recalling the above product codes and lot numbers. There is the potential for the packaging of this device to become compromised. If this occurs, there is the further possibility that the sterility of the device itself may not be assured. If the device’s sterility is consequently compromised and the device subsequently used this may lead to an increase risk of infection. No complaints, patient injuries or deaths have been reported at this time.

Depending on your device location please adhere to the following Action list:

Device location	Action List Number
Medical facilities (hospitals, medical staff, etc.)	1
Distributors	2

Action list number 1 – Medical facilities

1. We request that you check your inventory for product within the scope of this FSCA. Users should cease use and distribution of impacted product and quarantine immediately.
2. If you do not have stock in scope of this FSCA mark the according checkbox on the Acknowledgement Form (Appendix 1) and return the form to the fax number or e-Mail address mentioned below.
3. If you do have stock in scope of this FSCA, mark the according checkbox on the Acknowledgement Form (Appendix 1) and contact customer service by calling the phone number mentioned below. Customer service will issue you with a return number. Write the return number into the respective field in the Acknowledgement Form and return this form immediately to Customer Service.
4. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

Action list number 2 – Distributors

1. Provide this field safety notice to all customers who have received product in scope of this FSCA. Your customer is then required to complete the acknowledgement form and return to you.
2. We request that you check your inventory for product within the scope of this FSCA. Cease use and distribution of impacted product and quarantine immediately. You may then return all product in scope, refer to Appendix 2 for the list of impacted codes & lots, to Teleflex.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
4. 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.
5. If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below.
6. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, 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 customers, employees of Teleflex and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation 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.

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)86 3479154

Email: Recalls.Intl@teleflex.com

Please be advised that all 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 apologise 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.

For and on behalf of Teleflex,

Padraig Hegarty VP, Global QA (Manufacturing)

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000432

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +353 (0) 1 4370773 **E-Mail:** Recalls.Intl@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory DOES include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. Return Authorisation No _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY

PRODUCT NUMBER	LOT NUMBER	QUANTITY (Returning)

- Include a copy of the **completed Acknowledgement Form** in the returns package with the returned units
- Ensure the **RAN number** is clearly visible on the returns package
- Please label returns as **"Field Safety Returns"**

Complete this Acknowledgement form and return immediately by using fax number or e-Mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSITIUTION ADDRESS	Phone/FAX
FORM COMPLETED BY:	Stamp
PRINT NAME: _____	
SIGNATURE: _____	
DATE	

Appendix 2 – Product codes and Lots in Scope

Product Code	Lot Number					
A-8000I	74A1602932	74C1801547	74E1802464	74G1902569	74K1500387	74L1902305
	74A1703007	74C1801548	74E1900510	74H1602162	74K1502281	74L1902306
	74A1802909	74C2000213	74E1901525	74H1602618	74K1600247	74M1600558
	74A1900358	74C2000214	74F1502198	74H1701206	74K1601780	74M1700229
	74A2001172	74C2000473	74F1600345	74H1703208	74K1700695	74M1800724
	74A2002639	74C2000754	74F1600460	74H1801031	74K1701305	74M1801532
	74B1600856	74C2002285	74F1600461	74H1802122	74K1701886	
	74B1600857	74D1600915	74F1603155	74H1900242	74K1801271	
	74B1700269	74D1800630	74F1702091	74H1900251	74K1801272	
	74B1701278	74D1800632	74F1702491	74H1902213	74K1900069	
	74B1702684	74D1900143	74F1800692	74J1500448	74K1902094	
	74B1801734	74D1900144	74F1802178	74J1500865	74L1600158	
	74B1900875	74D1902087	74F1901722	74J1600969	74L1602510	
	74B1901993	74E1600936	74G1601816	74J1700548	74L1800465	
	74B1902825	74E1700397	74G1602512	74J1702261	74L1800953	
	74B2000066	74E1701189	74G1700142	74J1703038	74L1801262	
	74B2000361	74E1701196	74G1701822	74J1800939	74L1901155	
	74C1700392	74E1702207	74G1801551	74J1801384	74L1901156	
	74C1701906	74E1800301	74G1900712	74J1801385	74L1901427	
	74C1703150	74E1801286	74G1901738	74J1902581	74L1901428	
A-8000I-06	74A1801125	74C1902202	74F1900391	74J1901144		
	74A1902739	74C2000217	74F1901723	74J1901636		
	74A2000267	74C2000474	74G1600770	74K1500375		
	74A2000268	74C2001737	74G1601461	74K1500917		
	74A2000745	74C2001769	74G1801221	74K1501031		
	74A2000746	74C2001770	74G1900713	74K1502282		
	74A2000747	74D1700243	74H1502743	74L1500196		
	74A2001170	74D1801534	74H1502805	74L1500197		
	74A2001171	74D1802402	74H1800551	74L1500198		
	74A2001934	74D1902703	74H1802708	74L1801592		
	74A2001935	74E1701799	74H1802709			
	74A2001936	74E1900882	74H1900252			
	74B1800758	74E1901526	74H1901558			
	74B2000067	74F1500554	74J1500223			
	74B2000068	74F1500555	74J1500904			
	74B2000363	74F1500731	74J1502363			
	74B2000364	74F1700647	74J1800509			
	74C1800921	74F1700648	74J1802225			
	74C1801541	74F1702092	74J1802226			
	74C1900767	74F1900390	74J1900253			