

April 2022

URGENT – FIELD SAFETY NOTICE

Type of Action	Recall Notice
Teleflex Reference	EIF-000505
Lot Number	Refer to Appendix 2
Product Codes	Commercial Name
17731; 17732	Gibeck® Humid-Vent® 2S Flex DC
19061; 19062	Gibeck® Humid-Vent® Filter Compact S with Smooth-Flo® / Swivel
19812	Gibeck® Humid-Vent® Filter Compact S with Flex Tube
20011	Flex Tube
22511; 22512	Smooth-Flo® Flex with Double Swivel
22552	Smooth-Flo® Flex

Dear Customer,

Details of affected devices

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

Description of the problem & immediate actions required

Teleflex is initiating a voluntary Field Safety Corrective Action (FSCA) for the above-mentioned products due to reports of torn corrugated breathing tube.

- Should a tear be detected before use, a delay may be experienced while another product is located.
- Should a tear be detected during use, this may result in a leak and insufficient air supply to the patient with potential desaturation. Medical intervention in the form of a replacement of the defective tubing would be necessary for this instance.

Our records indicate you have received products that are in scope of this Field Safety Notification.

Depending on your 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 immediately quarantine the product.
2. If you do not have stock in scope of this FSCA, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and return the form to Teleflex at the contact details provided.
3. If you do have stock in scope of this FSCA, mark the applicable checkbox on the Acknowledgement Form (Appendix 1) and contact Customer Service by calling the phone number mentioned below. Customer Service will issue a return number to you. Write the return number into the respective field in the Acknowledgement Form and return this form immediately by email 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. Each 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 immediately quarantine the product. You may then return all product in scope.
3. As a distributor, you are then required to confirm to Teleflex that you have completed the field activity outlined in actions 1 and 2 of this Action List Number 2. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
Important - Please ensure you only list batch numbers in scope of this Field Safety Notice when completing this form.
4. Please be aware that all European Economic Area/Switzerland, United Kingdom (EEA/CH/UK) and Turkey (TR) 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 Customer Service 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/UK/TR 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 impacted 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. Please 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

Telephone: +353 (0)86 3479154

Email: Recalls.Intl@teleflex.com

Teleflex is committed to providing high quality, safe and effective products. We regret any inconvenience this action may cause your operations. If you have any other questions, please contact your local sales representative or Customer Service.

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty VP, Global QA (Manufacturing)

Appendix 1

Customer No

FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM

PRODUCT FIELD ACTION BY TELEFLEX – IMMEDIATE ATTENTION REQUIRED

Ref. EIF-000505

RETURN COMPLETED FORM IMMEDIATELY TO:

E-Mail: shereen.tay@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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Complete this Acknowledgement form and return immediately by using the contact information above.

Product code	Lot/batch number	Quantity returning
Important - Please ensure you only list batch numbers in scope of this Field Safety Notice when completing this form.		
<ul style="list-style-type: none"> 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" <p>Note: Non FSCA product returns should be processed per standard product return processes.</p>		

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

Appendix 2: Scope of Products for EIF-000505

Product Code	Batch					
17731	KMH21G0428	KMH21H0142	KMH21L0020	KMH22A0068	KMH21C0130	KMH21C0162
	KMH21C0262	KMH21C0265	KMH21E0077	KMH21F0231	KMH21F0276	
17732	KMZ21G0733	KMZ21G0742	KMZ21G0989	KMZ21G1049	KMZ21K0159	KMZ21K0160
	KMZ21K0275	KMZ21K0451	KMZ21L0103	KMZ21L0602	KMZ21C0125	KMZ21C0235
	KMZ21C0300	KMZ21C0347	KMZ21C0351	KMZ21C0475	KMZ21C0609	KMZ21C0851
	KMZ21C0863	KMZ21C1154	KMZ21C1342	KMZ21D0016	KMZ21D0200	KMZ21D0311
	KMZ21D0357	KMZ21D0404	KMZ21D0481	KMZ21D0510	KMZ21E0096	KMZ21F0475
	KMZ21F0483	KMZ21F0484	KMZ21F0873			
19061	KMH21F0418	KMH21G0357	KMH21H0060	KMH21H0062	KMH21H0252	KMH21J0021
	KMH21J0260	KMH21K0159	KMH21K0375	KMH21L0139	KMH21C0188	KMH21C0191
	KMH21C0194	KMH21C0280	KMH21C0388	KMH21D0094	KMH21D0289	KMH21D0290
	KMH21E0240	KMH21F0155				
19062	KMZ21C0425	KMZ21C0923	KMZ21F0379			
19812	KMZ21G0681	KMZ21G0710	KMZ21K0459	KMZ21C0141	KMZ21C0948	KMZ21F0361
	KMZ21F0627					
20011	KMH21F0393	KMH21F0394	KMH21F0395	KMH21F0412	KMH21H0094	KMH21H0095
	KMH21H0096	KMH21H0110	KMH21H0112	KMH21J0109	KMH21J0110	KMH21J0118
	KMH21J0121	KMH21J0124	KMH21K0302	KMH21K0303	KMH21K0306	KMH21K0307
	KMH21K0308	KMH21K0320	KMH21K0341	KMH21K0345	KMH21L0156	KMH21B0479
	KMH21B0480	KMH21B0482	KMH21B0483	KMH21C0229	KMH21C0230	KMH21C0231
	KMH21C0232	KMH21C0241	KMH21C0242	KMH21C0245	KMH21C0246	KMH21C0252
	KMH21C0366	KMH21C0367	KMH21C0368	KMH21C0377	KMH21C0378	KMH21D0204
	KMH21D0205	KMH21D0206	KMH21E0002	KMH21E0003	KMH21E0004	KMH21F0196
KMH21F0197	KMH21F0198	KMH21F0199	KMH21F0210	KMH21F0394		
22511	KMH21F0419	KMH21F0433	KMH21G0362	KMH21G0363	KMH21G0439	KMH21H0061
	KMH21H0171	KMH21H0199	KMH21H0222	KMH21H0248	KMH21J0209	KMH21J0220
	KMH21K0168	KMH21K0376	KMH21K0385	KMH21B0490	KMH21C0159	KMH21C0160
	KMH21D0172	KMH21D0316	KMH21D0360	KMH21E0024	KMH21E0223	KMH21F0148
	KMH21F0232	KMH21F0272	KMH21F0433			
22512	KMZ21F0898	KMZ21G0757	KMZ21G0865	KMZ21H0006	KMZ21H0106	KMZ21J0245
	KMZ21J0302	KMZ21J0504	KMZ21J0505	KMZ21J0538	KMZ21L0084	KMZ21L0407
	KMZ21L0660	KMZ21C0007	KMZ21C0166	KMZ21C0372	KMZ21C0422	KMZ21C0722
	KMZ21C0744	KMZ21C0924	KMZ21C1306	KMZ21D0858	KMZ21D0926	KMZ21D1057
	KMZ21D1116	KMZ21E0135	KMZ21E0203	KMZ21E0360	KMZ21F0387	KMZ21F0554
	KMZ21F0595	KMZ21F0702	KMZ21F0898	KMZ21G0757		
22552	KMZ21G0680	KMZ21G0689	KMZ21G0711	KMZ21G0801	KMZ21H0181	KMZ21H0182
	KMZ21J0246	KMZ21J0401	KMZ21J0584	KMZ21K0364	KMZ21K0365	KMZ21K0608
	KMZ21B1212	KMZ21B1213	KMZ21B1241	KMZ21C0130	KMZ21C1266	KMZ21D0957
	KMZ21F0181	KMZ21F0182	KMZ21F0518	KMZ21G0680		

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