

20th of October 2014

URGENT - FIELD SAFETY NOTICE

TYPE OF ACTION:		Recall		
TELEFLEX REFERENCE:		CAPA 006/14 (SCAR 040/13)		
Commercial Name	Model	Product Code	Alternative Part No.	Batch
BOSS SYSTEMS Soft Flex	01-06-7008-9	XKC01-06-7008-9	01-06-7008-09	Appendix 2
ICOR FH with Soft Flex & Swivel	01-06-9680-8	XKC01-06-9680-8	01-06-9680-8	
MAQUET Servo Filter Humidifier 173	01-06-8425-8	XKC01-06-8425-8	64 19 381	
MAQUET Servo Humidifier 163	01-06-8125-8	XKC01-06-8125-8	64 19 365	
VYGON Filtraflux + SoftFlex	01-06-6000-8	XKC01-06-6000-8	551.61	
	01-06-6200-8	XKC01-06-6200-8	551.31	
VYGON HEPA Filter Humidifier + SoftFlex	01-06-6600-8	XKC01-06-6600-8	551.33	
VYGON Softflex	01-06-7000-9	XKC01-06-7000-9	805.02	

Dear Customer,

1. Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed products.

2. Description of the problem

Teleflex Medical has issued a voluntary recall for the products listed in Appendix 2. Some connector mount cracks may lead to a leak failure during use, which will cause an equipment alarm and will necessitate immediate replacement in the breathing circuit.

If a leak exists and is left untreated, then the patient may be deprived of adequate anesthetic gases over a period of time and serious adverse health consequences may occur.



FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

1. We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
2. If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 2) and return the form to the fax number or e-Mail-address mentioned below.
3. If you have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 2). Contact customer service by calling the phone number mentioned in Section 6 who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.

4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.
2. As a Distributor you are 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.
3. 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.
4. 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.

3. Teleflex

Teleflex informs all customers, employees of Teleflex and distributors on this Field Action.

4. 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 centers etc. in the circulation of this notice.

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

5. Contact reference person

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

Customer Service:

Contact Shane Kenny

Telephone: +353 (0)90 6460869

FAX: +353 (0)1 4370773

E-mail: orders.intl@teleflex.com

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.

For and on behalf of Teleflex,

Padraig Hegarty

Padraig Hegarty

Senior Director of Quality International

Appendix 1

Customer No: _____

FIELD SAFETY CORRECTIVE ACTION

Teleflex Ref: CAPA 006/14 (SCAR 040/13)

Acknowledgement Form

URGENT ATTENTION REQUIRED

Return completed form immediately to:

FAX: +353 (0)1 4370773

E-mail: orders.intl@teleflex.com

Please check applicable box:

<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 has been stopped. All products are on hold and the quantity stated below will be returned.
<div style="border: 1px solid red; padding: 5px; display: inline-block; margin: 0 auto;"> Return Authorisation No _____ </div>	

Please CLEARLY print the below return information:

Names of Affected Products:			
BOSS SYSTEMS Soft Flex MAQUET Servo Filter Humidifier 173 MAQUET Servo Humidifier 163	VYGON Filtraflux + SoftFlex ICOR FH with Soft Flex & Swivel	VYGON HEPA Filter Humidifier + SoftFlex VYGON SoftFlex	
Product Number	(Size)	Lot Number	Quantity (Returning)

Return Instructions for Warehouse / Pharmacy Personnel:

- Please label product returns as "Field Action Returns".
 - Include a copy of this form (including RAN Number) with product returns.
- Returns excluding ALL necessary documentation **CANNOT** be processed.

Institution Name - (Hospital, Health Care Organisation, etc.)	
Institution Address:	Email Address:
Form completed by:	Phone Number:
Print Name:	Institution Stamp:
Signature:	
Date:	

Appendix 2

Commercial Name	Model	Product Code	Batch	Alternative Part No.	Commercial Name	Model	Product Code	Batch	Alternative Part No.				
BOSS SYSTEMS Soft Flex	01-06-7008-9	XKC01-06-7008-9	201326	01-06-7008-09	VYGON Filtraflux + SoftFlex	XKC01-06-6000-8	XKC01-06-6000-8	201319	551.61				
			201341					201324					
			201343					201325					
201244	201327												
ICOR FH with Soft Flex & Swivel	01-06-9680-8	XKC01-06-9680-8	201245	01-06-9680-8		VYGON Filtraflux + SoftFlex	01-06-6200-8	XKC01-06-6200-8	201329	551.31			
			201248						201334				
			201252						201245				
			201303						201249				
			201306						201252				
			201310						201303				
			201314		201310								
			201325		201314								
			201327		201318								
			201333		201319								
MAQUET Servo Filter Humidifier 173	01-06-8425-8	XKC01-06-8425-8	201335	64 19 381	VYGON Filtraflux + SoftFlex	01-06-6200-8	XKC01-06-6200-8	201324	551.31				
			201337					201325					
			201245					201326					
			201306					201327					
			201308					201329					
			201318					201330					
			201319					201331					
201331	201333												
MAQUET Servo Humidifier 163	01-06-8125-8	XKC01-06-8125-8	201336	64 19 365				VYGON HEPA Filter Humidifier + SoftFlex		01-06-6600-8	XKC01-06-6600-8	201335	551.33
			201337									201336	
			201321		201337								
201323	201339												
VYGON Filtraflux + SoftFlex	01-06-6000-8	XKC01-06-6000-8	201324	551.61	VYGON HEPA Filter Humidifier + SoftFlex	01-06-6600-8	XKC01-06-6600-8		201303	805.02			
			201249						201308				
			201252						201314				
			201306						201325				
			201310						201331				
			201314										
201318													
								VYGON Softflex	01-06-7000-9	XKC01-06-7000-9	201314	805.02	