

23rd December 2014

## URGENT - FIELD SAFETY NOTICE

TYPE OF ACTION:		Recall		
INMED REFERENCE:		CAPA 007/14 (SCAR 035/14)		
Commercial Name	Model	Product Code	Alternative Code	Batch
551.31 Filtraflux + Softflex	01-06-6200-8	XKC01-06-6200-8	551.31	Appendix 2
551.33 Hepa Filter Humidifier + Softflex	01-06-6600-8	XKC01-06-6600-8	551.33	
7 + Sft Triplus	01-06-3703-8	XKC01-06-3703-8	9017	
7+Sft	01-06-3780-8	XKC01-06-3780-8	01-06-3780-8	
805.02 Soft - Flex	01-06-7000-9	XKC01-06-7000-9	805.02	
Fh Soft	01-06-6280-8	XKC01-06-6280-8	01-06-6280-8	
Fh With Soft - Flex And Swivel Mounted	01-06-9680-8	XKC01-06-9680-8	01-06-9680-8	
Humid Vent Filter Compact S With Soft Flex/ Swivel Mounted	19412	XKC19412	19412	
Humid Vent Filter Compact S With Soft Flex/Swivel Mounted With Tethered Cap	19412T	XKC19412T	19412T	
Humid-Vent Filter Compact S With Soft - Flex / Elbow Mounted	19882	XKC19882	19882	
Humid-Vent Filter Light S With Soft Flex/Swivel Mounted	19112	XKC19112	19112	
Sfh173 Maquet	01-06-8425-8	XKC01-06-8425-8	6419381	
Sh163 Maquet	01-06-8125-8	XKC01-06-8125-8	6419365	
Soft Flex Tube	01-06-7080-9	XKC01-06-7080-9	01-06-7080-9	
Soft Flex With Cap Mounted	22582	XKC22582	22582	
Soft Flex With Double Swivel Sterile	22521	XKC22521	22521	
Soft Flex With Swivel Connector	01-06-9080-9	XKC01-06-9080-9	01-06-9080-9	
Soft-Flex With Double Swivel	22522	XKC22522	22522	
Soft-Flex With Elbow	22572	XKC22572	22572	
Vygon Fh+Sft With Elbow Connector Nm 551.61	01-06-6000-8	XKC01-06-6000-8	551.61	

Dear Customer,

### 1. Details of affected devices

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

### 2. Description of the problem

Inmed Medical has issued a voluntary recall for the products listed in Appendix 2. Some cracks may occur in the center of the corrugated flex tube of the 15mm and 22mm ISO female connector, 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. Inmed (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 Inmed 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 Inmed distribute directly will be notified by Inmed.
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 Inmed.

**3. Inmed**

Inmed informs all customers, employees of Inmed 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**  
**FAX: +353(0)1 4370773**

**Telephone: +353 (0) 906460869**  
**E-mail: [orders.intl@teleflex.com](mailto:orders.intl@teleflex.com)**

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

Inmed 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 Inmed,***

*Karen Boylan*

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**Karen Boylan**

**Global VP QA/RA**

**Appendix 1**

**Customer No:** \_\_\_\_\_

**FIELD SAFETY CORRECTIVE ACTION**

Inmed Ref: CAPA 007/14 (SCAR 035/14)

**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 <b>NOT</b> 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 <b>DOES</b> 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: 2px solid red; display: inline-block; padding: 5px 20px;"> <b>Return Authorisation No</b> _____         </div>	

**Please CLEARLY print the below return information:**

Names of Affected Products:						
551.31 Filtraflux + Softflex	7+SFT	FH with soft - Flex and Swivel Mounted	Humid-Vent Filter Compact s with Soft - Flex / Elbow Mounted	SH163 Maquet	Soft Flex with Double Swivel Sterile	Soft-Flex with Elbow
551.33 HEPA Filter Humidifier + Softflex	805.02 Soft - Flex	Humid Vent filter Compact s with Soft Flex/ Swivel Mounted	Humid-Vent Filter Light s with Soft Flex/Swivel Mounted	Soft Flex Tube	Soft Flex with Swivel Connector	Vygon FH+SFT with Elbow Connector nm 551.61
7 + SFT Triplus	FH Soft	Humid Vent Filter Compact s with Soft Flex/Swivel Mounted with Tethered Cap	SFH173 Maquet	Soft Flex with Cap Mounted	Soft-Flex with Double Swivel	
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.

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

Appendix 2

Commercial Name	Model	Product Code	Alternative Code	Batch No	Commercial Name	Model	Product Code	Alternative Code	Batch No	Commercial Name	Model	Product Code	Alternative Code	Batch No	Commercial Name	Model	Product Code	Alternative Code	Batch No														
551.31 Filtraflux + Softflex	01-06-6200-8	XKC01-06-6200-8	551.31	201350	Humid Vent filter Compact s with Soft Flex/ Swivel Mounted	19412	XKC19412	19412	201352	Soft Flex with Cap Mounted	22582	XKC22582	22582	201401	Soft-Flex with Double Swivel	22522	XKC22522	22522	201435														
				201351	Humid Vent Filter Compact s with Soft Flex/Swivel Mounted with Tethered Cap	19412T	XKC19412T	19412T	201350					22582	XKC22582	22582	201405	22572	XKC22572	22572	201405	Soft-Flex with Elbow	22572	XKC22572	22572	201350							
				201401					201352								201406				201351												
				201402					201403								201408				201352												
				201403					201405								13LT07				201402												
				201405					201406								13LT09				201405												
				201406					201410								14AT01				201406												
				201410	201349	14AT17	201407																										
				551.33 HEPA Filter Humidifier + Softflex	01-06-6600-8	XKC01-06-6600-8	551.33	201350	Humid-Vent Filter Compact s with Soft - Flex / Elbow Mounted					19882	XKC19882	19882	201352	Soft Flex with Double Swivel Sterile	22521	XKC22521	22521	201402	22572	XKC22572	22572	201408							
								201402	201402					14BT03	201410																		
201405	201405	14BT18	201419																														
201409	201410	14CT14	201422																														
201410	201349	14DT26	201423																														
7 + SFT Triplus	01-06-3703-8	XKC01-06-3703-8	9017	201403	Humid-Vent Filter Light s with Soft Flex/Swivel Mounted	19112	XKC19112	19112	201352	22521	XKC22521	22521	201406	22572	XKC22572	22572	201426																
7+SFT	01-06-3780-8	XKC01-06-3780-8	01-06-3780-8	201430	Humid-Vent Filter Light s with Soft Flex/Swivel Mounted	19112	XKC19112	19112	201409				22521				XKC22521	22521	201411	22572	XKC22572	22572	201427										
805.02 Soft - Flex	01-06-7000-9	XKC01-06-7000-9	805.02	201401					SFH173 Maquet										01-06-8425-8				XKC01-06-8425-8	6419381	201416	22521	XKC22521	22521	201415	22572	XKC22572	22572	201434
				201407																					201351				201349				201409
				201426																					201401				201404				201404
FH Soft	01-06-6280-8	XKC01-06-6280-8	01-06-6280-8	201439					SFH173 Maquet	01-06-8425-8	XKC01-06-8425-8	6419381		201402	22521	XKC22521			22521				201406	22572	XKC22572	22572	201402						
				201406	201403	201404	201402																										
FH with soft - Flex and Swivel Mounted	01-06-9680-8	XKC01-06-9680-8	01-06-9680-8	201349	SFH173 Maquet	01-06-8425-8	XKC01-06-8425-8	6419381	201404	22521	XKC22521	22521	201402	22572	XKC22572	22572	201402																
				201350					201403				201404				201402																
				201352					201404				201404				201402																
				201401					201404				201404				201402																
				201403					201404				201404				201402																
				201404					201404				201404				201402																
				201410					201413				201413				201427																
				201413					201414				201414				201428																
				201421					201415				201415				201433																
				201422					201417				201417				201433																
				201425					201419				201419				201433																
				201433					201422				201422				201433																
				201434					201434				201434				201433																
				Humid Vent filter Compact s with Soft Flex/ Swivel Mounted					19412				XKC19412				19412	201349	Soft Flex Tube	01-06-7080-9	XKC01-06-7080-9	01-06-7080-9	201350	22582	XKC22582	22582	201350	22572	XKC22572	22572	201427		
201350	201352	201428																															