INMED

**INMED MANUFACTURING SDN BHD**. ("Inmed")
c/o Teleflex,
IDA Business & Technology Park
Dublin Road,
Athlone Co. Westmeath,
Ireland

9th of December 2014

# URGENT - FIELD SAFETY NOTICE

| **TYPE OF ACTION:** | | Recall | | |
|---|---|---|---|---|
| **INMED 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

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



## 2. Description of the problem

Inmed 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. 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** **Telephone: +353 (0) 906460869**
**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 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,***

*Padraig Hegarty*

***Padraig Hegarty***
***Senior Director of Quality International***

**Appendix 1**

**Customer No: _____**

# FIELD SAFETY CORRECTIVE ACTION

**Inmed 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:**

| | |
|---|---|
| ☐ 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. | ☐ 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.<br>**Return Authorisation No _____** |

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

| **Names of Affected Products:** | | |
|---|---|---|
| **BOSS SYSTEMS Soft Flex**<br>**MAQUET Servo Filter Humidifier 173**<br>**MAQUET Servo Humidifier 163** | **VYGON Filtraflux + SoftFlex**<br>**ICOR FH with Soft Flex & Swivel** | **VYGON HEPA Filter Humidifier + SoftFlex**<br>**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:** |
| | **Phone Number:** |
| **Form completed by:** | |
| **Print Name:** | **Institution Stamp:** |
| **Signature:** | |
| **Date:** | |

## Appendix 2

| 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 |
| | | | 201341 | |
| | | | 201343 | |
| ICOR FH with Soft Flex & Swivel | 01-06-9680-8 | XKC01-06-9680-8 | 201244 | 01-06-9680-8 |
| | | | 201245 | |
| | | | 201248 | |
| | | | 201252 | |
| | | | 201303 | |
| | | | 201306 | |
| | | | 201310 | |
| | | | 201314 | |
| | | | 201325 | |
| | | | 201327 | |
| | | | 201333 | |
| | | | 201335 | |
| | | | 201337 | |
| MAQUET Servo Filter Humidifier 173 | 01-06-8425-8 | XKC01-06-8425-8 | 201245 | 64 19 381 |
| | | | 201306 | |
| | | | 201308 | |
| | | | 201318 | |
| | | | 201319 | |
| | | | 201331 | |
| | | | 201336 | |
| | | | 201337 | |
| MAQUET Servo Humidifier 163 | 01-06-8125-8 | XKC01-06-8125-8 | 201321 | 64 19 365 |
| | | | 201323 | |
| | | | 201324 | |
| VYGON Filtraflux + SoftFlex | 01-06-6000-8 | XKC01-06-6000-8 | 201249 | 551.61 |
| | | | 201252 | |
| | | | 201306 | |
| | | | 201310 | |
| | | | 201314 | |
| | | | 201318 | |

| Commercial Name | Model | Product Code | Batch | Alternative Part No. |
|---|---|---|---|---|
| VYGON Filtraflux + SoftFlex | XKC01-06-6000-8 | XKC01-06-6000-8 | 201319 | 551.61 |
| | | | 201324 | |
| | | | 201325 | |
| | | | 201327 | |
| | | | 201329 | |
| | | | 201334 | |
| | 01-06-6200-8 | XKC01-06-6200-8 | 201245 | 551.31 |
| | | | 201249 | |
| | | | 201252 | |
| | | | 201303 | |
| | | | 201310 | |
| | | | 201314 | |
| | | | 201318 | |
| | | | 201319 | |
| | | | 201324 | |
| | | | 201325 | |
| | | | 201326 | |
| | | | 201327 | |
| | | | 201329 | |
| | | | 201330 | |
| | | | 201331 | |
| | | | 201333 | |
| | | | 201335 | |
| | | | 201336 | |
| | | | 201337 | |
| | | | 201339 | |
| VYGON HEPA Filter Humidifier + SoftFlex | 01-06-6600-8 | XKC01-06-6600-8 | 201303 | 551.33 |
| | | | 201308 | |
| | | | 201314 | |
| | | | 201325 | |
| | | | 201331 | |
| VYGON Softflex | 01-06-7000-9 | XKC01-06-7000-9 | 201314 | 805.02 |