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01 February 2022

Updated Urgent Medical Device Field Safety Notice-Cover Letter for LEVEL 1® Fast Flow and Irrigation Fluid Warming Systems Potential for Aluminum Ions to Leach into Warmed Fluids

Dear Customer,

The purpose of this notice is to update you on the status of the attached Field Safety Corrective Action (FSCA) initiated by Smiths Medical regarding certain affected LEVEL 1 Fast Flow Fluid Warming and Irrigation System devices due to the potential for aluminum ion leaching into warmed fluids.

Please find attached the Updated Field Safety Notice and Response Form in English. Translated versions of the Updated Field Safety Notice and Response Forms in your local language will be sent to you as soon as they are available.

Instructions:

1. Please carefully read the attached Field Safety Notice.
2. Complete and sign the enclosed Response Form. Return the Response Form to OUS-Smiths@Sedgwick.com to acknowledge your receipt and understanding of this Updated Field Safety Notice within 10 days of receipt.

For questions or difficulties encountered regarding this Field Safety Corrective Action contact fieldactions@smiths-medical.com.

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,

Smiths Medical

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UPDATED URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

LEVEL 1® Fast Flow and Irrigation Fluid Warming Systems

Potential for Aluminum Ions to Leach into Warmed Fluids

Affected Device Models: Level 1® Fast Flow Fluid Warming System and Level 1® NORMOFLO® Irrigation System

Type of Action: Correction

Date: February 01, 2022

Attention: Nurses, Clinicians, Physicians, Risk Managers, Field Safety Coordinators

Affected Devices: Level 1® Fluid Warming System disposable products listed below:

Affected Product Model Name	Affected Product Model Number
Level 1® Fluid Warmer	H-1000, H-500
Level 1® Fluid Warming System	H-1025, H-1028, H-1200
Level 1® Normothermic I.V. Fluid Administration Set	D-100, D-300, D-50, D-60HL, DI-100, DI-300, DI-50, DI-60HL, D-70, DI-70
NORMOFLO® Fluid Warmer	H-1100, H-1129
NORMOFLO® Irrigation Warming Set	IR-40, IR-500, IR-600, IRI-600, IRI-600B, IR-700
H-2 Level 1® Pressure Chamber	7204012, 7204016, 7204017, 7204018, 7204019, 7204020, 7204030, 7204031, 7204034, 7204036, 7204037, 7204068, 7204066, 7204074
Level 1® High-Flow 3 Way Stopcock	SC-3
Level 1® High Flow Extension Line	X-36
Level 1® High Flow Extension with Injection Site	Y-INJ
Level 1® High Flow Y-Type Extension	Y-30
Level 1® Gas Vent/Filter Assembly Replacement	F-10, F-30
Level 1® Patient Line Sets	PL-6, PL-7

Reference Page 4 for representative pictures for some of these devices.

Dear Customer,

The purpose of this notice is to update you on the status of the voluntary Field Safety Corrective Action (FSCA) that Smiths Medical has initiated for certain Affected Product Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System devices listed above due to the potential for aluminum ion leaching into warmed fluids. Aluminum ion leaching has been identified in the disposables sets used with these systems.

UPDATE: The Notified Body completed their review of the Affected Product Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System devices listed on page 1 and has temporarily suspended the CE mark for the affected devices until further notice. Smiths Medical has initiated a project to address the issues raised by the Notified Body. Smiths Medical will contact you regarding updates to the status of the Field Safety Corrective Action when available. The List of Affected Devices (refer to page 1 of this notice) has been updated to include accessories associated with the affected devices.

REASON FOR FIELD SAFETY CORRECTIVE ACTION

Smiths Medical has investigated the potential for aluminum ion leaching in certain Smiths Medical fluid warming products and is providing recommendations to users of these devices in Switzerland based on feedback from Competent Authorities and our Notified Body.

Please note that this is an advisory notification and not a product removal. **No product return is necessary.**

This Field Safety Corrective Action is being performed with the knowledge of the Regulatory Bodies.

RISK TO HEALTH

Exposure to toxic levels of aluminum could potentially lead to serious injury or possibly death, depending on the treatment being administered and the patient's condition. Symptoms of toxic levels of aluminum exposure may not be readily recognizable and exposure effects may vary including bone or muscle pain and weakness, anemia, seizures, or coma.

The US Food and Drug Administration (FDA) has recently published additional information regarding this threshold: https://www.fda.gov/medical-devices/letters-health-care-providers/potential-risk-aluminum-leaching-use-certain-fluid-warmer-devices-letter-health-care-providers.

Smiths Medical has identified no complaints, or reports of injury or death, associated with this issue.

INSTRUCTIONS FOR ALL CUSTOMERS AND USERS

All customers who purchased Affected Product Models listed in the table on page 1 of this notice must identify any of these products within their possession and refer to the detailed information below.

- Please temporarily discontinue use of the Affected Product Models. Affected devices are on distribution hold for Switzerland until further notice.
- Users of Affected Product Models should seek out alternative devices where available. For hospitals without alternative devices immediately available, an assessment on the use of Smiths Medical's affected products should be limited primarily to the most urgent cases.
- In urgent cases where no replacement devices are available, and only for patients requiring ongoing therapy at ***slower flow rates***, Level 1® HOTLINE® products may be considered. Note, however, that these are not high flow devices and that the products subject to this FSCA are typically used in acute settings where high volumes of warmed fluids and blood are administered for clinical situations such as: trauma, post-partum hemorrhage and transplant.
- Healthcare facilities can report issues arising from device availability or any of the implementation actions requested in this FSN to Smiths Medical via fieldactions@smiths-medical.com.

ACKNOWLEGEMENT OF FIELD SAFETY NOTICE UNDERSTANDING – REQUIRED STEPS BELOW

1. Locate all Affected Devices in your possession and ensure all users or potential users of these devices are immediately made aware of this notification.

2. Complete and return the attached Response Form for the Updated Notice to OUS-Smiths@Sedgwick.com to acknowledge your receipt and understanding of this Updated Field Safety Notice within 10 days of receipt.

3. **DISTRIBUTORS:** Please immediately forward a copy of this notification and attachments to any of your customers to whom you've distributed affected product. Request that they complete the Response Form and return it to you. Please indicate your identity as the distributor and the consignees name and address.

Adverse events or quality problems experienced with the use of this product must be reported to Smiths Medical via globalcomplaints@smiths-medical.com.

For questions or difficulties encountered regarding this Field Safety Corrective Action contact fieldactions@smiths-medical.com.

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

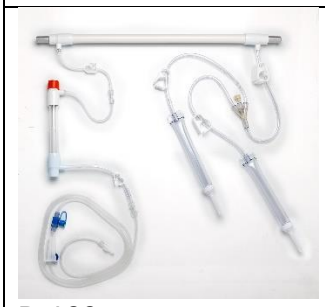
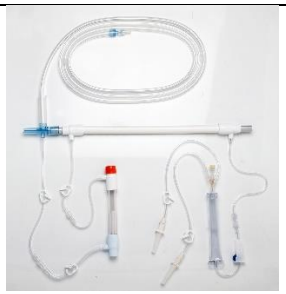
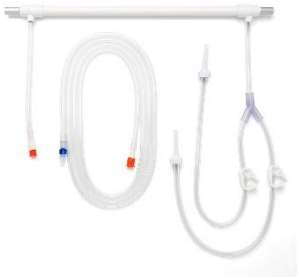
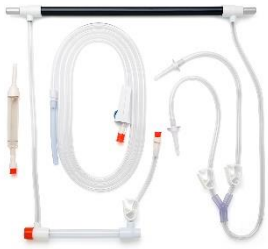
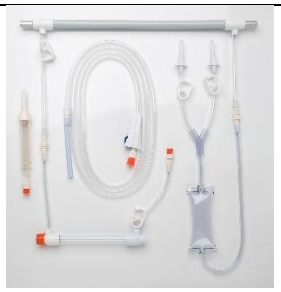
Sincerely,

Gitte Larsen

General Manager and Sales Director WEEA
Swiss Authorized Representative

Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442 USA

Enclosures:
Attachment 1 – Field Safety Notice Response Form

 H-1200	 H-1025	 H-1100	 H-1129
 D-100	 D-300	 IR-700	 D-60HL
 D-70	 IRI-40	 IR-500	 IR-600

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ATTACHMENT 1

UPDATED MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

Level 1® Fast Flow and Irrigation Fluid Warming Systems Potential for Aluminum Ions to Leach into Warmed Fluids

Business Name
Address 1
Address 2
Address 3
Address 4
City, State, Postal Code, Country

Please acknowledge receipt of the accompanying Urgent Medical Device Field Safety Notice by completing and returning this Response Form to OUS-Smiths@Sedgwick.com within 10 days. The Response Form must be completed and returned to Smiths Medical's representatives at Sedgwick even if you have no Affected Devices in your possession.

DISTRIBUTORS – Please provide a copy of this Response Form and the accompanying Field Safety Notice to any of your customers to whom you distributed affected devices and complete the For Distributors Only table at the end of page 1.

I certify that I have read and understand the information in the attached Field Safety Notice:

Affected Devices in your Inventory

Product Name	Product Code	Quantity

Name and Title (Please Print)	Signature and Date	Customer Number	Facility Name and Address*
Email Address	**Telephone Number**		

*If you are submitting a response form for multiple locations, please include the address for each facility you are responding for on the form or in an attachment.

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For Distributors Only

I have identified and notified my customers that were shipped or may have been shipped this product

Distributor Name_____

Distributor Address_____

Distributor Email Address/Phone Number_____