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URGENT MEDICAL DEVICE RECALL 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: August 17, 2021

Attention: Nurses, Clinicians, Physicians, Risk Managers, Recall 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

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

Dear Customer,

The purpose of this notice is to advise you that Smiths Medical has initiated a voluntary recall for certain Affected Models of LEVEL 1 Fast Flow Fluid Warming and Irrigation System Disposables listed above which contain aluminum heat exchangers, due to the potential for aluminum ion leaching into warmed fluids.

REASON FOR RECALL

Smiths Medical has investigated the potential for aluminum ion leaching in Smiths Medical fluid warming products and is providing users with operating parameters to ensure safe operation of the devices under certain clinical use conditions.

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

This recall is being performed with the knowledge of the Food and Drug Administration.

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.

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 Devices listed in the table on page 1 of this notice must identify any of these products within their possession and refer to the detailed instructions below. To mitigate the risk of exposure to aluminum, users must be aware of the following instructions when using affected device models. This information will also be provided in a printable placard which will be sent to you by a separate mailing.

WARNING: USE OF THESE DEVICES UNDER CERTAIN CONDITIONS MAY RESULT IN EXPOSURE TO HARMFUL LEVELS OF ALUMINUM

- Potentially higher aluminum leaching from these devices may occur when using lower flow rates (e.g., 30mL/min), with certain solutions and blood products, and longer duration of use.
- Normal Saline is preferred instead of balanced electrolyte solutions such as lactated Ringer's. Lactated Ringer's solution should be avoided, when clinically possible.
- The following patient populations are especially at risk: pediatric patients (particularly neonates and infants) pregnant women, elderly, patients with poor renal function or on dialysis.
- Evaluate the benefits and risks of using the device versus the patient condition.

These products 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. For patients requiring ongoing therapy at slower flow rates, Level 1® HOTLINE® products do not contain an aluminum heating element in the fluid path and may be considered as alternative devices.

Instructions to Customers:

1. If you are not the actual user of the device, please ensure this notification is provided to the end users of the products.
2. Information regarding the use of the placard will be provided in a future mailing.
3. Proceed to the acknowledgement instructions detailed below.

ACKNOWLEGEMENT OF RECALL 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 to smithsmedical7367@stericycle.com to acknowledge your receipt and understanding of this Recall 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.

Questions regarding this recall notification may be forwarded to fieldactions@smiths-medical.com.

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, the contact information is listed below.

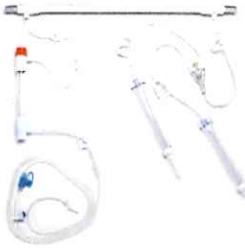
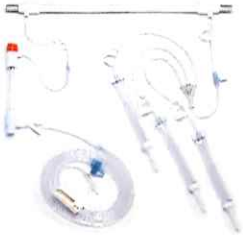
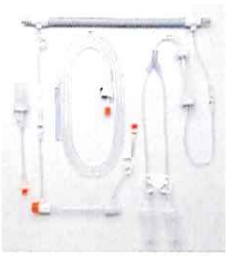
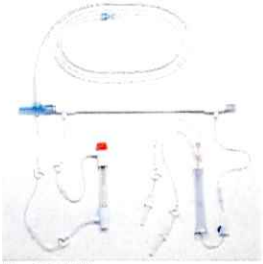
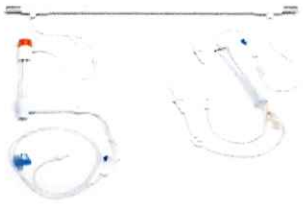
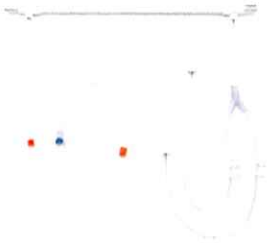
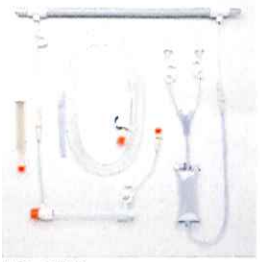
- **FDA Online: www.fda.gov/medwatch**
- **Call FDA at: 1-888-INFO-FDA**

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

Sincerely,

Daniel Khalili
Senior Vice President and Chief Global Regulatory and Quality Officer
Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442 USA

Enclosures:
Attachment 1 – Recall 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

MEDICAL DEVICE RECALL RESPONSE FORM

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

UNIVERSITY OF CAL DAVIS MEDICAL CENTER
2315 STOCKTON BLVD STE 0630
CLINCAL ENGINEERING DEPT
SACRAMENTO, CA 95817
US

Please acknowledge receipt of the accompanying Urgent Medical Device Recall Notice by completing and returning this Response Form to smithsmedical7367@stericycle.com within 10 days. The Response Form must be completed and returned Smiths Medical's representatives at Stericycle even if you have no Affected Devices (refer to List of Affected Devices on page 2 of this Response Form) in your possession.

DISTRIBUTORS – Please provide a copy of this Response Form and the accompanying Recall 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 Recall Notice:

Name and Title (Please Print)	Signature and Date	Customer Number	Facility Name and Address*	Number of Devices in Inventory Requiring Placards
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.

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_____