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: XXXXX

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

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 Field Safety Corrective Action 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 FIELD SAFETY CORRECTIVE ACTION

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 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.

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 accompanying this notice, which may be secured to or displayed near the product:

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. Enclosed you will find a Laminated Card with the "Warning" information mentioned above. This card contains a hole in the left top corner. A Ring is provided to secure it to a pole near the device.
3. Remove the Laminated Card and Ring from the package.
4. With the open end of the Ring, attach the Laminated Card to the pole clamp on the affected fluid warmer product.
5. Proceed to the acknowledgement instructions detailed below.

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 to smithsmedical7367@stericycle.com to acknowledge your receipt and understanding of this 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.

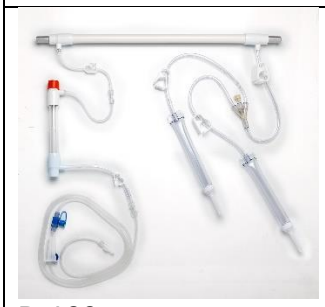
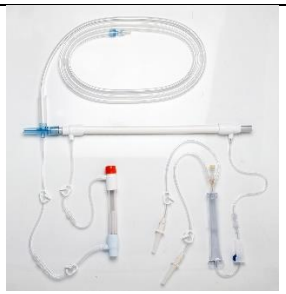
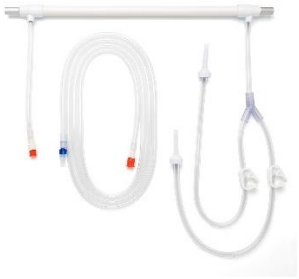
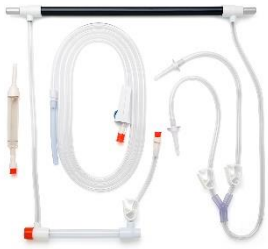
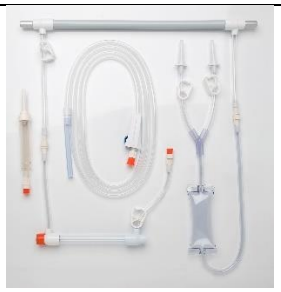
Questions regarding this Field Safety Notice may be forwarded to fieldactions@smiths-medical.com.

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

Sincerely,

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

Enclosures:
Attachment 1 – Field Safety Notice Response Form
Attachment 2 – Product Insert (Placard)

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