Smiths Medical International
Boundary Road
Hythe, Kent.
CT21 6JL

URGENT FIELD SAFETY NOTICE

For Level 1® Normothermic IV Fluid Administration Sets

Affected Devices:	Level 1® Normothermic IV Fluid Administration Sets
Type of Action:	Urgent Field Safety Corrective Action - Recall
Date:	February 28, 2011
Attention:	Risk/ Safety Managers, Clinicians, Nursing, Emergency Departments, Operating Rooms, Anaesthesia Department, Distributors and other users of these devices
Details on affected devices:	Product Reorder and Lot Numbers on the Attached List

Smiths Medical is conducting a voluntary Field Safety Corrective Action for a limited number of Level 1® Normothermic IV Fluid Administration Sets (“Sets”). This voluntary Action is being conducted with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has become aware of an increased trend in reports of kinking of the tubing on certain Sets. In some cases, the kink may lead to a decrease in the flow of fluid to the patient. A reduction in flow rate may lead to a delay of therapy, which could result in patient injury or death.

Kinking of the tubing can occur in the triple lumen tubing where the tubing connects to the aluminum tube heat exchanger (only applicable to the DI-65HL product) and in the small bore tubings – in the tube that connects from the heat exchanger to the F-50 Gas Vent Filter (“GVF”) and in the tube that connects from the manifold to the F-50 GVF.

This Urgent Field Safety Notice only applies to Sets equipped with the F-50 Gas Vent Filter Assembly listed on the Attached List. While Smiths Medical has received no reports of serious injury or death, and not all Sets will experience this issue, Smiths Medical is proactively recalling all potentially affected Sets.

Advice on Action to be Taken by the User:

Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers with Sets listed on Attachment 2 to return all unused Sets:

1. Inspect your inventory and segregate any unused product listed on Attachment 2; and
2. Complete and return the attached Confirmation Form (see Attachment 1) by Fax to +44 (0) 1303 266761 or by email to fluidadminsets@smiths-medical.com

<u>Advice on Action to be Taken by the Distributor</u>:

Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers with Sets listed on Attachment 2 to return all unused Sets:

1. Immediately stop distributing and quarantine all inventory listed on Attachment 2;

2. Perform a count of affected product currently in inventory; and
3. Complete and return the attached Confirmation Form (see Attachment 1) by Fax to +44 (0) 1303 266761 or by email to fluidadminsets@smiths-medical.com

As soon as we are able to resume supply for replacement product with the F50 Gas Vent Filter Assembly, we will notify you. Smiths Medical understands the critical nature of these Sets; therefore, until replacement product is available, we are providing the following options to clinicians who choose to use the affected Sets as a result of a critical clinical need:

- Set up product as described in the product's Instructions For Use. <u>Avoid moving the position of the clamps,</u> on the small bore tubing, located at the exit of the heat exchanger and the manifold (see Photo A). If the clamps are left in place on this tubing, as originally packaged, then the potential for a kink to diminish the flow rate is removed.

PHOTO A

- Closely monitor flow rates during use. If a diminished flow rate is observed, as a result of a kink in the tubing, the clinician can manually hold the tubing to support the tubing and establish a more normal flow (see Photo B).

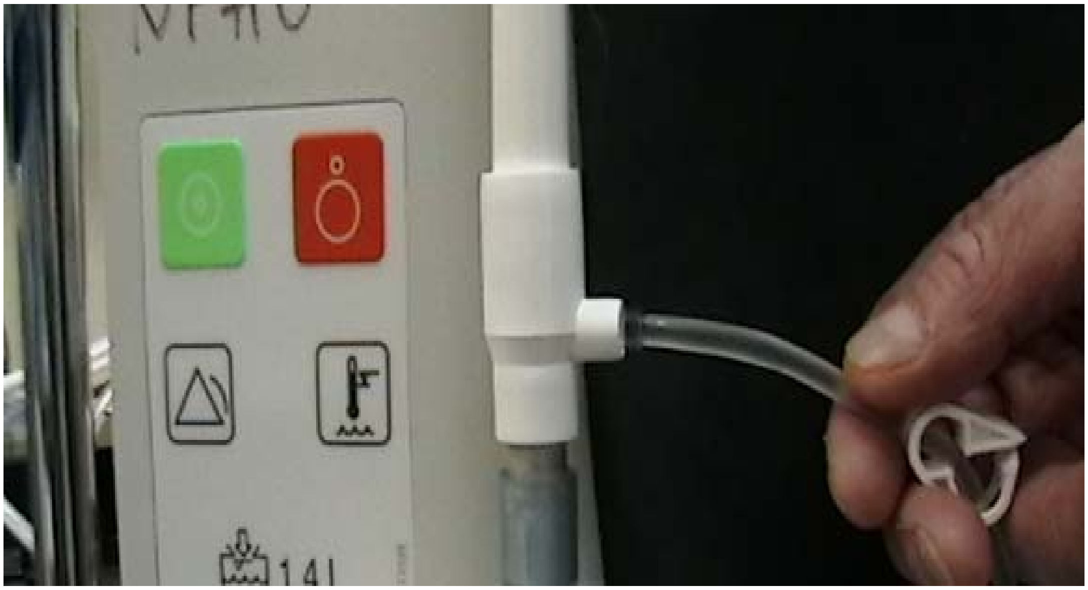

PHOTO B

Customers also have the option of temporarily reverting to use of the original Level 1® Normothermic IV Fluid Administration Sets that are not equipped with the F-50 Gas Vent Filter Assembly. These products are immediately available as replacements.

Product Codes WITH the F50 GVF Assembly	**Alternative Product Codes WITHOUT the F50 GVF Assembly**
DI-65HL	DI-60HL
DI-75	DI-50
DI-150	DI-100

If you choose to temporarily revert to use of the Level 1® Normothermic IV Fluid Administration Sets described above, please refer to the Quick Reference Guide attached to the Fluid Warming device for details on the safe use of these disposables. These instructions include the following warning:

Do not turn OFF the Fluid Warmer when the Air Detector alarm is active. If the Fluid Warmer is powered OFF in an active alarm state, the Air Detector/Clamp will open and the Air Detector will become disabled. This could allow any air within the Patient Line to be delivered to the patient resulting in serious injury or death.

If you require additional copies of the Quick Reference Guides, please contact Smiths Medical at fluidadminsets@smiths-medical.com or by telephone on 01923 241411

Transmission of this Urgent Field Safety Notice

This notice needs to be passed on to all personnel who need to be aware within your organization, including points of use or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this Field Safety Corrective Action.

If you should have any questions regarding this information, please contact Smiths Medical at fluidadminsets@smiths-medical.com or by telephone on 01923 241411

Smiths Medical is committed to providing quality products and service to its customers. We apologize for the inconvenience this situation may have caused.

Sincerely,

Mike Herbert
Regional Director Quality Systems UK
Smiths Medical
E-Mail: fluidadminsets@smiths-medical.com

Enclosures:
- Attachment 1 – Urgent Field Safety Notice Confirmation Form
- Attachment 2 – List of All Affected Product Reorder and Lot Numbers

Attachment 1

URGENT FIELD SAFETY NOTICE CONFIRMATION FORM
for Level 1® Normothermic IV Fluid Administration Sets

Please complete and return this Form by Fax to +44 (0) 1303 266761 or by sending an electronic copy via email to fluidadminsets@smiths-medical.com

Check the applicable boxes below:

☐	I **DO NOT** have affected Level 1® Normothermic IV Fluid Administration Sets remaining. All have been used or discarded.	
☐	I **DO** have unused inventory of affected Level 1® Normothermic IV Fluid Administration Sets, which I will return for credit. Please provide Product Reorder and Lot No. details on page 2 of this Form.	
☐	I no longer have any the affected Level 1® Normothermic IV Fluid Administration Sets. The Sets have been transferred to the following location:	

Printed Name: ______________________

Department: ______________________

Signature: ______________________

Date: ______________________

Facility Name: ______________________

Facility Address: ______________________
____
____

Shipping Address: ______________________
____
____

Phone Number: (   )   -   Ext:

Email: ______________________

Inventory of Affected Level 1® Normothermic IV Fluid Administration Sets

Facility Name: ____

Returning Product For **CREDIT**

Reorder Code		**Quantity**		**Please check if Qty is by: ☐box of 10 or ☐each**
Reorder Code		**Quantity**		**Please check if Qty is by: ☐box of 10 or ☐each**
Reorder Code		**Quantity**		**Please check if Qty is by: ☐box of 10 or ☐each**
Reorder Code		**Quantity**		**Please check if Qty is by: ☐box of 10 or ☐each**
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Reorder Code		**Quantity**		**Please check if Qty is by: ☐box of 10 or ☐each**
Reorder Code		**Quantity**		**Please check if Qty is by: ☐box of 10 or ☐each**

Attachment 2

List of Affected Product Re-Order and Associated Lot Numbers

Re-Order No.	Lot no.
DI-150	1816230
	1818485
	1830913
	1855261
	1792659
DI-65HL	1792659
	1792660
	1792661
	1798153
	1818482
	1824185
	1824186
	1830934
	1830935
	1839591
	1839592
	1839593
	1839594
	1865967
	1865968
	1880863

Re-Order No.	Lot no.
DI-75	1792664
	1824193
	1826783
	1839595
	1839596
	1839597
	1843949
	1870656
	1870658
	1873608
	1880864
	1913892