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Smiths Medical ASD, Inc.
160 Weymouth Street
Rockland MA 02370 USA

URGENT FIELD SAFETY NOTICE

For Level 1® D/DI-60HL Normothermic IV Fluid Administration Sets,

Affected Devices:	Level 1® D/DI-60HL Normothermic IV Fluid Administration Sets
Type of Action:	Urgent Field Safety Corrective Action - Recall
Date:	28 November 2011
Attention:	Risk/ Safety Managers, Clinicians, Nursing, Emergency Departments, Operating Rooms, Anaesthesia Departments, Distributors and other users of these devices
Details on affected devices:	Lot Numbers of D-60HL/ DI-60HL Sets on the Attached List

Smiths Medical is conducting a voluntary recall for a limited number of Level 1® D/DI-60HL Normothermic IV Fluid Administration Sets ("Sets"). This voluntary recall is being conducted with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has become aware of an increased trend in reports of disconnections of the Luer lock connector at the patient end of the tubing on certain Sets. If the Luer lock connector disconnects during use, this could result in fluid/ blood loss and/ or a delay in therapy, which could result in patient injury or, while highly unlikely, death.

This Urgent Field Safety Notice only applies to Sets 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 781.610.9859 or by email to hotlineconnectorrecall@smiths-medical.com

Advice on Action to be Taken by the Distributor:
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 781.610.9859 or by email to hotlineconnectorrecall@smiths-medical.com

Replacement product is currently available. Smiths Medical understands the critical nature of these Sets; therefore, until you receive your replacement product, Smiths Medical is providing the following options to clinicians who choose to use the affected Sets as a result of a critical clinical need:

- Inspect the Luer connector connection to the tubing prior to use and if the connection is not secure, do not use the Set. Use an alternative D-60HL/ DI-60HL Set.
- Use a DI-50, D-70, D-100/DI-100, or D-300/ DI-300 Disposable as an alternative Set.

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 1-781-763-9330.

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

Sincerely,

Alejandro Guzman
Manager, Quality Systems
Smiths Medical ASD, Inc.

Enclosures:
Attachment 1 – Urgent Field Safety Notice Confirmation Form
Attachment 2 – List of Affected Lot Numbers

Attachment 1

URGENT FIELD SAFETY NOTICE CONFIRMATION FORM
for Level 1® D-60HL/ DI-60HL Normothermic IV Fluid Administration Sets from Lots listed in Attachment 2

Please complete and return this Form by Fax to 781.610.9859 or by sending an electronic copy via email to hotlineconnectorrecall@smiths-medical.com

Check the applicable boxes below:		
☐	I **DO NOT** have affected Level 1® D-60HL/ DI-60HL Sets remaining. All have been used or discarded.	
☐	I **DO** have unused inventory of affected Level 1® D-60HL/ DI-60HL Sets, which I will return for replacement or credit. Please provide Lot No. details on page 2 of this Form.	
☐	I no longer have any the affected Level 1® D-60HL/ DI-60HL Sets. The Sets have been transferred to the following location:	

Printed Name: ____________________

Department: ____________________

Signature: ____________________

Date: ____________________

Facility Name: ____________________

Facility Address: ____________________

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Shipping Address: ____________________

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____

Phone Number: ( ) - Ext:

Email: ____________________

Inventory of Affected Level 1® D-60HL/ DI-60HL Sets

Facility Name: ______________________________

Returning Product For ☐ **REPLACEMENTS** ☐ **CREDIT**

Lot No.		**Quantity**		**Please check if Qty is by:** **☐box of 10 or ☐each**
Lot No.		**Quantity**		**Please check if Qty is by:** **☐box of 10 or ☐each**
Lot No.		**Quantity**		**Please check if Qty is by:** **☐box of 10 or ☐each**
Lot No.		**Quantity**		**Please check if Qty is by:** **☐box of 10 or ☐each**
Lot No.		**Quantity**		**Please check if Qty is by:** **☐box of 10 or ☐each**
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Lot No.		**Quantity**		**Please check if Qty is by:** **☐box of 10 or ☐each**
Lot No.		**Quantity**		**Please check if Qty is by:** **☐box of 10 or ☐each**

D and DI-60HL Customer Notification Letter
Attachment 2

D-60HL Lot Numbers

2007387	
2007481	
2039138	
2049500	
2064090	
2099045	

DI-60HL Lot Numbers

2033447	
2039136	
2046398	
2046400	
2047961	
2047963	
2064528	
2064529	
2064530	
2077404	
2077405	
2077406	
2077407	
2087667	
2099050	
2099766	
2102361	