

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

URGENT FIELD SAFETY NOTICE

**For HOTLINE[®] Blood and IV Fluid Warming Sets,
Certain Lots of Product Codes L-70, L-70NI, L-80, L-270, and L-370**

Affected Devices:	HOTLINE [®] Blood and 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 L-70, L-70NI, L-80, L-270, and L-370 Sets on the Attached List

Smiths Medical is conducting a voluntary recall for a limited number of HOTLINE[®] Blood and IV Fluid Warming Sets, Product Codes L-70, L-70NI, L-80, L-270, and L-370 ("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 +44(0)1233 722153 or by email to ukcs@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

7 November 2011

Page 2

3. Complete and return the attached Confirmation Form (see Attachment 1) by Fax to +44(0)1233 722153 or by email to ukcs@smiths-medical.com.

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 +44(0)1923 241411, Option 1.

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

Sincerely,



Daniel Murray
Manager, Quality Systems
Smiths Medical International.

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 HOTLINE® Blood and IV Fluid Administration Sets
Lots of Product Codes L-70, L-70NI, L-80, L-270, and L-370 Listed in Attachment 2**

Please complete and return this Form by Fax to +44(0)1233 722153 or by sending an electronic copy via email to ukcs@smiths-medical.com

Check the applicable boxes below:	
<input type="checkbox"/>	I DO NOT have affected HOTLINE® L-70, L-70NI, L-80, L-270, or L-370 Sets remaining. All have been used or discarded.
<input type="checkbox"/>	I DO have unused inventory of affected HOTLINE® L-70, L-70NI, L-80, L-270, or L-370 Sets, which I will return for replacement or credit. Please provide Product Code and Lot No. details on page 2 of this Form.
<input type="checkbox"/>	I no longer have any the affected HOTLINE® L-70, L-70NI, L-80, L-270, or L-370 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: _____

Hotline Customer Notification Letter Attachment 2

L-70 Lot Numbers

1961565		2025128		2077207	
1967233		2025129		2083507	
1967234		2025130		2083508	
1967235		2025131		2084305	
1967236		2025133		2090782	
1967237		2025134		2090783	
1967238		2025135		2093663	
1967239		2033081		2093664	
1967240		2033082		2095298	
1973118		2033083		2095300	
1973119		2033084		2101204	
1982938		2033085		2101205	
1982939		2033086		2101206	
1983243		2042613		2101207	
1983244		2042614		2101208	
1983246		2042615			
1989241		2042617			
1989242		2042618			
1989243		2049316			
1989244		2049317			
1989245		2049318			
1995431		2049437			
1995554		2049438			
1995555		2055173			
1995556		2055174			
1995698		2055175			
1995699		2055176			
1995700		2059473			
1995701		2059474			
1995702		2059475			
2007275		2064014			
2007276		2064015			
2007277		2064017			
2007278		2064018			
2019640		2068138			
2019641		2068139			
2019642		2068140			
2019643		2068141			
2019644		2068142			
2025123		2077203			
2025125		2077204			
2025126		2077205			
2025127		2077206			

Attachment 2 continued

L-70NI Lot Numbers

1967243		2068144	
1967244		2068145	
1973126		2068146	
1979964		2077341	
1979965		2077342	
1979966		2083509	
1981255		2087640	
1981256		2090784	
1981257		2090785	
1981258		2090786	
1981259		2095293	
1995557		2095294	
2007279		2099545	
2007280		2099546	
2007281		2105392	
2007282			
2019645			
2019646			
2025136			
2025137			
2025138			
2025140			
2025143			
2025144			
2025145			
2042619			
2042620			
2042621			
2042622			
2042623			
2042624			
2042625			
2049440			
2049441			
2049442			
2059476			
2059477			
2059478			
2059479			
2064019			
2064020			
2064021			
2068143			

Attachment 2 continued

L-80 Lot Numbers

1974580	
2007256	
2064012	
2089416	
2093985	

L-270 Lot Numbers

1947531	
1952652	
1957058	
1957059	
1967245	
1967246	
1979007	
1995553	
1995693	
1998983	
1998984	
2019637	
2019638	
2019639	
2025120	
2025121	
2038143	
2038144	
2038146	
2038147	
2049439	
2059469	
2059470	
2064010	
2068137	
2077198	
2077199	
2077200	
2090779	

Attachment 2 continued

L-370 Lot Numbers

1995695	
1995696	
2038150	
2038151	
2038152	
2047423	
2061923	
2061924	
2061929	
2061930	
2061931	
2061932	
2061933	
2077201	
2077202	
2090780	
2090781	
2095295	
2095302	
2095306	