IRISH MEDICINES BOARD
SAFETY NOTICE

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Level 1® Normothermic IV fluid administration sets for use with the Level 1® fast flow fluid warmer units

IMB Safety Notice: SN2011(05)
Circulation Date: 08 April 2011

MANUFACTURER/SUPPLIER
Smiths Medical

TARGET GROUPS
All Hospital Staff
Emergency Departments
Intensive Care Units
Cardio Thoracic Units
Clinical Perfusionists
Theatre Managers
Theatre Nurses
IV Nurse Specialists
Risk Managers
Central Sterile Supply Department (CSSD) Personnel
Clinical / Biomedical Engineering
Purchasing Managers

ISSUE
Smiths Medical has become aware of an increased trend in reports of kinking of the tubing on certain Level 1® Normothermic IV Fluid Administration Sets (Models DI-65HL, DI-75 and DI-150). 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.

BACKGROUND
Smiths Medical has ceased production and supply of the affected devices and has initiated a removal of affected devices from the market. To prevent recurrence of this kinking issue, Smiths Medical will implement a design change on the affected sets. As outlined in the attached field safety notice, Smiths Medical will supply alternative replacement sets pending availability of the new product.

Users should note that these alternative replacement sets are <u>not</u> equipped with the F-50 Gas Vent Filter Assembly and there is a risk of air embolism with the device if the power supply to the fluid warmer unit is interrupted during an air detection alarm e.g. by manually switching off the power during an air detection event. Smiths Medical issued a quick reference guide in 2007 to notify users of this air embolism issue. Refer

SAFETY NOTICE

to the attached IMB Safety Notice SN2008(2) for additional information on the quick reference guide.

ACTION OR RECOMMENDATIONS

The Irish Medicines Board advises users of this product to inspect their inventory and segregate the affected products for return to the manufacturer as per the attached field safety notice.

Users should exercise extreme caution when using the alternative replacement products and remain cognisant of the clinical risks associated with these sets, which are not equipped with the F-50 Gas Vent Filter Assembly.

Users should also take care to:

- Ensure that all Level 1® fast flow fluid warmer units contain a copy of the quick reference guide distributed by Smiths Medical in 2007.
- Contact the manufacturer to request a copy of the quick reference guide if required.

ENQUIRIES

Enquiries to the manufacturer / European authorised representative should be addressed to:

Mr. Franz Korner
Smiths Medical
Bretonischer Ring 3
Grasbrunn
D-85630
Germany

Tel: +49 89 242959 345
Fax: +49 89 242959 327
E-mail: eu.rep@smiths-medical.com

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie