Smiths Medical International Ltd
Bramingham Business Park,
Enterprise Way,
Luton,
Beds, LU3 4BU
UK

URGENT FIELD SAFETY NOTICE

Omnifuse UK Mains Power Leads

Affected Devices:	UK Mains Power Lead, Part # 0151-0651 – for use with all models of Omnifuse Syringe Pumps
Type of Action:	Field Safety Corrective Action - Recall
Date:	5 September 2014
Attention:	Risk/Safety Managers, Biomedical Professionals, Clinicians who oversee the use of Omnifuse pumps, and other users of these devices
Details on affected devices:	UK Mains Power Lead, Part # 0151-0651 – for use with all models of Omnifuse Syringe Pumps

Dear Customer,

Smiths Medical is providing this Urgent Field Safety notice to advise its customers of a voluntary recall for UK Mains Power Leads, Part # 0151-0651, for use with all models of Omnifuse Syringe Pumps.

Smiths Medical has identified an issue with the UK Mains Power Lead supplied for use with the Omnifuse Syringe Infusion Pump. The power lead has surface depressions in the area specifically stated on the product specification drawing to be kept free of approval marks, etc. See photograph below. The surface needs to be flat.

Additionally, the angle of the chamfered edge of the incorrect power lead is <u>different</u> from the original mains lead. The shape of the incorrect power lead makes it more difficult to fit the power lead retainer as described in the Operation Manual. This creates a potential risk that the user may give up and use the pump without the power lead retainer. Use of the power lead without the power lead retainer increases the vulnerability of fluid ingress into the power

receptacle. It is also more likely that the retainer screw thread would become damaged after several fitments and would then become impossible to fit.

Original Mains Lead

Incorrect Mains Lead

If fluid enters the power receptacle there is a potential for electrical shorting, which would most likely render the pump inoperable, resulting in an interruption or delay in therapy. Loss of power resulting from the mains power lead becoming inadvertently disconnected from the pump (because the power retainer does not fit over the mains power lead) may result in interruption or delay in therapy. There have been no reports of patient injury associated with this issue.

Advice on Action to be taken by the User:

Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers to dispose of all affected mains power leads and contact Smiths Medical for replacement.

1) Inspect your inventory and remove all affected mains power leads from use.
2) Complete and return the attached Urgent Field Safety Notice Confirmation Form by fax to +44 (0)1582 430001 or by email to ukcs@smiths-medical.com within five (5) days of receipt of this notice. Upon receipt of the completed form, a customer service representative will contact you to arrange for exchange of your affected devices for replacement.

Transmission of this Urgent Medical Device Recall Notice

This notice shall 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. If you or your facility has distributed these affected products to other persons or facilities, please promptly forward the recipients a copy of this Urgent Medical Device Recall Notice.

Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this recall.

Customers shall report any issues with these products to Smiths Medical's Global Complaint Department at +00 800 76 48 47 00 or globalcomplaints@smiths-medical.com.

If you should have any questions regarding this information, please contact Smiths Medical's Customer Service Department at (0) 845 850 0445.

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

Sincerely,

Jason Whittle
Regional Manager, Quality Systems (UK)
Smiths Medical International Ltd

Enclosures: Attachment 1 – Urgent Field Safety Notice Confirmation Form

ATTACHMENT 1 Smiths Medical International Ltd

URGENT FIELD SAFETY NOTICE CONFIRMATION FORM
For Omnifuse UK Mains Power Leads – 5 September 2014

Please complete and return this Form by fax to +44 (0)1582 430001 or by sending an electronic copy via email to ukcs@smiths-medical.com.

☐ YES –I have affected UK Mains Power Lead, Part # 0151-0651 and will dispose of them. Please contact me using the details provided below to provide me with instructions on obtaining a replacement. ____ Number of mains power leads disposed of	
☐ NO – We do not have any of the affected products – they have been disposed of. _____ Number of mains power leads disposed of	
☐ We no longer have any of the affected products. We transferred them to the following location: *(please provide name, address, and phone number and email address):* _____ Number of mains power leads transferred	
Customer/ Facility Name:	Facility Address:
Signature:	Facility Shipping Address:
Print Name:	Date:
Department:	
Email:	Phone Number: