smiths medical

URGENT: FIELD SAFETY NOTICE

Medfusion™ Syringe Infusion Pumps – Potential Syringe Misrecognition

21st December 2023

Dear Valued Medfusion Customers:

On 13 April 2018, Smiths Medical advised you about a potential issue with certain Medfusion Model 4000 and 3500 syringe infusion pumps manufactured or serviced with specific lots of Barrel Clamp Guides. Smiths Medical is issuing this updated communication to make you aware that three additional lots of Barrel Clamp Guides are affected and notify you of the actions taken by Smiths Medical. Please review all products in your inventory to determine if they are affected by the issue in this notice.

Affected Products:

Medfusion Model 4000 and 3500 pumps manufactured or serviced with the additional lots of the Barrel Clamp Guide are potentially affected by this issue. See table below for the device serial numbers of affected devices distributed in Germany.

SKU/Model/Item	Item Description	Affected Device Serial Numbers
3500-0600-51	PUMP, MEDFUSION, MODEL GLOBAL 3500, V6	M110385
		M110386
		M110387
		M110966

Overview of the Issue:

Smiths Medical identified that certain Barrel Clamp Guides from the above lots may contain a molding defect that could potentially lead to slippage of the spring within the barrel clamp assembly. If this occurs, it could result in the inability of the pump to recognize a syringe or the pump may misidentify the size of the syringe loaded.

Potential Risk:

The inability of the pump to recognize a loaded syringe can potentially lead to a delay in the initiation of an infusion due to clinicians being unable to complete programming. Interruption of therapy may potentially occur if syringe recognition is lost during an active infusion. Note, the pump will display a visual and audible alarm in this scenario. Misidentification of the syringe size may potentially result in over-delivery or under-delivery if the clinician does not verify the syringe size prior to starting an infusion.

As reported in the 2018 communication, Smiths Medical had received one (1) report of a serious injury potentially related to this issue. There are no new reports of serious injury or death.

Customer Required Actions – Medfusion Infusion Pumps:

1. Locate any affected Medfusion Syringe Pumps that may be in your possession by referring to the table of affected devices on page 1 and ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations. Note each pump has a unique serial number found on the label on the bottom of the pump.

2. You may continue to use the pumps but utilize the Syringe Verification Reference Tool originally included with the 2018 Notice (also provided as Attachment 2 of this communication) until pumps containing potentially affected Barrel Clamp Guides are repaired.

3. Complete and return the attached Response Form to EMEA-FSN@icumed.com within **ten days** of receipt to acknowledge your understanding of this notification.

4. **DISTRIBUTORS**: If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to YOU. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

For further inquiries, please contact Smiths Medical using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Technical Support / Field Safety Notice	servicece@icumed.com	Additional information or technical assistance, Questions about this Field Safety Notice

Smiths Medical's Actions:

Smiths Medical implemented the corrective actions necessary to address the manufacturing variations that led to these issues and will contact the customer for repair after the response form is completed and returned.

General Information

Your country regulatory agency has been notified of this action.

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

Sincerely,

[redacted]

***Note:** Response form on next page*

smiths medical

URGENT FIELD SAFETY NOTICE: RESPONSE FORM

Medfusion™ Syringe Infusion Pumps – Potential Syringe Misrecognition

21st December 2023

Check your inventory and complete the information below, even if you do not have the affected product.

Complete this form and return it by email to *EMEA-FSN@icumed.com*. If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

☐ **YES**, I have affected product, I have notified users in my facility and I have followed the instructions provided to me (complete and return this form to EMEA-FSN@icumed.com).

☐ I have **NO** affected product (complete and return this form to EMEA-FSN@icumed.com)

☐ Devices transferred/no longer owned; please indicate new owner contact information:

- Business Name: _____
- Address/City/State/ZIP: _____
- Contact Name: _____
- Contact Phone/E-mail Address: _____

- Have you distributed the product further to the retail level? ☐ **YES** ☐ **NO**
  - If yes, have you notified your retail customers and asked them to contact Smiths Medical to obtain a response form? ☐ **YES** ☐ **NO** (if no, explain below)

If you have distributed the product further, please provide the list of your retail customers, inclusive of customer name, address, city, state, zip code, telephone number and quantity of product distributed along with your completed response form to the contact information listed above so Smiths Medical can verify effectiveness of the recall notification to the appropriate level.

Adverse events and complaints associated with the use of this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.