Updated URGENT MEDICAL DEVICE CORRECTION

Medfusion™ Syringe Infusion Pumps – Syringe Recognition Barrel Clamp Guide

19 December 2023:

Dear Valued Medfusion Customers:

- Director of Pharmacy
- Director of Nursing
- Director of Risk Management

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 of three additional lots of affected Barrel Clamp Guides and 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. Table 1 below identifies the additional (3) lots.

Affected Products:

Medfusion Model 4000 and 3500 pumps manufactured or serviced with the lots of Barrel Clamp Guide (Part Number G6000716) listed below are potentially affected by this issue.

This includes:

- Medfusion Model 4000 and 3500 pumps manufactured or serviced with these potentially affected Barrel Clamp Guides between Jul-2016 and Apr-2021.
- Individually sold Barrel Clamp Guides from the identified lots, distributed between Jul-2016 and Oct-2018.

Table 1:

Affected Barrel Clamp Guide Lots (Additional 3 Lots)
P0407365
P0486670
P0561740

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 list of affected devices included with the Response Form. This list includes any specific pump model/serial number(s) your organization purchased that were manufactured or serviced with potentially affected Barrel Clamp Guides. 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.

Customer Required Actions – Individually Sold Barrel Clamp Guides:

1. Locate any affected Barrel Clamp Guide (Part Number G6000716) lots in your parts inventory or within the Medfusion Syringe Pump(s) you have repaired at your facility. NOTE – If you have purchased affected individually sold Barrel Clamp Guides, the Response Form included with this notice will indicate the order numbers shipped to your organization and a Return Label will be provided.

2. If any potentially affected Barrel Clamp Guides have already been installed in pumps, 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 the pumps installed with potentially affected Barrel Clamp Guides are repaired. If you have affected devices, please contact Smiths Medical for repair of the pump.

Customer Required Actions – All Customers

- Ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations.
- Complete and return the attached Response Form via fax at 1-800-517-3560 or email to smithsmedical3853@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification.

- DISTRIBUTORS: If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Ask them to contact Sedgwick at 1-866-535-5093 (M-F, 8am-5pm ET) to obtain a Response Form.

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 1-(866)-216-8806	To report adverse events or product complaints
Technical Support	icumed.custhelp.com/app/market-action	Additional information or technical assistance
Field Corrections	icumed.custhelp.com/app/market-action	Questions about this Field Correction 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.

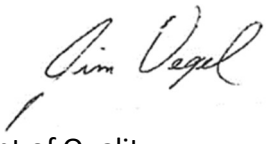
General Information:

This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA). If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch
- 1-888-463-6332

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

Sincerely,



Jim Vegel
Vice President of Quality

Enclosures:
Attachment 1 – Response Form
Attachment 2 – Syringe Verification Reference Tool