URGENT MEDICAL DEVICE RECALL NOTICE

Medfusion® Model 4000 and 3500 Syringe Pump – Syringe Recognition

Type of Action:	Recall – Correction and Removal
Date:	February 20, 2018
Attention:	Distributors of and Clinicians who use the Medfusion® Syringe Pump Model Series 3500 and 4000
Affected Devices:	**The following products are potentially affected by this issue:**

Medfusion® 3500 Series
Syringe Pump

Medfusion® 4000 Series
Syringe Pump

Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary recall for certain Medfusion® Syringe Pump Model Series 3500 and 4000. This recall affects certain serial numbers manufactured or serviced between February 2015 and November 2017. Serial number information for affected products in your possession can be found on page 2 of the Urgent Medical Device Recall Response Form accompanying this notice.

REASON FOR RECALL:

In January 2018, Smiths Medical issued a Field Safety Notice that included a Reference Tool reinforcing the need to check syringe size. Upon completion of our investigation, Smiths Medical identified that certain Medfusion® Syringe Pump Model Series 3500 and 4000 pumps were assembled with a barrel clamp guide that contained a ridge in the component. This ridge could potentially lead to spring slippage, resulting in the inability of the pump to recognize a syringe or the pump may misidentify the size of syringe loaded.

RISK TO HEALTH:

The inability of the pump to recognize a 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 loss of recognition occurs during an active infusion (Note – the pump will alarm in this scenario).

Misidentification of 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.

Smiths Medical has received 1 (one) report of serious injury related to this issue.

INSTRUCTIONS TO CUSTOMERS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS RECALL:

1. Locate the affected Medfusion® Syringe Pump(s) by referring to the list of affected devices on page 2 of the attached Urgent Medical Device Recall Notice Response Form. This form provides the specific serial number(s) your organization purchased. Each pump has a unique serial number which can be found on the label located on the bottom of the pump.

2. Review and complete the attached *Urgent Medical Device Recall Response Form* and return it to SmithsMedical3033b@stericycle.com within 10 days of receipt of this Recall Notice. The form must be returned even if you no longer have any of the potentially affected Medfusion® 4000 or 3500 Syringe Pumps in your possession.

3. A Smiths Medical Representative will be contacting your facility to discuss repair options once you have returned your completed Urgent Medical Device Recall Response Form.

Review and complete the attached *Urgent Medical Device Recall Response Form* and return it to SmithsMedical3033b@stericycle.com within 10 days of receipt of this Recall Notice. The form must be returned even if you no longer have any of the potentially affected Medfusion® 4000 or 3500 Syringe Pumps in your possession.

If you have distributed potentially affected devices to your customers, please immediately notify your customers of this Recall. If you have any questions regarding this notification, please contact Stericycle via email at SmithsMedical3033b@stericycle.com.

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

Sincerely,

David Halverson
Global Compliance Manager
Smiths Medical
6000 Nathan Lane North, Minneapolis, MN 55442
fieldactions@smiths-medical.com

Enclosures: Urgent Medical Device Recall Response Form and List of Affected Devices