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AMENDED URGENT MEDICAL DEVICE RECALL

CADD® Non Flow-Stop Medication Cassette Reservoirs

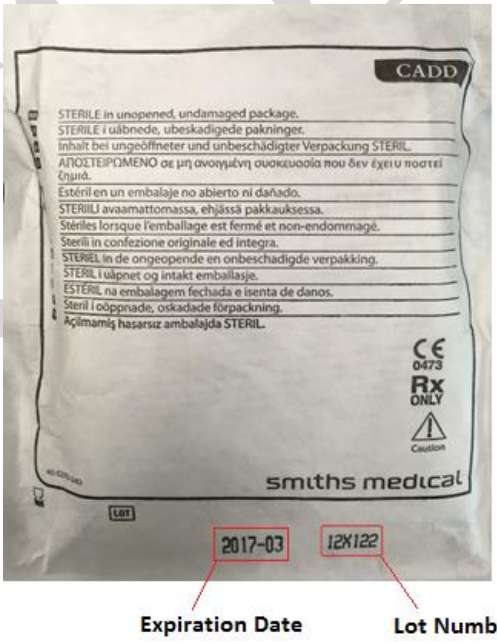
Affected Device:	**CADD® Medication Cassette Reservoirs**
Type of Action:	**Field Removal**
Date:	**January 2018**
Attention:	**Users and Distributors**
Potentially Affected Products:	**21-7001-24, 21-7002-24, 21-7100-24**
	Expiration Date: Prior to July 2022

Dear Valued Customer,

The purpose of this *Amended Recall Notice* is to advise you that Smiths Medical has elected to expand its' voluntary recall of certain (non flow-stop) CADD Medication Cassette Reservoirs to include additional lot numbers of the following products shipped between October 2012 and November 2017, that have expiration dates prior to July 2022:

21-7001-24 50mL CADD Medication Cassette
21-7002-24 100mL CADD Medication Cassette
21-7100-24 100mL CADD Medication Cassette, Yellow

The Lot Number and Expiration Date of these products may be located as shown below.



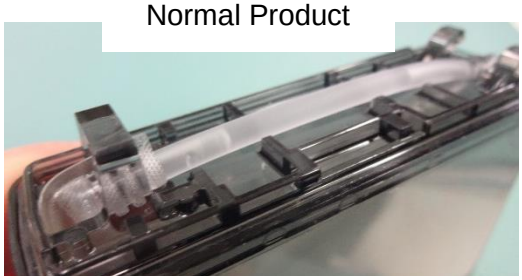
Model and Lot numbers of potentially affected product in your possession may be found on the Recall Response Form accompanying this Recall Notice. Additional Lot numbers due the expansion of this recall are identified in an amended table in addition to the lot numbers affected by the initial Recall Notice.

This amended Recall Notice restates the relevant information from the initial Recall Notice, but includes the expanded lots and expiration dates.

REASON FOR RECALL:

Smiths Medical became aware that certain Non Flow-Stop CADD® Medication Cassette Reservoirs may have been manufactured with an incorrect pressure plate.

Normal Product



Pressure Plate has tunnel for pumping tube

Product in Question

Arch on the pressure plate and pumping tube is pushed up over the arch

Product in Question

Normal Product

Arch on the top plate

Non Flow-Stop pressure plate is designed without an arch, however the product in question has the plate with the arch

This Recall is being performed with the knowledge of the appropriate regulatory authorities.

RISK TO HEALTH:

Under delivery of medication may result from the tubing becoming partially or completely occluded when the cassette is attached to the pump.

The immediate impact to the patient depends on the patient condition, the therapy involved, the degree of under delivery of medication, and possibly the time to discovery of the problem.

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

INSTRUCTIONS TO USERS AND DISTRIBUTORS:

1) Determine if you have any affected CADD® Medication Cassette Reservoirs in your possession, as indicated on the Recall Response Form accompanying this notice.

2) (Distributors) Please immediately notify your customers of this Recall and retrieve all affected product.

3) Please acknowledge receipt of this Recall Notice by completing and returning the Recall Response Form to: *smithscadd101@stericycle.com*. This form may also be returned via FAX at (+001) 844-265-7413. **The Response Form must be completed and returned even if you do not have product to return.**

4) Return all affected product to Stericycle for processing. Stericycle will provide you with pre-paid shipping labels for all products indicated on the Recall Response Form.

5) Package the affected product and include a copy of the completed Recall Response Form inside EACH BOX of returned devices so that you receive proper credit/replacement for returned devices. Ensure that boxes are sealed and labeled with your facility name prior to shipping devices to Stericycle.

If you have any questions regarding this recall please contact Stericycle at:

- *smithscadd101@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,

Dave Halverson
Global Compliance Manager
Smiths Medical

Attachment 1 – Recall Response Form