smiths medical
bringing technology to life

URGENT MEDICAL DEVICE RECALL

CADD® Medication Cassette Reservoir

Affected Device:	**CADD® Medication Cassette Reservoirs (Non Flow-Stop)**
Type of Action:	**Recall (Field Removal)**
Date:	**XXXX 2017**
Attention:	**Users and Distributors**
Potentially Affected Products:	**21-7001-24, 21-7002-24, 21-7100-24** **Lot Numbers: Multiple** **Ship Date: Multiple**

Dear Valued Customer,

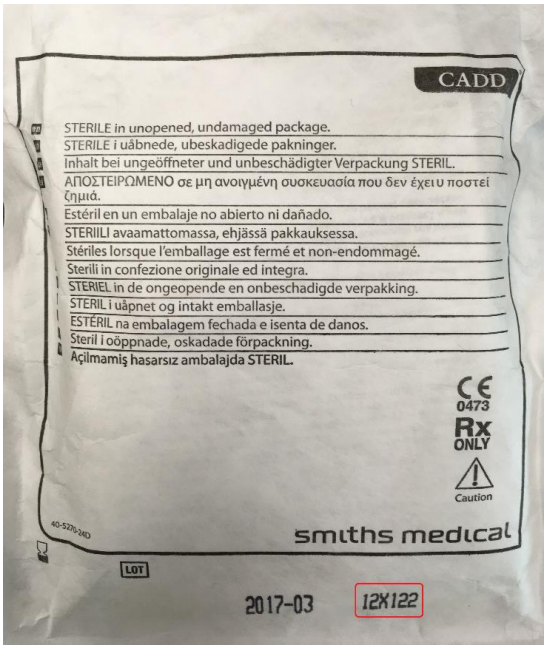
The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary recall of certain lots of 50 and 100 ml Non Flow-Stop CADD® Medication Cassette Reservoirs, part numbers 21-7001-24, 21-7002-24 and 21-7100-24.

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

Model and Lot numbers of potentially affected product in your possession may be found on the Recall Response Form accompanying this Recall Notice.

The lot number of this product may be located as shown in Figure 1.

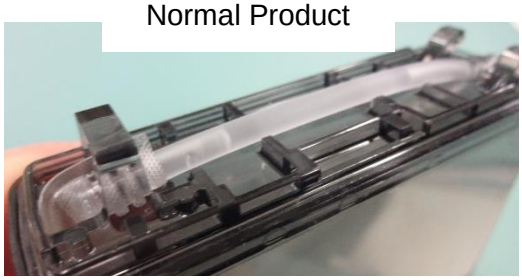
Figure 1



REASON FOR RECALL:

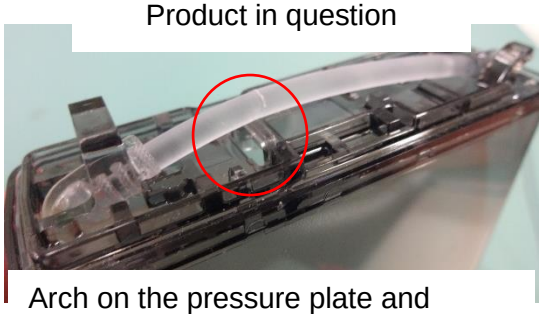
Smiths Medical became aware that certain Non Flow-Stop CADD® Medication Cassette Reservoirs may have been manufactured with an incorrect pressure plate.

Normal Product



Pressure Plate has tunnel for pumping tube

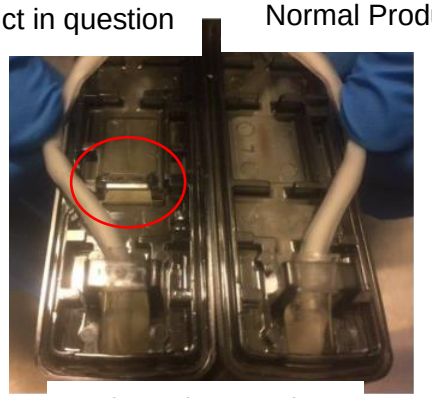
Product in question



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) Complete and return the attached Recall Notice Response Form to smithsmedical3682@stericycle.com within 10 days of receipt of this letter. **The form must be 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 smithsmedical3682@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,

Christine Thomas
Vice President Quality Systems, Regulatory and Compliance
Smiths Medical

Attachment 1 – Recall Response Form