



FIELD SAFETY NOTICE

1 December 2017

IDS REFERENCE:		2017-011	
MANUFACTURER REFERENCE:		CADD Medication Cassette Reservoirs	
SUBJECT: Recall of CADD Medication Cassette Reservoirs			
FOR THE ATTENTION OF: Chairman Medical Board (CMB), BME, Nursing and Medical staff using these devices in the various departments and the relevant Head of Departments.			
DEVICE :		CADD Medication Cassette Reservoirs	
PRODUCT CODE:	Device Name		Device Identifier
	CADD Medication Cassette Reservoir		21-7001-24
	CADD Medication Cassette Reservoir		21-7002-24
BATCH NO:		Please refer to affected batch no.	
PROBLEM:		Smiths Medical became aware that certain Non Flow-Stop CADD Medication Cassette Reservoirs may have been manufactured with an incorrect pressure plate.	
ACTION TO BE TAKEN:		Our records show that you have purchased the affected product and we request that you read through the letter for more detailed information. 1) Inspect your inventory for the Cassettes and listed in the acknowledgment form and quarantine the affected Cassettes. 2) Complete and return the acknowledgment form with quantity of the unused affected devices. Upon receipt of the completed form, an IDS Medical representative shall arrange and collect the affected Cassettes.	

We apologize for any inconvenience caused due to this notice.

Thank you.

With regards,
Kenneth Ow
Regulatory Specialist
IDS Medical Systems (Singapore) Pte Ltd
Email: kennethow@idsmed.com



IDS Reference: 2017-011
Manufacturer Reference: CADD Medication Cassette Reservoir
Device: CADD Medication Cassette Reservoir
Subject: Recall of CADD Medication Cassette Reservoir

I acknowledge receipt of this letter dated **1 December 2017**.

Customer Name:			
Department:			
Address:			
Name:		Tel:	
Designation:			
Signature:		Company Stamp:	

Check the applicable boxes below:

☐	I DO NOT have affected CADD Medication Cassette Reservoir remaining . All have been used or discarded.
☐	I DO have unused inventory of affected CADD Medication Cassette Reservoir, which I will return for credit.

Model	Batch Number	Quantity to be Returned
21-7001-24	12X397	
21-7001-24	12X410	
21-7001-24	12X513	
21-7001-24	13X022	
21-7001-24	13X037	
21-7001-24	13X058	
21-7001-24	13X077	
21-7001-24	13X104	
21-7001-24	13X118	
21-7001-24	13X233	



21-7001-24	13X271	
21-7001-24	13X322	
21-7001-24	13X369	
21-7001-24	13X397	
21-7001-24	13X408	
21-7001-24	13X475	
21-7001-24	14X023	
21-7001-24	14X052	
21-7001-24	14X122	
21-7001-24	14X144	
21-7001-24	14X157	
21-7001-24	14X236	
21-7001-24	14X290	
21-7001-24	14X297	
21-7001-24	14X323	
21-7001-24	14X447	
21-7001-24	14X485	
21-7001-24	14X513	
21-7001-24	14X541	
21-7001-24	14X566	
21-7001-24	14X599	
21-7001-24	15X004	
21-7001-24	15X009	
21-7001-24	15X019	
21-7001-24	15X146	
21-7001-24	15X178	
21-7001-24	15X206	



21-7001-24	15X303	
21-7001-24	15X318	
21-7001-24	15X335	
21-7001-24	15X349	
21-7001-24	15X378	
21-7001-24	15X379	
21-7001-24	15X410	
21-7001-24	15X515	
21-7001-24	15X547	
21-7001-24	16X003	
21-7001-24	16X099	
21-7001-24	16X396	
21-7001-24	16X404	
21-7001-24	16X411	
21-7001-24	16X438	
21-7001-24	16X476	
21-7001-24	16X522	
21-7001-24	16X542	
21-7001-24	16X774	
21-7001-24	16X794	
21-7001-24	16X841	
21-7001-24	16X928	
21-7001-24	17X013	
21-7002-24	12X450	
21-7002-24	13X054	
21-7002-24	13X085	
21-7002-24	13X091	



21-7002-24	13X124	
21-7002-24	13X127	
21-7002-24	13X170	
21-7002-24	13X239	
21-7002-24	13X401	
21-7002-24	13X443	
21-7002-24	13X548	
21-7002-24	14X002	
21-7002-24	14X010	
21-7002-24	14X125	
21-7002-24	14X200	
21-7002-24	14X204	
21-7002-24	14X400	
21-7002-24	14X408	
21-7002-24	14X457	
21-7002-24	14X568	
21-7002-24	14X593	
21-7002-24	14X605	
21-7002-24	14X674	
21-7002-24	14X762	
21-7002-24	15X114	
21-7002-24	15X116	
21-7002-24	15X364	
21-7002-24	15X365	
21-7002-24	15X411	
21-7002-24	15X443	
21-7002-24	15X482	



21-7002-24	15X487	
21-7002-24	15X517	
21-7002-24	15X586	
21-7002-24	16X042	
21-7002-24	16X162	
21-7002-24	16X344	
21-7002-24	16X345	
21-7002-24	16X505	
21-7002-24	16X605	
21-7002-24	16X747	
21-7002-24	16X811	
21-7002-24	16X930	
21-7002-24	17X115	
21-7002-24	17X179	

*** Please fax this acknowledgement to IDS Medical Systems at 66907380 or email to kennethow@idsmed.com.**

If there is any discrepancy in the above list, please advise us of the changes.

Thank you.

URGENT MEDICAL DEVICE RECALL – 2nd NOTICE

CADD® Medication Cassette Reservoir

Affected Device:	CADD® Medication Cassette Reservoirs (Non Flow-Stop)
Type of Action:	Recall (Field Removal)
Date:	November 27, 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,

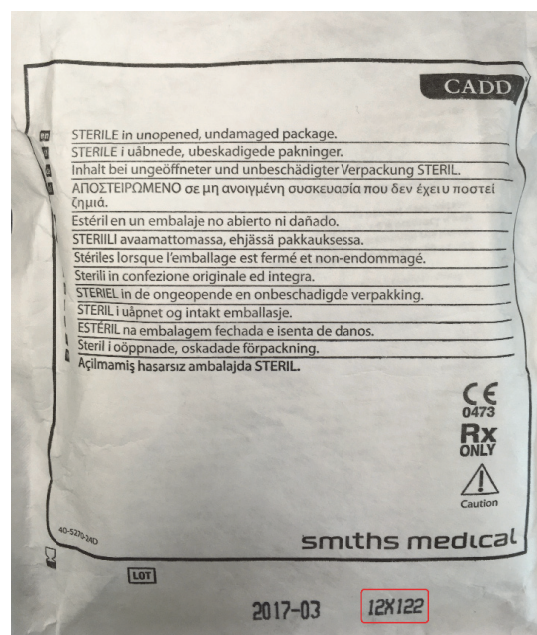
The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary recall of certain lots of 50 and 100 ml Non Flow-Stop CADD® Medication Cassette Reservoirs, part numbers 21-7001-24, 21-7002-24 and 21-7100-24.

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.

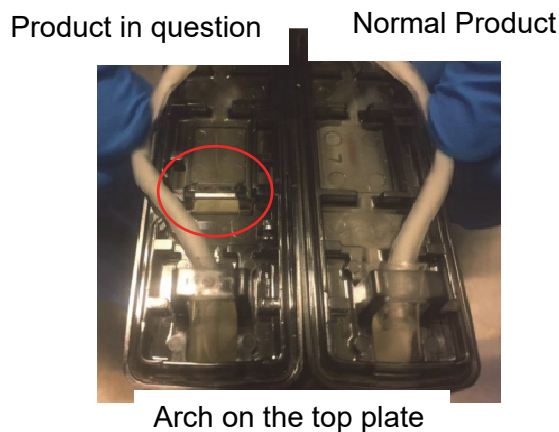
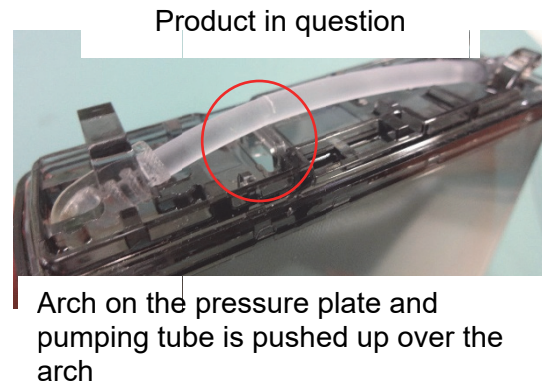
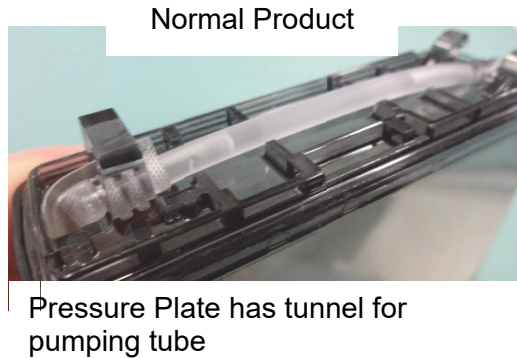
The lot number of this product may be located as shown in Figure 1.

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.



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.

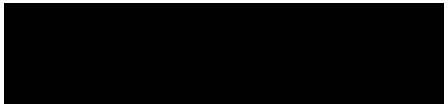
INSTRUCTIONS TO USERS AND DISTRIBUTORS:

- 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