smiths medical
bringing technology to life

URGENT MEDICAL DEVICE RECALL

CADD® Medication Cassette Reservoir

Affected Devices:	**CADD® Medication Cassette Reservoir**
Type of Action:	**Field Removal**
Date:	**May 31, 2017**
Attention:	**User, Distributors**
Details on affected devices:	**Part Number: 21-7002-24** **Lot Number: 16X659**

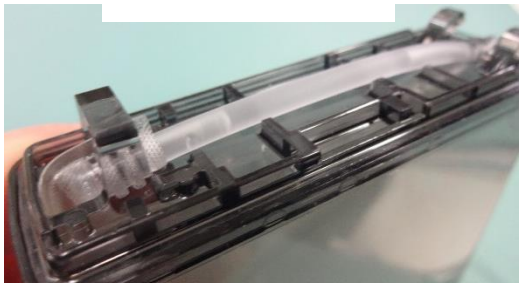
Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary recall of the CADD® Medication Cassette Reservoir, part number 21-7002-24, lot number 16X659.

REASON FOR RECALL:

Smiths Medical has become aware that the medication cassette reservoir, part number 21-7002-24, with lot number 16X659, may have been manufactured with the incorrect pressure plate. Additionally, the tubing used on the cassette may have been routed incorrectly.

Normal Product



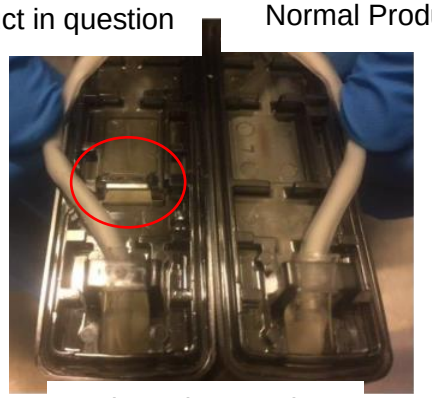
Top Plate has runnel for pumping tube

Product in question

Arch on the top plate and pumping tube is pushed up

Product in question

Normal Product



Arch on the top plate

Top plate of 21-7002-24 is designed without an arch, however the product in question has the plate with the arch. Additionally, the tubing may have been routed under the arch on the top plate.

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

RISK TO HEALTH:

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

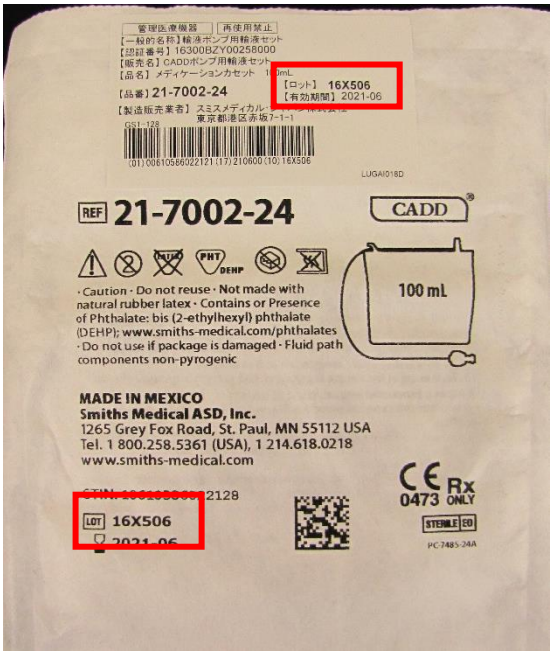
The immediate impact to the patient depends on the patient condition, the therapy involved, the degree of under delivery of medication, and possibly the time to discovery of the problem.

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

INSTRUCTIONS TO CUSTOMERS:

1. Determine if you have any affected CADD® Medication Cassette Reservoirs by locating the lot number on the reservoir (see Figure 1)

Figure 1



2. Return any affected devices in your possession and receive replacements:

   Your Smiths Medical sales representative will collect the affected product in your possession and replacement product will be sent to you.

3. Complete and return the attached Recall Notice Response Form. **Please return the response form, even if you do not have product to return.**

4. If you are a distributor and have distributed affected devices to your customers, please immediately notify your customers of this Recall and retrieve all affected devices.

If you have any questions regarding this recall or find any issues with these products, please contact your Smiths Medical Sales Representative.

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

Attachment 1 – Recall Notice Response Form

ATTACHMENT 1

smiths medical
bringing technology to life

URGENT MEDICAL DEVICE RECALL RESPONSE FORM

CADD® Medication Cassette Reservoir (Non Flow-Stop)

Please assist us in making this device recall process as efficient and convenient for you by completing and returning this form as soon as possible. This will serve as confirmation that you have received and understand the notification, and will allow us to ensure that we have reached all customers who may be affected by this Recall Notice.

Facility Name
Address
Zip code, city, Country

Please acknowledge receipt of this Recall Notice by completing and returning this Recall Response Form to **smithsmedical3682@stericycle.com.**

Please complete the *Quantity to be Returned* field below.

Product Number	Product Name	Lot Number	Quantity Purchased	Quantity to be Returned

I certify that I have read and understand the information in the attached Recall Notice.

Name and Title (Please Print)	Signature	Date