

**Smiths Medical ASD**  
6000 Nathan Lane N  
Plymouth, MN 55442

**URGENT MEDICAL DEVICE FIELD SAFETY NOTICE**

**Affected Device: CADD® Administration Device**

**Type of Action:** Field Corrective Action

**Date:** March 17, 2017

**Attention:** Risk Manager

**Affected devices:** **Product Number: 21-7339-24**  
**Product Name/Description: CADD® Administration Set**  
**Lots Numbers: See Table 1 below**

**TABLE 1: Affected Lots**

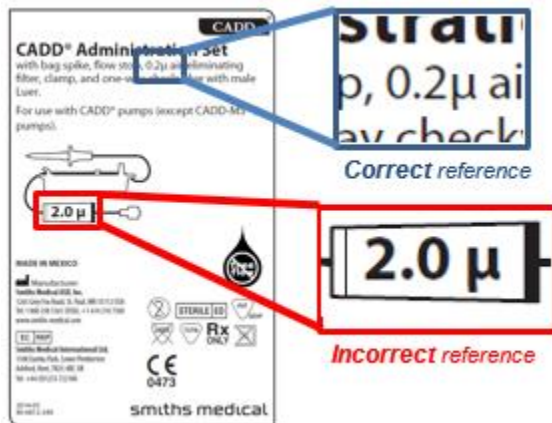
46X817	46X829	46X899
46X828	46X896	46X990
46X831	46X897	46X1001

Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical has become aware that the drawing on the Instructions for Use (IFU) on certain yellow striped CADD® Administration Sets (part number 21-7339-24), incorrectly represent the actual filter size of the product. Although the text description on the IFU correctly identifies the product to include a 0.2 micron filter, the illustration on the IFU identifies the filter size as 2.0 microns (See Figure 1). A list of affected lots with this incorrectly labeled IFU is included in Table 1 on the first page of this notice. 40,968 devices are included in this Field Corrective Action.

If you are using the illustration on the IFU to identify the filter size of CADD® Administration Sets, part number 21-7339-24, with lot numbers listed in Table 1, please be aware that the filter size is not 2.0 microns as illustrated. The correct filter size, 0.2 microns, is identified in the text description at the top of the IFU.

FIGURE 1-IFU



This Field Corrective Action is being performed with the knowledge of the appropriate regulatory authorities.

**RISK TO HEALTH:**

The labeling error on the IFU could cause confusion during therapy set-up leading to therapy delay. The labeling error is unlikely to lead to any adverse health consequences.

**Smiths Medical has not received any reports of deaths or serious injuries related to this issue.**

**PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY  
EXECUTE THIS FIELD CORRECTIVE ACTION:**

**INSTRUCTIONS TO DISTRIBUTORS:**

If you are a distributor, please immediately notify your customers of this Field Corrective Action

**INSTRUCTIONS TO CUSTOMERS:**

1. Determine if you have any affected CADD® Administration Sets by locating the part number and lot number on the lower left corner of the front of the pouch (see figure 2).

**FIGURE 2-Front of Pouch**



2. Reference the affected lots in Table 1.
3. Use the text description on the IFU to identify the filter size of CADD® Administration Sets, part number 21-7339-24, lot numbers listed in Table 1. Do not use the illustration on the IFU.
4. You do not need to return any of the affected product to Smiths Medical.
5. Complete the *Urgent Medical Device Field Safety Notice (FSN) Response Form* enclosed with this letter within 10 days of receipt and send it to [smithsmedical3947@stericycle.com](mailto:smithsmedical3947@stericycle.com). The form must be returned even if you do not have any of the affected product.
6. If you are a distributor and have distributed affected devices to your customers, please immediately notify your customers of this Field Corrective Action.

If you have any questions regarding this notification, contact Stericycle at 844-265-7407.

Please report any issues with these products to Smiths Medical's Global Complaint Department at [globalcomplaints@smiths-medical.com](mailto:globalcomplaints@smiths-medical.com).

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

Sincerely,

Jennifer C. Meng  
Director of Government Relations and Compliance  
Smiths Medical ASD, Inc.

Enclosures: Enclosure 1 – Field Safety Notice Response Form  
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