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Smiths Medical ASD
1265 Grey Fox Rd
St. Paul MN 55112

URGENT FIELD SAFETY NOTICE

Smiths Medical ASD
CADD® Administration Sets with Flow Stop
04 May 2016
Additional Instructions

Attention: Clinicians who oversee the use of the CADD® Administration Sets with Flow Stop and Distributors of the medical device.

Affected devices: **The following Product Re-order Numbers for devices with a device expiration date on or before March 2021 are affected by the issue described below.**

Product Re-order Number				
21-7321-01	21-7321-24	21-7322-01	21-7322-24	21-7323-24
21-7324-01	21-7324-24	21-7333-24	21-7336-01	21-7336-24
21-7339-01	21-7339-24	21-7359-01	21-7359-24	21-7383-01
21-7383-24	21-7390-01	21-7390-24	21-7391-01	21-7391-24
21-7394-01	21-7394-24	21-7395-24		

Customer FSN

Dear Clinician and Distributor,

The purpose of this Urgent Field Safety Notice is to advise you that Smiths Medical has initiated a voluntary global Field Safety Corrective Action for CADD® Administration Sets with Flow Stop with a product reorder number and that expire on or before March 2021 listed in the table above.

REASON FOR FIELD SAFETY CORRECTIVE ACTION:

Smiths Medical has become aware that under delivery to patients of medicinal products may occur when administered using CADD® Administration Sets with Flow Stop.

RISK TO HEALTH:

The CADD® Administration Sets with Flow Stop identified in the table above have the potential to impact flow rate when used with a variety of CADD® ambulatory infusion pumps. This may result in under delivery of medication.

Our test data indicates that under infusion has the potential to contribute to an average of an additional 5.2% under delivery beyond the $^{+/-}$ 6% stated in the Operator's Manual for the CADD® pumps. If drug under delivery occurs, patients may not receive their full volume of medicinal product in the prescribed timeframe.

CADD® Ambulatory Infusion Pumps are used for a variety of infusion therapies. Potential health consequences from an under delivery will depend on the patient condition, the therapy involved, the degree of under delivery that occurs, and possibly the time to discovery of the under delivery.

Our risk analysis identified the following possible serious adverse health consequences with a very remote probability of occurrence:

1) Inadequate symptom control (dependent on therapy being delivered). For example: Increase in pain or increase in cardiac symptoms (heart rate, rhythm, blood pressure);

2) Inadequate treatment (dependent on therapy being delivered). For example: Sub-therapeutic doses delivered of medication in which a specific volume needs to be infused such as antibiotics, chemotherapy, or nutritional therapy.

Our risk analysis concluded that there is a very remote probability that under delivery may occur resulting in patient harm, as all possible levels of patient harm were evaluated to be rare.

Smiths Medical has not received any reports of deaths or serious injuries related to the under delivery with the CADD® Administration Sets with Flow Stop.

Only those CADD® Administration Sets with Flow Stop with Product Re-order numbers listed above and that expire on or before March 2021 are affected by this Action.

In accordance with applicable rules, the competent authorities in your country have been notified of this corrective action.

INSTRUCTIONS TO CUSTOMERS:

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

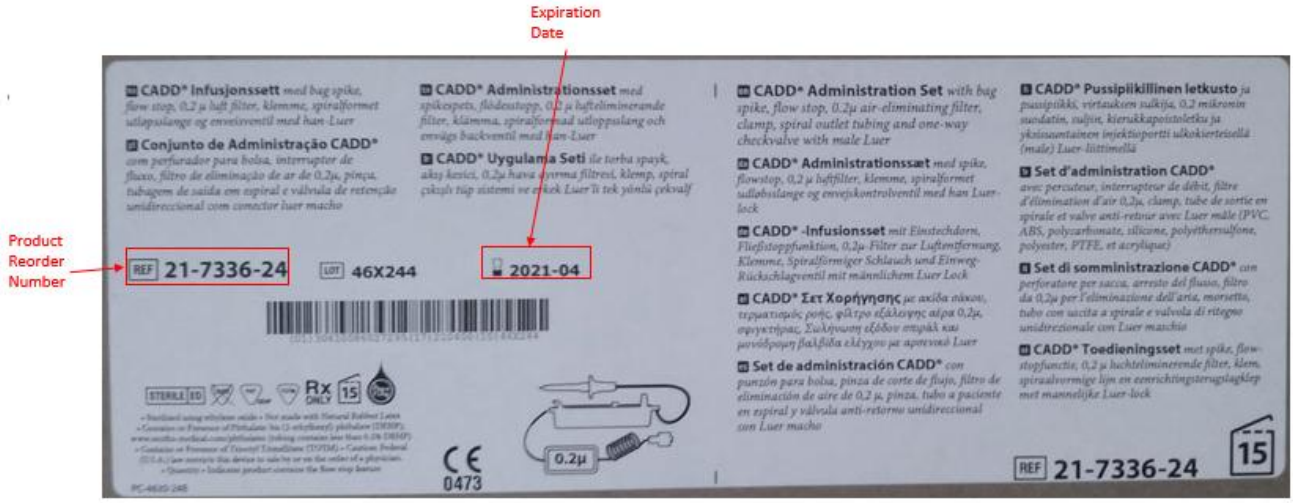
There is no need to return your product.

1. For Distributors: If you are a distributor and you have distributed CADD® Administration Sets with Flow Stop to your customers, please immediately notify them of this Field Safety Corrective Action. Skip to step 4 below.

2. For Clinicians: Prior to use of the product, review the product reorder number and the expiration date on product labeling for all CADD® Administration Sets with Flow Stop devices in your inventory to determine if the device(s) are affected by this Field Safety Corrective Action.

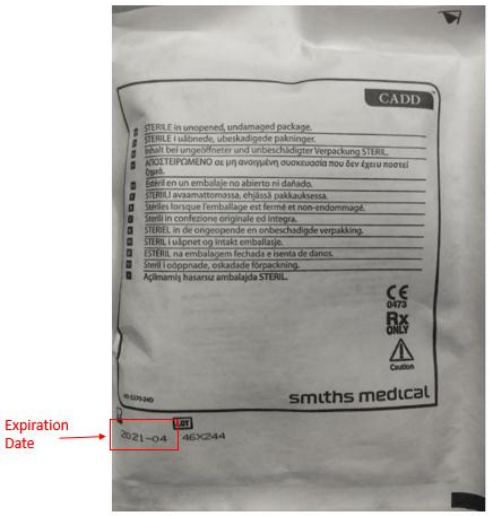
   Outer Carton

   If you are looking at the outer carton, the picture below depicts where you can locate the re-order number and the expiration date:



Primary Sterile Pack

If you are looking at the primary sterile pack that contains the device, the pictures below depicts where you can locate the re-order number and the expiration date:

Product re-order number is visible from the clear side of the packaging:	Expiration date is visible from the reverse side of the packaging:
	

3. For Clinicians: If during review of the product reorder number and the expiration date on product labeling for CADD® Administration Sets with Flow Stop devices, both in your inventory and devices that have been supplied to patients or their caregivers as provided in Step 2 above, you determine that a medical device falling within this Field Safety Corrective Action has been supplied to your patients and their caregivers please immediately communicate this Field Safety Corrective Action to the patients and their caregivers.

   Please continue to monitor for under delivery when utilizing the CADD® Administration Sets with Flow Stop.

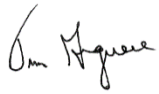
4. For Distributors and Clinicians: Review and complete the Urgent Field Safety Notice Reply Form and return it to Smiths Medical by Fax to +49(0)89 / 24 29 59-310 or by email to FCA.Response@smiths-medical.com within 10 days of receipt of this letter. The form must be returned to us even if you do not have any CADD® Administration Sets with Flow Stop sets in your possession.

If you have any questions regarding this notification, please contact Smiths Medical Customer Service Department at +49(0)89 / 24 29 59 – 309 Monday – Thursday 9:00am – 4:30pm and Friday 9:00am – 12:30pm.

Should you experience under delivery of the identified product contact the Smiths Medical Global Complaints Department at +00 800 76 48 47 00 between 8am and 4pm or email 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,



Tim Giguere
Manager, Quality Systems
Smiths Medical ASD, Inc.

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

Enclosures: Attachment 1 – Field Safety Corrective Action Confirmation Form

ATTACHMENT 1

URGENT FIELD SAFETY NOTICE

Smiths Medical ASD
CADD® Administration Sets with Flow Stop
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Reply Form

Smiths Medical ASD is committed to providing the highest quality products to its customers. We would be grateful if you could acknowledge receipt of this Field Safety Notice by completing and returning this Reply Form by fax to +49(0)89 / 24 29 59-310 or by sending an electronic copy via email to FCA.Response@smiths-medical.com within 10 calendar days of receipt of this Notice. Please return the Reply Form even if you do not have any CADD® Administration Sets with Flow Stop sets in your possession.

I have read and understood the information in the attached Urgent Field Safety Notice.

CLINICIANS:

Please complete as appropriate:

☐ I have no inventory of CADD® Administration Sets with Flow Stop.

☐ I have inventory of CADD® Administration Sets with Flow Stop.

☐ I have contacted patients and caregiver to whom I have or will provide[d] CADD® Administration Sets with Flow Stop and informed them of the information contained in the field safety notice.

DISTRIBUTORS:

Please complete as appropriate:

☐ I have no inventory of CADD® Administration Sets with Flow Stop.

☐ I have inventory of CADD® Administration Sets with Flow Stop.

☐ I have contacted customers and sub-distributors to whom I have or will provide[d] CADD® Administration Sets with Flow Stop and informed them of the information contained in the field safety notice on _____.
(month) (day)

Facility Name:	Facility Address:
Signature:	Facility Shipping Address:
Print Name:	Date:
Department:	
Email:	Phone Number: ( )