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Regulatory Affairs

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[Redacted]

Kleve, January 25th, 2016

URGENT: FIELD SAFETY NOTICE – FSCA 16-01

Medical Device Safety Advisory Notice

Object: SECURITY INFORMATION OF Medline Sterile Procedure Trays containing Baxter Uromatic Tur Administration Set References - EMC4015N

Our Ref: FSCA 16-01

Product Codes concerned: Listed in the Acknowledgement receipt.

Dear Customer,

Description of the problem:

You are being informed of this field safety notice because you are purchasing Medline Sterile Procedure Kits that contain Uromatic Tur Admin. Set References - EMC4015N from the supplier Baxter concerned by this safety information.

Baxter is issuing a recall of the Uromatic Tur Administration Sets due to customer complaints received related to the disconnection of the spike from the tubing of the set.

Potential Hazard

The most likely hazard resulting from this issue is delay/interruption of therapy. However, disconnections also have the potential to lead to microbial contamination of the fluid path and hence contamination of the surgical field. Baxter has not received any reports of adverse events or patient injury related to this issue.



Actions to be Taken

Step 1) Please urgently check your stock and promptly put on quarantine the concerned Sterile Procedure Kits – ONLY the lot numbers that contain the recalled irrigation sets – other lot numbers of these sets can be used without problems.

Step 2) As soon as Medline knows if and how many sets concerned are in your stock (that you please indicate in the acknowledgement form sent back) Medline will send WARNING stickers to you, that we request you to put on every kit concerned still in your stock. Please indicate the address where and how many warning stickers you need, so Medline can send them to you in sufficient quantity to be applied visibly on the concerned kits.

The “warning sticker” is to inform the concerned users that the Uromatic Tur Administration Set included has to be removed from the kits. Other components can be used safely

Step 3) Please complete and send back the enclosed attachment by either fax or email as soon as possible, but not later than February 19th 2016 with information about the quantity in stock and where to send needed amount of stickers.

Step 4)

The Sterile Procedure kits can be released and used once they have been labelled with a warning sticker.

Step 5)

Discard all Uromatic Tur Administration Sets taken out of the used Sterile Procedure Kits

All stock of your kits currently in our warehouses, will be labelled with the warning sticker.

New production of Sterile Procedure kits containing EMC4015N will be manufactured without the Uromatic Tur Administration Sets, until Medline receives new lots from Baxter.

Please communicate this information to all concerned Depts and complete the below acknowledgement form by February 19th, 2016 and return by fax to: +49 2821 7510 7822 or E-Mail to: gmb-eu-ra-kleve@medline.com

For any further information on custom pack, please do not hesitate to contact Medline Regulatory Affairs Department – Tel : +49 2821 7510 7210

Yours Sincerely,

A handwritten signature in black ink, appearing to read "Ade Meijer".

Andrea de Meijer, RA specialist
Quality and Regulatory Affairs Dept.



**Acknowledgement receipt to be faxed or emailed
before February, 19th. 2016 to the following:**

+49 2821 7510 7822 / gmb-eu-ra-kleve@medline.com

Reference: FSCA-16/01

SETS/LOTS CONCERNED - Please indicate quantity in your stock:

REFERENCES	Lot N°s	Quantity SETS Quarantined by the customer
FGRBA014D TUR PACK	615950;619856;635021	
FGRBA014E TUR PACK	652626;663787	

I have read and understood this Field Safety Notice and have distributed the information to all possibly impacted departments within my organization.

We have stock and order warning stickers to be sent to below address in the quantity of quarantined sets

OR

We have NO sets left in our stock concerned by this Safety information

Organization / Hospital / Clinic :		Customer number: 5700030
Department (if applicable) :		
Address :		
Postcode :		City :
Contact Name :		
Job Title :		
Contact Telephone Number :		
Contact E-mail Address :		
Signature :		Date :

This form must be returned to Medline before this action can be considered closed for your account