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URGENT MEDICAL DEVICE RECALL NOTICE

Affected Devices: Sterile Water, Saline and Eye Wash

Type of Action: Removal

Date: August 2017

Attention: Distributors of, and Clinicians who use, Sterile Water, Saline, and Eye Wash

Model Number	Product Name	Lot Numbers
352	350 ml Sterile Water Humidifier w/5psi Adapt. 20/CA	A214, A215, Z263, Z532, Z555
552	550 ml Sterile Water Humidifier w/5psi Adapt. 12/CA	A054, A089, A090, Z262
1065	1000 ml Sterile Water USP Pour Bottle 12/CA	B209, Z225
1565	500 ml Sterile Water USP Pour Bottle 12/CA	Y371
R0059	Unit Dose 5 ml Normal Saline (0.9%) 1000/CA	B360
R0159	Unit Dose 15 ml Normal Saline; 144/CA	A661, B067, A526, A536, A569, B201

Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical has initiated a voluntary recall for 71 lots of Sterile Water, Saline and Eye Wash. Model and lot number information of affected product in your possession can be found on the Urgent Medical Device Recall Response Form accompanying this notice.

REASON FOR RECALL:

Smiths Medical became aware that 71 lots of Sterile Water, Saline and Eye Wash may be susceptible to leaking. If the container barrier were to be compromised, this could potentially result in the exposure to infectious agents.

RISK TO HEALTH:

Exposure to infectious agents due to a compromised container barrier could result in infection and may require treatment with antibiotics.

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

INSTRUCTIONS TO CUSTOMERS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS RECALL:

1. Locate the affected Sterile Water, Saline and Eye Wash in your possession by referring to the attached Urgent Medical Device Field Recall Response Form. This form provides the specific number(s) of Sterile Water, Saline and Eye Wash your organization purchased.

2. Determine the number of affected devices in your possession and complete the Urgent Medical Device Field Recall Response Form attached to this letter within 10 days of receipt and send it to smithsmedicalste00100@stericycle.com. The form must be returned even if you do not have any of the affected Sterile Water, Saline and Eye Wash in your possession. Product credit will be processed once the Urgent Medical Device Field Recall Response Form and affected product is received.

3. All affected devices must be returned to Stericycle for processing. Pre-paid shipping labels are included with this notice. Package the affected devices and include a copy of the completed Urgent Medical Device Field Recall Response Form inside EACH BOX of returned devices so that you will obtain proper credit for returned devices. Make sure boxes are sealed and labeled with your facility name prior to shipping devices to Stericycle.

4. Distributors, if you have distributed potentially affected devices to your customers, please immediately notify your customers of this Recall.

If you have any questions regarding this notification, please contact Stericycle via email at smithsmedicalste00100@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,

[redacted]

Enclosure: Attachment 1 – Recall Response Form

ATTACHMENT 1

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URGENT MEDICAL DEVICE RECALL

RESPONSE FORM

Affected Devices:

Sterile Water, Saline and Eye Wash

Please assist us in making this Recall Notification process as efficient and convenient for you as possible by completing and returning this form via email to smithsmedicalste00100@stericycle.com within 10 calendar days of receipt of this *Urgent Medical Device Recall Notice*. 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. Please return this response form even if you do not have any potentially affected product.

Facility Name
Address
Zip code, city, Country

According to our records, you have received the following Sterile Water, Saline, and Eye Wash products affected by this recall:

Product Number	Product Description	Lot Number	Quantity Purchased	Quantity to be Returned
		Totals		

Name and title (Please print)	Signature	Date
Email Address	**Telephone Number**	