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6000 Nathan Lane N.
Minneapolis, MN 55442
https://www.smiths-medical.com

URGENT MEDICAL DEVICE RECALL

DuraLife® Autoclavable Extension Sets and Swivel Connectors

05 April 2023

Dear Valued Customers:

Smiths Medical, Inc. is issuing this Urgent Medical Device Recall letter to notify you of a potential issue with the DuraLife® Autoclavable Extension Sets and Swivel Connectors. This letter details the issue and the required steps for you to perform.

Issue:
Smiths Medical has identified that the DuraLife devices instructions for cleaning and sterilization have been determined to be inadequate. Specifically, for the DuraLife product, the IFU does not provide the cleaning method, duration of autoclave cycle or specify the number of cycles the product can be reused on a single patient.

Potential Risk:
Insufficient cleaning and sterilization may occur due to the inadequate device instructions leading to the potential for the product to deteriorate due to incorrect cleaning, the product not being changed or maintained properly during use, and/or the product not being appropriately cleaned prior to use. To date, Smiths Medical has not received any complaints associated with this issue.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed in the United States between 06 February 2018 and 30 January 2023. The affected item and lot numbers that are within product expiry are provided in Table 1.

Table 1: Affected Product and Lot Numbers

Item Number	Product Description	Lot Number					
60-0010	DuraLife®Autoclavable Double Swivel Elbow	3577218	3738865	3887812	4024574	4151070	4258733
		3582650	3752126	3901443	4029610	4153964	4258734
		3587542	3761923	3911867	4038968	4164878	4264897
		3596826	3768558	3914813	4041942	4173946	4269655
		3604794	3768559	3917564	4063257	4176082	4279829
		3613310	3772121	3931273	4063258	4182389	4279830
		3623879	3779557	3933681	4067165	4187590	4284606
		3627084	3784957	3936715	4072088	4192791	4284607
		3643070	3788286	3942733	4076804	4201183	4290269
		3671340	3798095	3952706	4081672	4204667	4290270
		3671341	3802450	3956054	4086259	4215512	4318561
		3673809	3805780	3959458	4090323	4219068	4335149
		3687267	3819513	3970976	4093610	4229475	4335150
		3690140	3828396	3974773	4104647	4242508	4337436
		3700821	3836009	3988375	4108513	4242509	4361916
		3709028	3849849	4001786	4111190	4247925	
		3712265	3863155	4005980	4116119	4247926	
		3723465	3867378	4011955	4132044	4254339	
		3735446	3880821	4018725	4138935	4258732	

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60-1502	DuraLife®Autoclavable Silicone Extension Tube	3569291	3802463	3974741	4093611	4219069	4340640
		3582651	3832622	4001787	4108514	4242510	4340642
		3609721	3871182	4011956	4116120	4254340	
		3609743	3891814	4032896	4122394	4264898	
		3693349	3914797	4041943	4151071	4279831	
		3723464	3927549	4063256	4167796	4290272	
		3761125	3952707	4090324	4182390	4340638	
60-1510	DuraLife®Autoclavable Silicone Extension Tube	3572938	3709023	3917565	4081673	4176083	4258736
		3582668	3735447	3936716	4090325	4176084	4272705
		3602084	3784974	3974795	4100952	4187591	4272706
		3617047	3812333	4011957	4104648	4207974	4284609
		3623883	3828394	4029611	4119019	4207975	4290273
		3631678	3836006	4038969	4138936	4220676	4333910
		3662331	3874536	4063254	4148601	4242511	4340649
		3688907	3884430	4067164	4160298	4254341	4348704
		3693346	3904854	4076803	4167797	4258735	

Required Actions for Users:

1) Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility. If you have expired product, do not use.

2) Inform potential users of the product in your organization of this notification and complete the attached response form. Return the completed response form to the fax number or e-mail address on the form, even if you do not have the affected product.

3) Return affected product using the return label provided with this letter. Contact Sedgwick at 1-844-861-6220 (M-F, 8am-5pm ET) if you have not received a return label or require additional labels for returning the affected product. The return labels are for single use only. Please do not reproduce. Please visit http://expertezlabel.com to request additional labels for returning affected product. To ensure proper and timely credit, follow the instructions on the return label for returning product. Upon receipt of the completed response form and return of the affected product, ICU Medical will credit you for any product returned. You will only receive credit for product that you return. NOTE: Credits for product purchased through distributor will be credited by the distributor.

4) If you have distributed the product further, immediately notify your accounts that received the product identified in the Affected Product / Table 1 sections of this notification and ask them to contact Sedgwick at 1-844-861-6220 (M-F, 8am-5pm ET) to obtain a response form.

Follow up Actions:

Please contact Customer Service using the information provided below for assistance reordering replacement product.

Dura Life Product Code	Product Description	Alternative UltraSet Product Code	Product Description
60-0010	DuraLife®Autoclavable Double Swivel Elbow	**66-1991**	Swivel Elbow with Suction Port
60-1502	DuraLife®Autoclavable Silicone Extension Tube	**66-2509**	UltraSet® Non-Ported Double Swivel Elbow
60-1510	DuraLife®Autoclavable Silicone Extension Tube	**66-2505**	UltraSet® Ported Double Swivel Elbow

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For further inquiries, please contact Smiths Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Customer Service	1-866-829-9025, option 8 or customerservice@icumed.com (M-F, 8am-6pm CT)	Additional information or assistance

The U.S. Food and Drug Administration (FDA) has been notified of this action.

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Krishna Uppugonduri
Corporate Vice President,
Quality, Regulatory & Medical Affairs

Enclosures:

- Customer Response Form (separate document)