

URGENT: MEDICAL DEVICE CORRECTION

BCI Airway Adapters

14 February 2025

Dear Valued Customers:

Director of Nursing
Director of Risk Management

Smiths Medical is issuing this letter to notify you of a potential issue with specific Airway Adapters supplied individually and with certain kits. This letter details the issue, the affected models and lots, and the required actions for users to perform.

Issue:

Smiths Medical has become aware of the potential for breakage of these Airway Adapters. Investigation determined that the weld between the mating parts may not meet specification. Please reference the correctly assembled view in *Figure 1* and the separated components in *Figure 2*.



Figure 1



Figure 2

Potential Risk:

The issue may be detected at setup, however if the Airway Adapter breaks after therapy is initiated, inaccurate readings, a break in the airway circuit and loss of ventilation are also possible. A break in the airway circuit could result in an inability to ventilate, hypoxia, cardiopulmonary collapse or death.

If this issue occurs, the breathing circuit must be reconnected using a new Airway Adapter to address the issue. Smiths Medical has received two (2) complaints related to this issue. Of those two (2) complaints, there were zero (0) reports of death, and zero (0) reports of serious injuries associated to this issue.

Affected Product:

Our records indicate that your facility may have received potentially affected products. Refer to Table 1 below for a list of affected devices and lot numbers.

Table 1 - List of Affected Devices

Affected Product Model Number	Affected Product Model Name	UDI
WW1100	Airway Adapter, Straight	35019517062667
WW8214	Kit, Patient Attachment	30610586038444

Please see the affected lots in Appendix A

Required Actions for Users:

To address the described risk, users should follow the instructions below:

1. Check all inventory locations within your institution for the affected product listed in this notification. If you have an affected product quarantine it.

2. Destroy all affected products following your institution’s process for discarding. If discarding is not immediately possible at your facility, then the product should be quarantined until disposal.
3. Share this notification with all potential users of the devices to ensure they are aware of this notification. If the devices are used at another location, please ensure this communication is delivered there.
4. Complete and return the attached Customer Response Form to smithsmedical8046@sedgwick.com within 10 days of receipt to acknowledge your understanding of this notification. Please contact customer service for a credit.

DISTRIBUTORS: If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to smithsmedical8046@sedgwick.com.

Follow up Actions by Smiths Medical:

Smiths Medical will contact customers who have returned completed response forms identifying affected products within their possession to discuss credit

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

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	Globalcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Customer Service	Customerservice@icumed.com 1-(877)-946-7747	Product credit information
Field Action Processing	smithsmedical8046@sedgwick.com 1-(888)-879-8145	Field Action Processing and Response

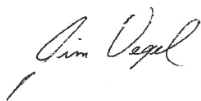
The U.S. Food and Drug Administration (FDA) has been notified of this action.

Adverse reactions 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,



Jim Vogel
Vice President of Quality

Enclosures:

- Response Form

Appendix A

Item/SKU	Lots					
WW1100	2367264	4120594	3785503	3372540	3291105	3274449
	2373071	4225429	3785504	3372541	3292653	3287858
	2658411	4236887	3788853	3381687	3294706	3289019
	2690517	4236889	3788854	3386807	3296610	3290566
	2695046	4256023	3788855	3406654	3297304	3294707
	2792606	4256024	3799595	3411359	3297306	3321359
	2823742	4256025	3807283	3437865	3297307	3332595
	2843746	4269090	3813374	3444606	3300487	3335022
	2898265	4269092	3816815	3444607	3300894	3337884
	2899311	4296456	3829561	3487626	3302400	3362410
	2929198	4296457	3833650	3490725	3303731	3367253
	2943659	4296458	3838834	3494347	3304217	3782353
	2950547	4296459	3856458	3494348	3304218	3782354
	2959836	4296460	3859137	3498521	3304219	3782356
	2978300	4301986	3880230	3501365	3308703	3782357
	2983686	4301987	3904106	3506535	3314198	3782358
	2986391	4301988	3911171	3511053	3314205	3785501
	3000742	4301989	3918565	3539360	3316934	4064150
	3027404	4313391	3918566	3539361	3318658	4070451
	3048157	4313392	3922224	3544089	3367254	4070452
	3057565	4397645	3937583	3547811	3370375	4080214
	3078619	4397646	3937584	3567400	4100059	4081996
	3097350	4397648	3937585	3575787	4100060	4087596
	3109127	4397649	3940759	3585974	4102743	4087597
	3123384	4397650	3953323	3590226	4123706	4090815
	3145330	4397651	3959793	3603780	4137598	4090816
	3159020	4397652	3966237	3607017	4164939	4094682
	3168379	4397653	3975879	3610650	4169446	4094683
	3172848	4397654	3988136	3614224	4169447	4204358
	3172849	4397655	3991088	3618131	4183765	4210647
	3190273	4397656	3999591	3621151	4183766	4213613
	3214132	4397657	4009212	3643871	4193996	4217228
	3227502	4397661	4013850	3647957	4193997	4217229
	3230971	4397662	4034322	3651290	4236888	4236885
	3243790	4397663	4037402	3660704	4437691	4236886
	3249030	4397664	4042639	3666830	4437692	4420995
	3255107	4397665	4049375	3782349	4446696	4420996
	3258815	4397666	4052823	3782350	4446697	4420997
	3267952	4397667	4055439	3782351	4446698	4420998
	3272253	4397668	4061794	3782352	4446699	4437690

	3785502	4397669	4109052	3782355	4446700	
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WW8214	022980-1-22	022404-1-17	021860-1-10	021110-1-7	020609-1-2	016288-1-1
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	022980-1-27	022404-1-21	021860-1-17	021110-1-11	020609-1-6	018252-1-1
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	020609-1-1	020561-1-1	020551-1-1	020505-1-1		