

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Bivona® Endotracheal Tubes – Inadequate Package Seal

Affected Device:	Bivona® Uncuffed Wire Endotracheal Tubes and Bivona® Aire Cuf Wire Endotracheal Tubes
Type of Action:	Removal
Date:	18-AUG-2021
Attention:	Clinical users of, and Distributors of the Bivona® Uncuffed Wire Endotracheal Tubes and Bivona® Aire Cuf Wire Endotracheal Tubes
Affected Devices:	Refer to Attachment 2: List of Affected Devices for Product Codes (SKU's) and Lots of affected devices.

Dear Customer,

The purpose of this Field Safety Notice is to advise you that Smiths Medical has initiated a recall for specific lots of Bivona® Uncuffed Wire Endotracheal Tubes and Bivona® Aire Cuf Wire Endotracheal Tubes as noted in Attachment 2.

REASON FOR THE FIELD SAFETY NOTICE

Smiths Medical became aware via field complaints that the bottom pouch seal of Bivona® Aire Cuff Wireless Endotracheal Tubes, was partially open allowing the tubes to protrude from the packaging compromising product sterility. See Figure 1 below for a depiction of this issue.



Figure 1. Photo of broken seal.

This FSCA is being performed with the knowledge of the appropriate regulatory authorities.

RISK TO HEALTH:

Smiths Medical has received zero (0) reports of death and zero (0) reports of serious injury related to this issue.

No observed adverse health consequences were identified based on the reported complaint; the issue was noted prior to patient use.

Urgent Medical Device Field Safety Notice: Bivona® Uncuffed Wire Endotracheal Tubes and Bivona® Aire Cuf Wire Endotracheal Tubes
Smiths Medical Ref # 3012307300-08/09/2021-011-R

INSTRUCTIONS TO CUSTOMERS AND DISTRIBUTORS:

This field action will be conducted with the assistance of Sedgwick, a third-party vendor.

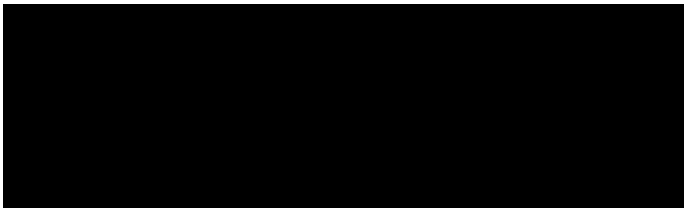
1. Locate and quarantine affected product in your possession by referring to the Affected Devices List on Attachment 2.
2. Determine the number of affected devices in your possession and complete the Response Form (Attachment 1) within 10 days of receipt, returning it to Smithsmedical3444OUS@Sedgwick.com. The form must be returned even if you do not have any affected Bivona® Uncuffed Wire Endotracheal Tubes and Bivona® Aire Cuf Wire Endotracheal Tubes in your possession.
3. All affected product must be returned to Sedgwick for processing. A pre-paid return shipping label will be sent to you when the Response Form is returned indicating whether impacted devices are in your possession. When returning product please include a copy of the Response Form (Attachment 1) inside EACH BOX.
4. Credit will be processed once the impacted product and Response Form (Attachment 1) has been received and processed.

DISTRIBUTORS: if you have distributed potentially affected product to your customers, please immediately notify them of this Field Safety Notice and instruct them to return the Response Forms to YOU for reconciliation. Please respond for each Distribution Center affected only.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

If you have any questions regarding this notification, please contact Smiths Medical via email at fieldactions@smiths-medical.com.

Sincerely,



Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442
fieldactions@smiths-medical.com

Enclosure:
Attachment 1 – Response Form
Attachment 2 – List of Affected Devices

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE
RESPONSE FORM

Bivona® Endotracheal Tubes – Inadequate Package Seal

Please assist us in making this Medical Device Field Safety Notice efficient and convenient for you by completing and returning this Field Safety Notice Response Form as soon as possible. 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 Field Safety Notice.

Please acknowledge receipt of this Urgent Field Safety Notice by completing and returning this Field Safety Notice Response Form to Smithsmedical3444OUS@Sedgwick.com within 10 days.

Affected Product Information		
Product Code (SKU)	Lot Number	Quantity to be Returned (individual units)

I certify that I have read and understand the information in the attached Recall Notice:

Name and Title (Please Print)	Signature and Date	Facility Name and Address
Email Address	Telephone Number	

*If you are submitting a Response Form for multiple locations, please include the address for each facility you are responding for on the form or in an attachment.

Affected Lots by SKU								
SKU 15W080			SKU 35W080			SKU 35W080		
3221795	3463690	3608114	3237503	3523718	3890125	3459490	3751160	4063133
3221796	3491443	3608131	3237504	3528478	3890127	3463693	3751163	4063134
3226185	3491444	3615305	3263029	3536391	3890128	3463694	3774410	4063135
3250343	3491445	3641651	3263030	3536392	3890129	3463695	3778485	4063136
3263023	3491446	3680769	3267969	3536393	3890130	3463696	3778493	4071990
3272646	3491447	3700904	3276517	3536395	3890131	3472875	3782472	4071991
3301497	3491448	3707798	3276518	3536398	3890132	3472876	3794166	4080805
3301498	3507938	3782473	3276519	3536399	3890133	3484265	3800536	4080806
3312810	3507939	3790044	3301034	3540955	3890134	3484266	3890117	4083993
3312811	3507940	3890025	3301035	3541009	3917895	3484267	3890118	4089280
3315720	3507941	3890026	3301036	3565654	3917896	3484273	3890119	4095958
3315721	3512284	3890027	3301479	3572777	3926899	3484274	3890120	4097867
3338833	3512285	3890028	3307931	3572790	3926900	3488047	3890121	4105268
3346070	3517254	3890029	3312816	3577132	3931090	3504014	3890122	4105269
3361916	3521999	3890030	3312817	3577134	3933423	3507849	3890123	3463693
3370107	3531347	3890031	3312818	3577142	3936455	3512360	3890124	
3379478	3540954	3890032	3312819	3582755	3952241	SKU 35W085		
3433337	3545300	3890033	3315710	3582756	3952242	3218553	3517266	3890195
3437237	3552748	3907873	3315711	3596290	3952243	3230635	3540956	3890196
3442378	3565644	3926897	3315712	3604256	3952244	3230636	3569173	3890197
3442379	3569215	3985080	3346087	3604272	3952245	3238617	3590693	3901068
3451013	3582745	3991281	3346088	3608155	3952246	3238618	3596299	3917865
3459483			3349554	3622333	3955677	3258464	3608106	3929833
SKU 25W080			3350510	3622334	3962474	3312935	3677631	3931093
3648874	3890459		3350511	3622336	3985139	3346089	3748025	3948979
SKU 25W085			3361918	3630052	3985140	3370123	3774374	3998080
	3387669		3361919	3637293	3985141	3437246	3870331	4015630
SKU 25W090			3370120	3656655	3985142	3491405	3870332	4035792
3322657	3342023		3370121	3661490	3985143	3507907	3890194	4047987
			3370122	3661491	3985144	SKU 35W090		
			3379494	3661492	3985145	3469110	3904517	4002358
			3423620	3664416	3985146	3504012	3929861	4002359
			3433341	3664417	3991321	3552747	3959226	4029451
			3437242	3677633	3991322	3700911	3991328	4060253
			3437243	3677634	4026705	SKU 35W095		
			3437244	3677635	4026706	3317880	3839565	4042023
			3437245	3700907	4039134	3360929	4035809	
			3442385	3700908	4042021			
			3450988	3700909	4042022			
			3450989	3700910	4043952			
			3451017	3721738	4043953			
			3454875	3721739	4047982			
			3454876	3726299	4060251			
			3459488	3730889	4060252			
			3459489	3748028	4063132			