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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:	16-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.

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,

Daniel Khalili
SVP Chief Global and Regulatory Affairs Quality Officer
Smiths Medical
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Minneapolis, MN 55442
fieldactions@smiths-medical.com

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