smiths medical
bringing technology to life

URGENT: FIELD SAFETY NOTICE

Nasopharyngeal Airway, Double Swivel Connector, 15mm Y Piece, Portex™ Orator Speaking Valve, Thermovent™ 1200

3rd October 2024

Dear Valued Customer,

Smiths Medical is issuing this letter to notify you of a potential issue with the packaging sterile seals on specific Nasopharyngeal Airway, Double Swivel Connector, 15mm Y Piece, Portex™ Orator Speaking Valve, Thermovent™ 1200 products packaged between 20 January 2021 and 27 August 2021. This letter details the issue and the required steps for you to perform.

Issue:
Smiths Medical has identified a timeframe where there is uncertainty in the seal integrity of the sterile packaging of sterilized Nasopharyngeal Airway, Double Swivel Connector, 15mm Y Piece, Portex™ Orator Speaking Valve and Thermovent™ 1200 products.

Potential Risk
The potential risk of the uncertainty in the seal integrity of the sterile packaging is that a product labeled as sterile, may not be sterile, which could potentially lead to infection.

To date, Smiths Medical has received zero (0) complaints or adverse events associated with this issue.

Affected Product
The affected product SKUs and lots, which were manufactured between 20 January 2021 and 27 August 2021 are listed below.

Table 1: Affected Product(s)

SKU	Description	Lot #
100/210/060	Nasopharyngeal Airway 6.0MM 10/BX	4125006
100/210/070	Nasopharyngeal Airway 7.0MM 10/BX	4097684, 4110350
100/210/080	Nasopharyngeal Airway 8.0MM 10/BX	4147168

Smiths Medical Actions:
Smiths Medical is sending this notification to all customers who received product(s) from Smiths Medical listed above. Smiths Medical has initiated a global ship hold on impacted lots to ensure affected product is no longer distributed. Smiths Medical will provide credit to affected customers.

Customer Required Actions:
1) Check all inventory locations within your institution for the affected catalog numbers and lot numbers listed in the notification and discontinue use. Discard 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.
2) Share this notification with all potential users of the device to ensure they are aware of this

notification and proposed mitigations. If the devices are used at another location, please ensure this communication is delivered there.

3) Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.
4) **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

For further inquiries, please contact the applicable team using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Field Safety Notice	EMEA-FSN@icumed.com or contact your sales representative	Questions about this Field Safety Notice

Your country regulatory agency has been notified of this action

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,

Andy Mathein
Vice President of Quality

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

Nasopharyngeal Airway, Double Swivel Connector, 15mm Y Piece, Portex™ Orator Speaking Valve, Thermovent™ 1200

3rd October 2024

Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-FSN@icumed.com, If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Please select one:

☐ I have **NO** affected products (complete and return this form to the e-mail address above)

☐ **YES**, I have affected products, I have notified users in my facility and I have followed the instructions provided to me and destroyed all affected items (see table below)

If you have affected product on hand, please complete table below:

TABLE 1

Lot Number	Quantity in inventory (eaches)	Quantity Destroyed	Date of Destruction	PO, debit memo or invoice

If you have distributed the product further, please complete table below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

Lot Number	Quantity destroyed locally by customer	Date of Destruction

Adverse events and complaints associated with the use of this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.

ADDITIONAL AFFECTED PRODUCT DESTROYED

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction