

URGENT MEDICAL DEVICE CORRECTION

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

19 July 2024:

Dear Valued Customer:

- Director of Respiratory
- Director of Nursing
- Director of Risk Management

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	4107295, 4115880, 4125006
100/210/070	Nasopharyngeal Airway 7.0MM 10/BX	4115879, 4122013, 4127688, 4130776, 4156815
100/210/080	Nasopharyngeal Airway 8.0MM 10/BX	4112944, 4125005, 4147168
100/550/000	PORTEX 'ORATOR' SPEAKING VALVE FOR TRACHEOSTOMY TUBE + 2/CA	4150794

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. Please contact your Smiths Medical customer service representative after the Customer Response Form has been provided to asiaquality@icumed.com, to coordinate credit.

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. Destroy all affected products following your institution's process for destruction. If destroying 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. 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 asiaquality@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.
- 4) DISTRIBUTORS: If you have distributed affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to asiaquality@icumed.com.

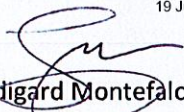
For further inquiries, please contact the applicable team using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	Customerservice@icumed.com 1-800-258-5361	Questions about product for credit

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,

19 Jul 2024


Leodigard Montefalcon Jr.
Senior Quality Assurance Manager - Asia

Enclosures:

- Customer Response Form