6000 Nathan Lane N.
Minneapolis, MN 55442

URGENT MEDICAL DEVICE RECALL

Portex™ Pro-Vent Arterial Blood Gas Kit

06 September 2023

Dear Valued Customers:
Director of Materials Management
Director of Nursing
Director of Risk Management

Smiths Medical, Inc. is issuing this Urgent Medical Device Recall to notify you of a potential defect with the Portex™ Pro-Vent products. This letter details the issue and the required steps for you to perform.

Issue:
Smiths Medical has identified the potential for a manufacturing defect within one specific lot of the 4599P-1 Pro-Vent arterial blood gas kit involving the absence of a component called "Filter-Pro ABG SYR CAP" from the packaging, as seen in Figure 1 below.

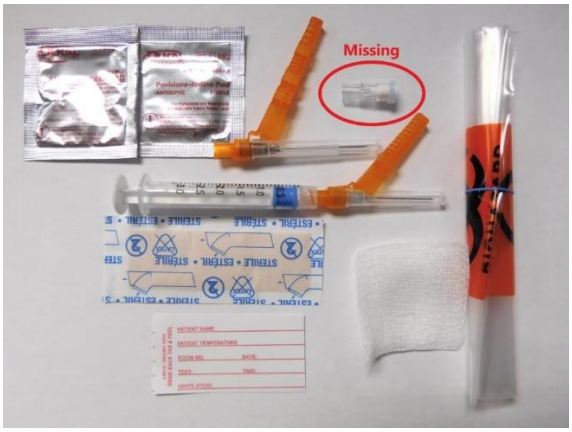

Figure 1: Image showing kit contents with missing Filter-Pro in red circle

Potential Risk:
The Filter-Pro is used after the blood sample is collected, it is placed on the end of the syringe after the needle hub is removed to allow for the evacuation of air in the syringe and also to seal the sample during transportation. This manufacturing defect (absence of component) can lead to the need for a second blood sample collection. To date, Smiths Medical has not received any reports of serious injury or death associated with this issue.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed between 04 November and 30 December 2022. The affected item and lot numbers are provided in Table 1, below:

Table 1: Affected Product and Lot Numbers

Item Number	Product Description	Lot Number
4599P-1	Pro-Vent Arterial Blood Sampling Kit with Dry Lithium Heparin for Gases and Electrolytes	4331283

Required Actions for Users:

1. Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility.

2. Inform all potential users of the product in your organization of this notification and complete and return the attached response form to smithsmedical4353@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification, even if you do not have the affected product and/or has already been used.

3. If you have distributed the product further, immediately notify your accounts that received the product identified in the Affected Product / Table 1 sections of this notification and ask them to contact Sedgwick at 1-888-202-3694 (M-F, 8am-5pm ET) to obtain a response form.

Follow up Actions by Smiths Medical:

Upon receipt of the affected product, or upon receipt of a Certificate of Destruction, Smiths Medical will credit you for any product returned/destroyed. You will only receive credit for product that you return or that you certify has been destroyed locally. NOTE: Credits for product purchased through a distributor will be credited by the distributor.

For further inquiries, please contact Smiths 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	1-(800)-258-5361	Additional information or technical assistance

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

Adverse events 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,

Joseph Canavan

Joe Canavan
Vice President, Quality, Consumables

Enclosure(s):

- Customer Response Form (separate document)