smiths medical

6000 Nathan Lane N.
Minneapolis, MN 55442

URGENT MEDICAL DEVICE RECALL

ProPort™ Plastic Implantable Ports

13 February 2025

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

Smiths Medical is issuing an Urgent Medical Device Recall informing affected customers of a potential lot-specific issue with the ProPort™ Plastic Implantable Ports. As a part of this notification, Smiths Medical is notifying each affected customer and authorized distributor of this issue.

Issue:

Smiths Medical has identified that the plastic port housing and port reservoir of the ProPort™ Plastic Implantable Ports may separate because of a manufacturing defect. This issue is limited only to the ProPort™ Plastic Implantable Ports.

Figure 1 shows non-defective port. The bottom of the port will have a flush surface and there will be no separation between the reservoir and the housing. On the top of the port, the septum will protrude from the housing.

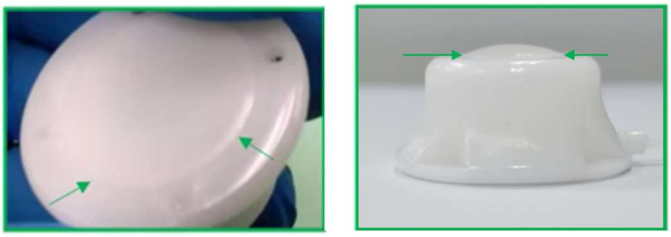

Figure 1: Non-defective Port

Figure 2 shows a defective port. The bottom of the port will not be a flush surface and there will be separation between the reservoir and the housing. On the top of the port, the septum will not protrude from the housing. The reservoir and the housing can completely come apart.

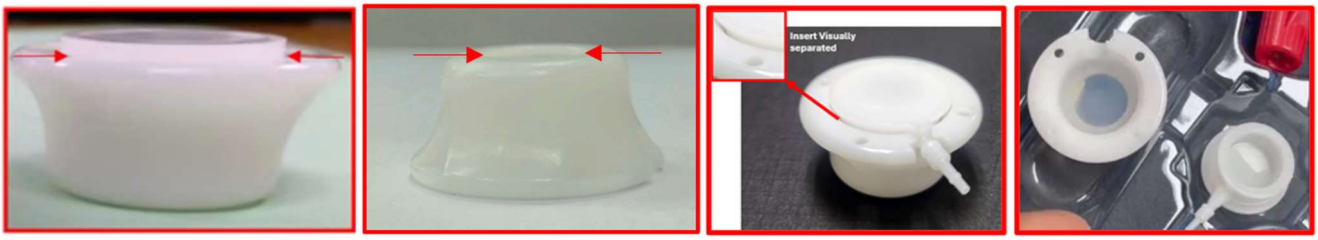

Figure 2: Defective Port

Potential Risk:

To date, Smiths Medical has received two (02) reports of serious injury, and zero (0) deaths associated with this issue. If the defect is not identified during preparation, identification of the separated port during implantation may result in delay of procedure or air introduced during implantation of the device. The IFU provides instructions to reduce air embolisms and includes a flow check to examine for leaks during implantation. After the portal and catheter are implanted, catheter tip location should be verified using fluoroscopy or x-ray to assure stability of the system. If the separation of the port housing occurs during use, the separation of the port housing from the reservoir could lead to a fluid leakage during therapy. This may result in extravasation potentially causing localized tissue irritation or tissue damage. The IFU provides instruction for examining

the portal pocket for swelling, tenderness, or infection which might indicate system leakage. If system leakage is suspected, radiologic imaging is recommended to determine if there are problems with the system.

Affected Products:

The affected item and lot numbers are provided in Table 1, below:

Table 1: Affected Products

Item Number	Item Description	UDI	Lot Number
21-4153-24	ProPort (Plastic standard portal) 1.9 mm PUR catheter – Kit	10610586012563	4453603
21-4155-24	ProPort (Plastic standard portal) 2.6 mm PUR catheter – Tray	10610586012594	3926119 3944833 3960347 3968098 3988451 4027913 4057817 4087000 4139520 4146467 4173474 4196758 4221725 4256939 4291484 4295931 4307473 4307474 4447572 4449876 4460619 6037144 6059285
21-4165-24	ProPort (Plastic standard portal) 2.6 mm PUR catheter. Pre-assembled – Tray	10610586012686	3984420 4235543 4242787 4294897
21-4171-24	ProPort (Plastic Low-Profile portal) 2.6 mm PUR catheter – Tray	10610586012716	3941279 3969275 3984421 4022601 4136364 4148590 4153873 4196768 4227788 4232310 4235600 4248718 4276227 4302980 4307478 4325880 4358053 4358054 4395512 4415445 4420760 4449877 4460620 6013083
21-4183-24	ProPort (Plastic Low-Profile portal) 1.9 mm PUR catheter – Tray	10610586012778	3916028 4163556 4221727 4235601 4248694 4256928 4256964 6026651
21-4187-24	ProPort (Plastic Low-Profile portal) 2.8 mm Silicone catheter – Tray	10610586012839	3922514 4196736

Required Actions for Customers

1. Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility.
2. Please return all affected product.
3. Inform all potential users of the product in your organization of this notification and complete and return the attached response form to smithsmedical8171@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.
4. 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 1-888-345-2656 (M-F, 8am-5pm ET) to obtain a response form.

Recommended Actions for Healthcare Providers:

1. As instructed in the IFU, continue to monitor patients who have an implanted ProPort™ Implantable Ports for signs of any adverse events.
2. As instructed in the IFU, ensure the housing and reservoir feel secure and stable when palpating the portal. Symptoms such as swelling, redness, or discomfort at the implant site may indicate leakage or system failure.

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Follow up Actions by Smiths Medical:

Upon receipt of the affected product, Smiths Medical will credit you for any product returned/destroyed or provide replacement product at no charge, as inventory allows. Credit or replacement product will only be provided for products that are returned or certified as 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	customerservice@icumed.com 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,

Joe Canavan

Joe Canavan
Vice President, Quality, Consumables

Enclosure(s):

- Customer Response Form (separate document)
- External FAQs