smiths medical
bringing technology to life

6000 Nathan Lane North
Minneapolis, MN 55442

URGENT: FIELD SAFETY NOTICE

ProPort™ Plastic Implantable Ports

27 February 2025

Dear Valued Customer:

Smiths Medical is issuing this letter 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.

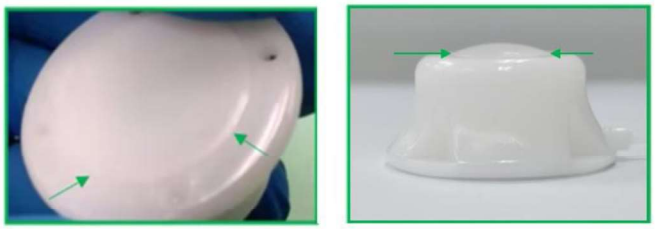

Figure 1: Non-defective Port

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.

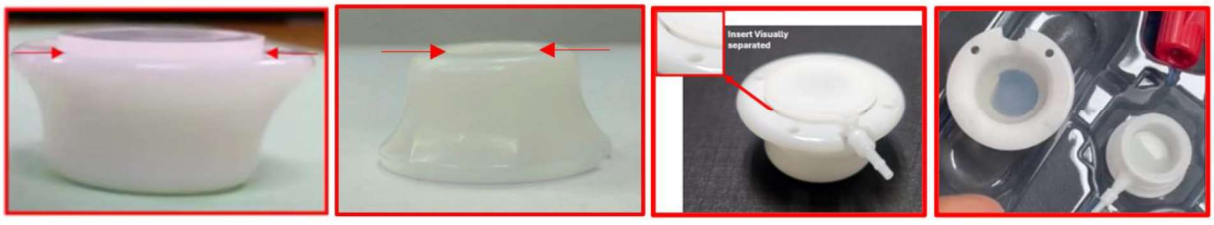

Figure 2: Defective Port

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 Product

Our records indicate that your facility may have received potentially affected products. Refer to Table 1 below for a list of affected devices and lot numbers.

Table 1: Affected Product(s)

Item Number	Item Description	Lot Number
21-4151-24	TRAY, PROPORT, PLASTIC, 2PC, STD, SGL LMN, 1.0, SIL 1/EA	(Refer to Appendix A)
21-4152-24	KIT, PROPORT, PLASTIC, 2PC, STD, SGL LMN, 1.0, PU 1/EA	
21-4153-24	KIT, PROPORT, PLASTIC, 2PC, STD, SGL LMN, 1.0, PU 1/EA	
21-4155-24	TRAY, PROPORT, PLASTIC, 2PC, STD, SGL LMN, 1.6, PU 1/EA	
21-4171-24	TRAY, PROPORT, PLASTIC, 2PC, LP, SGL LMN, 1.6, PU 1/EA	
21-4172-24	KIT, PROPORT, PLASTIC, 1PC, LP, SGL LMN, 1.6, PU 1/EA	
21-4173-24	TRAY, PROPORT, PLASTIC, 1PC, LP, SGL LMN, 1.6, PU 1/EA	
21-4183-24	TRAY, PROPORT, PLASTIC, 2PC, LP, SGL LMN, 1.0, PU 1/EA	

Smiths Medical Actions:

Smiths Medical is sending this notification to all customers who received affected product as listed above. Smiths Medical will provide full credit to affected customers. NOTE: Credits for product purchased through a distributor will be credited by the distributor.

Recommended Actions for Healthcare Providers:

a) As instructed in the IFU, continue to monitor patients who have an implanted ProPort™ Implantable Ports for signs of any adverse events.

b) 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.

Customer Required Actions:

1) Check all inventory locations within your institution for the impacted lot numbers listed in the notification (Appendix A) 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 EMEA-FSN@icumed.com **within 10 days of receipt** to acknowledge your understanding of this notification, even if you do not have the affected product.

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
Customer Service	https://www.icumed.com/about-us/contact-us	Questions about credit.

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,

Joe Canavan
Vice President, Quality, Consumables

See below:

- Appendix A – Impacted Lot Numbers
- Customer Response Form

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Appendix A – Impacted Lots

Item	Lot
21-4151-24	3968088 4052396 4063411 4317072
21-4152-24	4006475 4139518 4222392 4378522 4022600 4152689 4235597 4387732 4036893 4189866 4307472 4460618 4136362 4222392 4349806
21-4153-24	3928189 4146466 4317075 4453603 3953709 4173601 4317092 6051324 4108664 4235508 4358052 4114114 4235598 4366693 4114115 4294059 4387733
21-4155-24	3926119 4139520 4291484 3944833 4146467 4295931 3968098 4173474 4302979 3988451 4196758 4307473
21-4171-24	3941279 4136364 4227788 4276227 4325880 4415445 3969275 4148590 4232310 4302980 4358053 4420760 3984421 4153873 4235600 4307478 4358054 4460620 4022601 4196768 4248718 4317093 4395512 6013083
21-4172-24	4235509
21-4173-24	4317077
21-4183-24	3916028 4108453 4196775 4235601 3969277 4146468 4221727 4248694 4022602 4153874 4235565 4256927 4060894 4163556 4235567 6026651

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URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

ProPort™ Plastic Implantable Ports

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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.

Customer Number (Refer to the original email subject line for your CNXXXXXX /customer number)	
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 1 below:

TABLE 1

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

If you have distributed the product further, please complete table 2 below with collated information received from your customers and respond to Smiths Medical with the overall information.

TABLE 2

Item / SKU Number	Lot Number	Quantity destroyed locally (Eaches)	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.

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ADDITIONAL AFFECTED PRODUCT DESTROYED

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