6000 Nathan Lane N.
Minneapolis, MN 55442

URGENT MEDICAL DEVICE RECALL

Leaking Rotating Adapter (Rotator)

10 November 2023

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

Smiths Medical is issuing this Urgent Medical Device Recall letter to notify you of a potential defect with the rotating adaptor (rotator) which is incorporated as a component within the products listed in Table 1. This letter details the issue and the required steps for you to perform.

Issue:
Smiths Medical has identified a manufacturing defect affecting specific rotator lots. Within this population, the inner diameter of the device's o-ring may be oversized affecting seal integrity. Figure 1 illustrates where the o-ring is situated within the device. In the past 5 years, we have received 1 complaint regarding this issue. So far, we have not received any reports of related injury or illness.

Figure 1. Rotator shown with O-Ring in Blue

Potential Risk:
An inadequate seal may lead to a leak during infusion of medication which may potentially lead to under infusion of medication. The issue may also potentially introduce air into the patient's vascular system, which may cause an air embolism.

Affected Items:
Our records indicate that you may have received some of the affected product, which were distributed in the United States between 19 January 2023 and 29 August 2023. The affected item and lot number are provided in Table 1 below.

Table 1: Affected Product and Lot Numbers

List Number	Product Description	Lot Number
M20754	LOGICAL®CATH LAB KIT	4371054
MX1431MRL	1050 STOPCOCK LEFT ROTATOR OFF HANDLE	4387166
MX20617	6IN PRESSURE TUBING	4380614
		4416451
MX4331R	700PSI STPCK W/ROTATOR	4355397
		4380735
		4387234
		4404740
MX496HP	HIGH PRESSURE ROTATOR WITH MALE LUER LOCK	4332915
		4408772
MX497HP	HIGH PRESSURE ROTATOR WITH FEMALE LUER LOCK	4330826
		4384397
MX682BR	20IN (50.8CM) BRAIDED INJ LINE, ROTATING ADAPT	4398428
		4404690
MX682R	20IN (50.8CM) INJ LINE ROTATING ADAPT	4398433
MX694R	48IN (121.9CM) INJ LINE ROTATING ADAPT (900psi)	4383431
		4387987
		4404698

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 potential users of the product in your organization of this notification and complete and return the attached response form to smithsmedical7166@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 it has already been used.
3. If you have distributed the product further, immediately notify your accounts that receive the product identified in the Affected Items / Table 1 sections of this notification and ask them to contact Sedgwick at 1-855-215-5142 (M-F, 8am-5pm ET) to obtain a response form.
4. If the product has not already been used, please return affected lots to Smiths Medical and Smiths Medical will offer replacement units.

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 of Quality

Enclosures:

- Response Form
- FAQs

smiths medical

10 November 2023

Leaking Rotating Adapter (Rotator)

Urgent Medical Device Recall
Frequently Asked Questions

Smiths Medical is issuing an Urgent Medical Device Recall to notify you of a potential defect with the rotating adaptor (rotator) which is incorporated as a component within the products listed in Table 1. The Medical Device Recall letter details the issue and the required steps for you to perform.

Table 1: Affected Product and Lot Numbers

List Number	Product Description	Lot Number
M20754	LOGICAL®CATH LAB KIT	4371054
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1. Q What is the issue?

Smiths Medical has identified a manufacturing defect affecting specific rotator lots. Within this population, the inner diameter of the device's o-ring may be oversized affecting seal integrity. Please see the attached Urgent Medical Device Recall letter for additional information including specific actions we are requesting of your organization. In the past 5 years, we have received 1 complaint regarding this issue. So far, we have not received any reports of related injury or illness.

2. Q What is the potential risk?

An inadequate seal may lead to a leak during infusion of medication which may potentially lead to under infusion of medication or may potentially introduce air into the patient's vascular system, which may cause an air embolism.

3. Q What products are affected?
Refer to Table 1 above and in the Urgent Medical Device Recall letter for the affected product and lot number.

4. Q When was product distributed?
Affected products were distributed directly from Smiths Medical in the United States between 19 January 2023 and 29 August 2023.

5. Q How can customers identify which devices are affected?
The list number and lot number are printed on every box and individual packaging.

6. Q What action is Smiths Medical taking?
Smiths Medical is notifying affected customers via the Urgent Medical Device Recall letter.

7. Q Can devices at my facility continue to be used?
No. If the product has not already been used, please return affected lots to Smiths Medical and Smiths Medical will offer replacement units.

8. Q Should I return affected products?
As communicated in the attached Urgent Medical Device Recall letter, if the product has not already been used, please return affected lots to Smiths Medical and Smiths Medical will offer replacement units.

9. Q How do I order replacement product?
Please contact Customer Service using the information provided below for assistance ordering replacement product.

10. Q Will Smiths Medical credit customer accounts for impacted product returned?
Yes, Smiths Medical will credit customers for any product returned.

11. Q How is the customer communication sent?
The notifications are being sent to each facility. Each customer and distributor will receive a letter and response form.

12. Q Is this a voluntary action?
Yes. Smiths Medical is voluntarily taking this action.

13. Q Has FDA been notified?
Yes.

14. Q Where can I find more information?

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-(866)-216-8806 globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	1-800-258-5361	Additional information or assistance
Sedgwick	1-855-215-5142 (M-F, 8am-5pm ET)	Questions about product return or to obtain additional copies of the Medical Device Recall letter