URGENT MEDICAL DEVICE CORRECTION

September 20, 2023

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Dear Valued McKesson Customer:

Smiths Medical has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Correction regarding one lot of their Bivona Pediatric Tracheostomy Tube. This notice has been issued because Smiths Medical has identified that the manufacturing date was incorrectly included as the expiration date on the unit box. The actual individual packaging has the correct expiration date which is March 17, 2026. Affected product first shipped June 15, 2021.

This Urgent Medical Device Correction is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For clinical inquiries, please contact Smiths Medical at **(800) 258-5361**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table below for a list of affected item(s) and lot number(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)
446585	60P045	TUBE, TRACH PED SZ 4.5	4125816

McKesson Customer Instructions:

1.) Examine your inventory for any product matching the affected item and lot number listed above.

2.) A copy of the Urgent Medical Device Correction from Smiths Medical has been included for reference.

3.) Contact Sedgwick at **(855) 215-4961** to obtain a Response Form. If you have affected inventory and wish to continue to use before the correct expiry date of March 17, 2026, no further action is necessary.

4.) If you have product affected by this notice and have arranged for return to Sedgwick, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
- **Please note**: **Your submitted McKesson Reply Form must include the Reference ID # provided by Sedgwick. (The Ref ID # can be found in the 'Packing Instructions' section of the return label)**
- **Please place a new order for replacement product if there is an immediate need**.

5.) Once you have received the return label from Sedgwick, return the product to them following their instructions.

6.) If you have further distributed any of the item referenced in this notification, provide your accounts with a copy of this Urgent Medical Device Correction.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc.
Device Correction Reply Form: RC-2023-195
Smiths Medical Bivona Tracheostomy Tube

September 20, 2023

OCT 05 2023

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at **(866) 871-0270** should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account: 20011433 District: 20810000
SUPER CARE MEDICAL SUPPLY
ATTN: RISK MANAGEMENT
8345 FIRESTONE BLVD STE 210
DOWNEY, CA 90241-3871

☐ I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return to Sedgwick.

Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			446585	60P045	TUBE, TRACH PED SZ 4.5

*Return only the affected lot number to Sedgwick

*** The affected lot numbers are listed on the McKesson customer letter.**

- **Please note**: Prior to submission of this Reply Form to the McKesson Corporate Customer Service Center, contact Sedgwick at **(855) 215-4961** to initiate your product return. Please indicate you are a McKesson Medical Surgical Customer when requesting your return-kit.
- **Please enter** the Reference ID # provided by Sedgwick: _____

Your submitted McKesson Reply Form must include the Reference ID # provided by Sedgwick to receive credit. The Ref ID # can be found in the 'Packing Instructions' section of the return label.

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

See instructions on the reverse side of this form to access
McKesson Medical-Surgical's online product ordering system, "SupplyManager", for a fillable form.

Instructions for the McKesson Medical-Surgical online product ordering system – "SupplyManager", to access and download a "fillable" PDF reply form.

1) It is important to download the correct reply form for the specific recall you are responding to.
   a. Reply forms have a specific designation, example: RC-202X-XXX.
      - "202X" is the recall year, and "XXX" is the 3-digit unique numeric identifier for the recall.

2) Go to https://mms.mckesson.com/ and log in to "SupplyManager", with your username and password.

3) On the home page, under 'Essential Tasks' click 'Your Account.' Under 'Resources' a support link titled "Product Recalls" can be found on the right side.

4) Click on the hyperlink "Product Recalls" (this will open a listing of recalls for the last 3 months).

5) On the recalls list page, locate the "Find" box.
   a. From the drop-down options, select one of the following: "Keyword", "McKesson Item #" or "Manufacturer".
   b. Enter a Keyword, McKesson Item #, or Manufacturer name in the Find box and click "Find".

   c. A list of issued recalls will be made visible for you to select from.

6) Click on the blue hyperlink, found under the heading "Recall Notice," for the notice details you want to access.

7) The PDF customer documents associated with the notice will be displayed, *this includes the reply form to download and complete for your response.*

8) Click on the hyperlink(s) to open the Customer Document(s). Save/Download this document to your computer. Once the documents are saved, close out the document window.

9) Submit completed reply form to MMSRecalls@McKesson.com.

10) If you wish to view additional recalls, return to the home recall page by clicking the blue "View All Recalls" button at the upper right corner of the page above the blue alert banner.

URGENT MEDICAL DEVICE CORRECTION

Bivona™ Pediatric Tracheostomy Tube

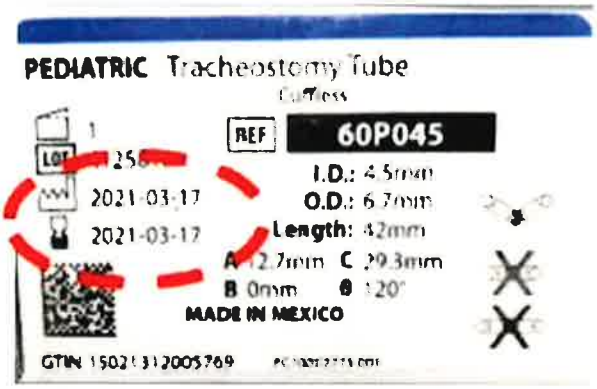
22 August 2023

Dear Valued Customers:

Out of an abundance of caution, Smiths Medical is issuing this letter to notify you of an issue on one lot of Bivona Pediatric Tracheostomy Tube. This notification details the issue, the affected items, and the required steps to perform.

Issue:
Smiths Medical has identified that the manufacturing date was incorrectly included as the expiration date on the unit box. The actual individual packaging has the correct expiration date which is March 17, 2026.

An example of the affected product labeling with the incorrect and correct expiration dates is below.



Unit box with incorrect expiration date

Individual packaging with correct expiration date

Potential Risk:
The identified incorrect expiration date on the unit box presents the potential for a customer to assess the product as expired, resulting in the potential for a delay in the availability to use the tracheostomy device. If the customer did not identify the incorrect device unit carton/secondary packaging labeling upon receipt and provided the items to clinicians, the individual device tray/primary packaging would still allow correct identification of the expiration date at the point of use, as the expiry date on the individual unit is correctly labelled. To date, there have been no reports of adverse events associated with this issue.

Affected Items:

Our records indicate that you may have received some of the affected product, which were distributed in the United States between 15 June 2021 and 28 July 2021. The affected item and lot number are provided in Table 1 below.

Table 1: Affected Product and Lot Numbers

Item Number	Product Description	Lot Number
60P045	Bivona Pediatric Tracheostomy Tube	4125816

Required Actions for Users:

1) Inform potential users of the product in your organization of this notification ~~and complete and return the attached response form to smithsmedical4076@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~~.
2) 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 1-855-215-4961 (M-F, 8am-5pm ET) to obtain a response form.

Follow up Actions by Smiths Medical:

If the product has not already been used, the product must be used before the correct expiry date of March 17, 2026.

For further inquiries, please contact Smiths Medical using the information provided below.

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	1-800-258-5361 or USOrders@icumed.com	Additional information or 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,

Andy Mathein
Vice President of Quality

Enclosures:

- Response Form (separate document)
- FAQs

Bivona™ Pediatric Tracheostomy Tube

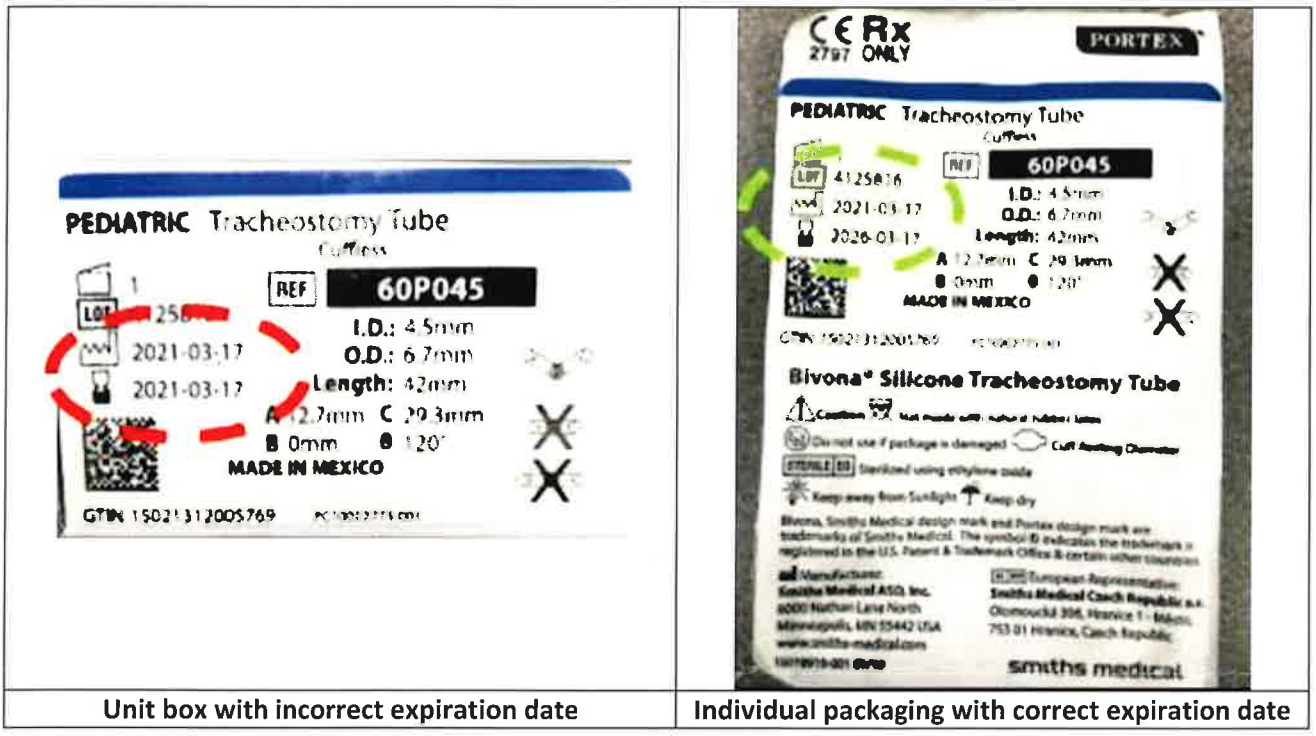
Urgent Medical Device Correction
Frequently Asked Questions

Out of an abundance of caution, Smiths Medical is issuing a medical device correction letter informing affected customers of an issue on one lot of Bivona Pediatric Tracheostomy Tube. As a part of this notification, Smiths Medical is notifying each affected customer and authorized distributor of this issue.

1. Q What is the issue?

Smiths Medical has identified that the manufacturing date was incorrectly included as the expiration date on the unit box. The actual individual packaging has the correct expiration date which is March 17, 2026.

An example of the affected product labeling with the incorrect and correct expiration dates is below.



Unit box with incorrect expiration date	Individual packaging with correct expiration date

2. Q What is the potential risk?

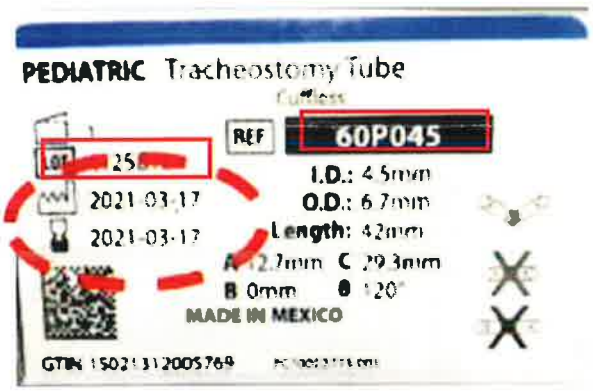
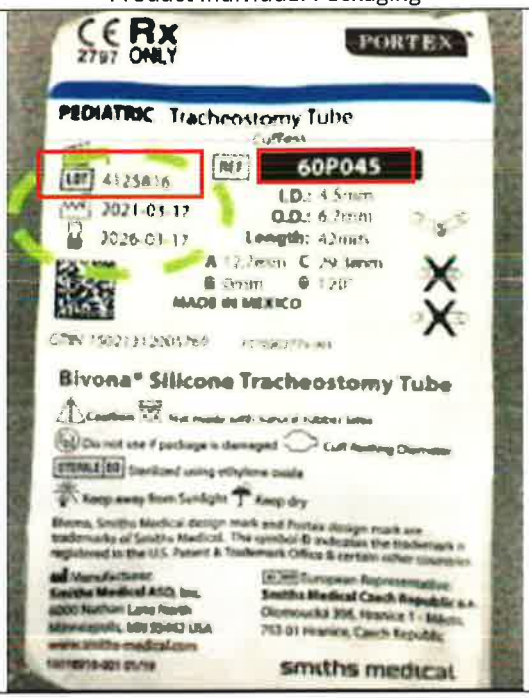
The identified incorrect expiration date on the unit box presents the potential for a customer to assess the product as expired, resulting in the potential for a delay in the availability to use the tracheostomy device. If the customer did not identify the incorrect device unit carton/secondary packaging labeling upon receipt and provided the items to clinicians, the individual device tray/primary packaging would still allow correct identification of the expiration date at the point of use, as the expiry date on the individual unit is correctly labelled. To date, there have been no reports of adverse events associated with this issue.

3. Q What products are affected?

Refer to Table 1 of the Urgent Medical Device Correction notice for the affected product and lot number.

4. Q **When was product distributed?**
Affected products were distributed directly from ICU Medical in the United States between 15 June 2021 and 28 July 2021.

5. Q **How can customers identify which devices are affected?**
The list number and lot number are printed on every box and individual packaging. Refer to below example:

Product Unit Box	Product individual Packaging
	

6. Q **What action is Smiths Medical taking?**
Smiths Medical is notifying affected customers via the attached letter.

7. Q **Can devices at my facility continue to be used?**
Yes. If the product has not already been used, the product must be used before the correct expiry date of March 17, 2026.

8. Q **Should I return affected products?**
As communicated in the attached Urgent Medical Device Correction letter, if the product has not already been used, the product must be used before the correct expiry date of March 17, 2026. If you wish to return the affected product, please contact Sedgwick to facilitate the return of your affected products.

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?

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	1-800-258-5361 or USOrders@icumed.com	Additional information or assistance
Sedgwick	1-855-215-4961 (M-F, 8am-5pm ET)	Questions about product return or to obtain additional copies of the Medical Device Recall letter