URGENT MEDICAL DEVICE RECALL

Rcvd 9/18/24 QS.

September 6, 2024

Dear Valued McKesson Customer:

Cypress Medical Products, LLC (Cypress) has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Recall regarding all lots of the McKesson Syringe 60cc, Luer Lock Tip, Sterile manufactured for Cypress by Jiangsu Shenli Medical Production Co., LTD (Shenli) beginning with alpha characters CLN. This notice has been issued because the FDA has stated that these Shenli syringes lack FDA clearance. Affected product first shipped March 1, 2019.

This Urgent Medical Device Recall 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 questions regarding this notification, please contact productcomplaint@McKesson.com.

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)
869662	102-S60C	SYRINGE, LL 60CC (25/BX 4BX/CS)	All lots beginning with alpha characters CLN

McKesson Customer Instructions:

1.) Immediately quarantine and discontinue use of any product matching the affected item(s) and lot number(s) listed above.

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

3.) Regardless of whether you have affected product, complete the manufacturer reply form included with this notification and submit it to Cypress via email at productcomplaint@McKesson.com.

4.) If you have product affected by this notice, 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**: Credit will only be issued for the affected lot(s) of the product(s) listed above and entered on the reply form.

5.) Please destroy on location any affected product in your possession per appropriate local, state and federal disposal requirements.

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

McKesson Medical-Surgical is committed to providing the highest level of customer service. Our primary objectives are patient safety, user safety and providing you with quality products. 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**.

Adverse reactions can be reported to the FDA online at www.FDA.gov/medwatch/report.htm.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

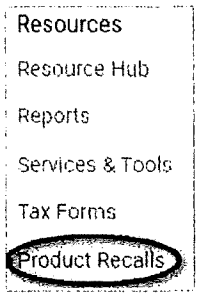
Instructions for the McKesson Medical-Surgical online product ordering system – "SupplyManager", to access and download a "fillable" PDF reply form.

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.

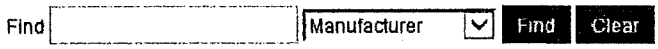
2) Go to https://mms.mckesson.com/ and log in to "SupplyManager", with your username and password.

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.

McKesson Medical-Surgical Inc.
Device Recall Reply Form: RC-2024-178
Cypress Medical Products McKesson 60cc Luer Lock Sterile Syringe

September 6, 2024

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: 20037573 District: 20270000
CARELINC MEDICAL EQUIP & SUPP
ATTN: RISK MANAGEMENT
89 54TH ST SW STE 1
GRAND RAPIDS, MI 49548-5503

☐ I acknowledge that I DO HAVE product affected by this notification and have disposed of this product in accordance with my institution's policies and procedures.

Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			869662	102-S60C	SYRINGE, LL 60CC (25/BX 4BX/CS)

*Discard Affected lot numbers only

*** The affected lot number(s) are listed on the McKesson customer letter. Please dispose of affected product in accordance with your institution's policies and procedures.**

Credit will only be issued for product(s) listed above with affected lots.

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.

CYPRESS MEDICAL PRODUCTS

9954 Mayland Drive
Suite 4000
Richmond, VA 23233

008742

URGENT Medical Device RECALL

Res Event 95041

McKesson Syringe 60cc Luer Lock Tip, Sterile

McKesson MFR number: 102-S60C

Lots beginning with alpha characters **CLN**

September 3, 2024

Dear Distributor:

Problem Description:
Cypress Medical Products, LLC (Cypress) is voluntarily recalling all lots of McKesson Syringe 60cc, Luer Lock Tip, Sterile manufactured for Cypress by Jiangsu Shenli Medical Production Co., LTD (Shenli) beginning with alpha characters CLN. This notice has been issued because FDA has stated that these Shenli syringes lack FDA clearance.

This Urgent Product Recall is being done with the knowledge of the U.S. Food and Drug Administration. Cypress has taken appropriate action per this notice.

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 items:

BRAND NAME	**DESCRIPTION**	**SKUs**	**UPC CODES**	LOT NUMBERS
McKesson	Syringe 60cc, Luer Lock Tip, Sterile	102-S60C	612479170315	All Lots beginning with alpha characters CLN

Actions to be Taken:

1.) Immediately quarantine and discontinue use of any product matching the affected items and lot numbers listed above. Affected items be destroyed on location per appropriate local, state and federal disposal requirements.

2.) Complete the Cypress Recall Response Form included with this notification and submit it via email to productcomplaint@McKesson.com.

3.) If you have further distributed any of the items referenced in this notification, provide your accounts with a copy of this Urgent Product Recall and the Cypress Recall Action Return Response Form.

Further Information:

Cypress is committed to providing the highest level of customer service. Our primary objectives are patient safety and user safety and providing you with quality products. We apologize for the inconvenience this situation will cause. For questions about this notification please contact productcomplaint@McKesson.com.

Adverse reactions can be reported to the FDA online at www/FDA/gov/medwatch/report.htm.

Thank you for your prompt attention to this matter.

Jill D. Early, Quality Manager
Cypress Medical Products, LLC

CYPRESS MEDICAL PRODUCTS

9954 Mayland Drive
Suite 4000
Richmond, VA 23233

008742

URGENT Medical Device RECALL

RES Event 95041

McKesson Syringe 60cc, Luer Lock Tip, Sterile

McKesson MFR number: 102-S60C

Lots beginning with alpha characters **CLN**

September 3, 2024

CUSTOMER ACKNOWLEDGMENT FORM

- Please complete this acknowledgment reply form even if you do not have any stock of the listed product by completing the appropriate boxes below. Return the completed form to the Cypress Product Complaint team at **ProductComplaint@McKesson.com**

	Acknowledgement
	I have submitted the Cypress Recall Return Response Form to ProductComplaint@McKesson.com.
	I **DO HAVE** product affected by this notification and have disposed of this product in accordance with my institution's policies and procedures.

Name of person completing the form	
Title of person completing the form	
Contact Information Tel. number or Email	

DESCRIPTION	**SKUs**	**Affected Lot # (s)** **Attach additional pages If necessary**	**Unit of Measure (UOM)**	**QTY per UOM**
Syringe 60cc, Luer Lock Tip, Sterile	102-S60C			

If you have any questions about the information provided in this communication, please contact the Cypress QA team at productcomplaint@McKesson.com.