

## URGENT MEDICAL DEVICE RECALL

August 5, 2022

Dear Valued McKesson Customer:

ICU Medical has notified McKesson Medical-Surgical (MMS) of an Urgent Medical Device Notice regarding specific lot(s) of their MicroClave Clear Connector. This notice has been issued due to inadequate connection between the MicroClave Clear connector's top and bottom housings. Affected product first shipped December 1, 2021.

This Urgent Medical Device Recall is being done with the knowledge of the U.S. Food and Drug Administration.

For Questions regarding this notification, please contact ICU Medical at 1(866) 829-9025.

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)	
1019000	SC3000	CONNECTOR, MICROCLAVE NEUTRAL (100/CS)	5726857; 5753967	
1028041	MC33326	EXT SET, PRESS INFUSION W/REMVMICROCLAVE 7" (50/CS)	5757376; 5772627; 5772638; 5810377	
766833	MC100	CONNECTOR, MICROCLAVE CLEAR (100/CS)	5716986; 5716988; 5716989; 5716992; 5716993; 5737649; 5737651; 5739477; 5739478; 5739482; 5739484; 5739493; 5755652; 5757426; 5771936; 5771950; 5771956; 5786565; 5815050	
993343	MC33213	EXT SET, SMALLBORE W/ROTATING LUER 7" (50/CS)	5736601; 5789780; 5789784	
1136545	MC33343	EXTENSION SET, REM CLR STB 15"W/MICROCLAVE (50/CS)	5762347	
993329	MC3302R	EXT SET, SMALLBORE W/REMV N/F CONN/CLAMP 7" (50/CS)	5745628	
1082458	MC33122	EXT SET, PRESSURE INFUSION W/MICROCLAVE (50/CS)	5757061; 5772640	
1150895	12517-01	EXTENSION SET, SM BORE HI- PRESSURE W/REMOVBLE MICROCLAVE 7"	5735675; 5755784; 5755788; 5812525	
1205420	MC330611	PRIMARY SET, MICROCLAVE 10DR OP 2GANG 4WAY 125" (25/CS)	5825526; 5850314	



## McKesson Customer Instructions:

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed above. If you have no products matching the affected item(s) and lot number(s), no further action is needed.
- 2.) A copy of the Urgent Medical Device Recall from ICU Medical has been included for reference.
- 3.) If you have product affected by this notice, contact Sedgwick at **1(888) 965-5798** to request a return kit. Please indicate you are a McKesson Medical Surgical Customer when requesting the return kit.
- 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 <a href="MMSRecalls@McKesson.com">MMSRecalls@McKesson.com</a> 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 <u>must include the Reference ID # provided by</u> 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(s) referenced in this notification, provide your accounts with a copy of this notification.

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 Medical Device Recall Reply Form: RC-2022-137 ICU Medical - MicroClave Clear Connector August 5, 2022

Complete this reply form and return all pages immediately via email to <a href="MMSRecalls@McKesson.com">MMSRecalls@McKesson.com</a> or fax at (866) 871-0270 should you have affected product.

(000) 01 1-0210 should you have affected product.	
To ensure timely credit to your account and support the con	npletion of this notice, please respond within 30 days.
Date:	
Your Name:	Email Address:
Phone Number:	Fax Number:
Account: 464622 District: 0650000	
YALE UNIVERSITY	
ATTN: RISK MANAGEMENT	
PO BOX 208228	

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

Qty	Unit of Measure	MMS#	MFG Catalog #	Description
		1019000	SC3000	CONNECTOR, MICROCLAVE NEUTRAL (100/CS)
		1028041	MC33326	EXT SET, PRESS INFUSION W/REMVMICROCLAVE 7" (50/CS)
		766833	MC100	CONNECTOR, MICROCLAVE CLEAR (100/CS)
		993343	MC33213	EXT SET, SMALLBORE W/ROTATING LUER 7" (50/CS)
		1136545	MC33343	EXTENSION SET, REM CLR STB 15"W/MICROCLAVE (50/CS)
		993329	MC3302R	EXT SET, SMALLBORE W/REMV N/F CONN/CLAMP 7" (50/CS)
		1082458	MC33122	EXT SET, PRESSURE INFUSION W/MICROCLAVE (50/CS)
		1150895	12517-01	EXTENSION SET, SM BORE HI-PRESSURE W/REMOVBLE MICROCLAVE 7"
		1205420	MC330611	PRIMARY SET, MICROCLAVE 10DR OP 2GANG 4WAY 125" (25/CS)

<sup>\*</sup> Return only the affected lot numbers to Sedgwick

NEW HAVEN, CT 06520-8228

<sup>\*</sup> The affected lot numbers are listed on the McKesson customer letter.



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.