McKESSON
McKesson Medical-Surgical
Quality Assurance
9954 Mayland Drive
Richmond, VA 23233-1464

Rec 11/26/26

MEDICAL DEVICE PRODUCT ADVISORY

000350

MCK50C 6226445 848702846 RC-2025-251 MMSP 357
VERICOR LLC
ATTN: RISK MANAGEMENT
703 WESTERN AVE
HOLMEN WI 54636-9787

URGENT MEDICAL DEVICE PRODUCT ADVISORY NOTIFICATION

January 9, 2026

Dear Valued McKesson Customer:

Cardinal Health has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Product Advisory Notice regarding all lot(s) of their Various Products. This notice has been issued to communicate to customers that the instructions for use (IFUs) on the above listed Cardinal Health Chest Drainage Units (CDUs) and accessories have been updated to clarify the intended target patient population as adults, 18 years and older. Affected product first shipped January 1, 2020.

A review of our records indicates that your company may have purchased items included in the attached manufacturer's notification.

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

MMS #	MFG Catalog #	Description	Affected Lot(s)
233420	8888571315	DRAIN, CHEST AUTOTRANSFUSION (5/CS)	ALL
239665	8888571299	DRAIN, CHEST STANDARD (5/CS)	ALL
194692	8888571513	DRAIN, CHEST DUAL SENTINEL SEAL (5/CS)	ALL
124300	8884713308	DRAIN, CHEST UNDERWTR 3BTL PLAS (4/CS)	ALL
129553	8884713900	BOTTLE, THORA-DRAIN REPLCMNT (6/CS)	ALL
31713	8884713100	DRAIN, CHEST UNDERWTR 1BTL SNGL (6/CS)	ALL
440174	8888571370	DRAIN, CHEST ALTITUDE DRY (5/CS)	ALL
161384	8888571562	DRAIN, CHEST COMPACT UNIT STR (5/CS)	ALL

Please note: This is ***not*** a recall. **Product returns will not be accepted**. Carefully review the information in the attached Urgent Medical Device Product Notification, and follow the instructions provided by Cardinal Health. If you have any questions regarding this notification, please contact Cardinal Health via phone at **(888) 444-5440**. 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 notification may have caused you and your staff.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

Cardinal Health 200, LLC
3651 Birchwood Drive
Waukegan, IL 60085
cardinalhealth.com

CardinalHealth

URGENT MEDICAL DEVICE PRODUCT ADVISORY

December 26, 2025

Dear Valued Customer:

Cardinal Health is issuing a Product Advisory Notice on our Sentinel Seal™, Altitude™, Aqua-Seal™, Thora-Seal™ Chest Drainage Units and accessories.

Product Code	Description	UDI
8888571562	Cardinal Health™ Sentinel Seal™ CDU	50192253003091 (CS) 10192253003093 (EA)
8888571513	Cardinal Health™ Sentinel Seal™ CDU, Dual Drain	50192253003084 (CS) 10192253003086 (EA)
8888571489	Cardinal Health™ Sentinel Seal™ CDU, with Easy Change Connector	50192253003077 (CS) 10192253003079 (EA)
8888571370	Cardinal Health™ Altitude™ CDU, Dry Suction, with Easy Change Connector	50192253003039 (CS) 10192253003031 (EA)
8888571299	Cardinal Health™ Aqua-Seal™ CDU, Wet Suction	50192253003015 (CS) 10192253003017 (EA)
8888571406	Cardinal Health™ Aqua-Seal™ CDU, Wet Suction, Dual Drain	50192253003060 (CS) 10192253003062 (EA)
8888571315	Cardinal Health™ Aqua-Seal™ CDU, Wet Suction, with Easy Change Connector	50192253003022 (CS) 10192253003024 (EA)
8884713100	Cardinal Health™ Thora-Seal™ Basic CDU, One Chamber, 2000 mL	50192253002643 (CS) 10192253002645 (EA)
1814713105	**OUS Only** - Cardinal Health™ Thora-Seal™ Basic CDU, One Chamber, 2000 mL (Bottle only)	50192253002308 (CS) 10192253002300 (CS)
1180571570	**OUS Only** - Cardinal Health™ Thora-Seal™ CDU, Two Chamber System, 2600 mL	50192253002292 (CS) 10192253002294 (EA)
8884713308	Cardinal Health™ Thora-Seal™ CDU, Three Chamber System, 2500 mL	50192253002650 (CS) 10192253002652 (EA)
8884713900	Cardinal Health™ Thora-Seal™ Replacement Collection Chamber, 2500 mL	50192253002667 (CS) 10192253002669 (EA)

Purpose of this letter:	The purpose of this letter is to communicate to customers that the instructions for use (IFUs) on the above listed Cardinal Health Chest Drainage Units (CDUs) and accessories have been updated to clarify the intended target patient population as adults, 18 years and older.

Risk to Health:	The company received complaints from outside the U.S. stating that when the above-identified CDUs are utilized on infants, the CDU may not consistently demonstrate tidaling / bubbling, which may be used by clinicians to determine if the unit is functional. The lack of consistent tidaling or bubbling may confound the clinician's assessment of device functionality and may lead to inadequate/inappropriate treatment/therapy, delay to treatment/therapy, and prolonged hospitalization. For clarity, when used in non-adult patient populations, the CDUs are capable of providing a seal; however, the CDU may not consistently demonstrate tidaling / bubbling due to the size of the

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	collection chambers, even when a seal is present. The CDUs have been under the same design since their release and continue to perform as intended.

Actions Required of the Customer:	1. **CONTINUE** utilizing the CDUs on adult patients (not pediatric patients or infants). 2. **REVIEW** the updated IFU for the product codes listed above. https://www.mycardinalmsds.com/ 3. **POST** a copy of this notification in your storeroom and clinical areas. 4. **NOTIFY** any customers to whom you may have distributed/forwarded affected product (or to whom you intend to distribute/forward product) about this medical device product advisory and share a copy of this notice. 5. ~~**RETURN** the enclosed acknowledgment form via fax to **614-652-9648** or email to **GMB-FieldCorrectiveAction@cardinalhealth.com**, whether you have affected product or not.~~

Available Customer Assistance:	**CONTACT** the appropriate Customer Service group with questions related to this notification. **Monday – Friday between 8:00am - 5pm EST**: • Hospital – 800-964-5227 • Federal Government – 800-444-1166 • Distributor – 800-635-6021 • All Other Customers – 888-444-5440 For questions related to this notification and/or acknowledgement form that are not adequately addressed in this letter, please contact the market action team at: **GMB-FieldCorrectiveAction@cardinalhealth.com or call 800-292-9332.** In the event you have experienced quality problems or adverse events related to the products listed, please utilize the contacts above.

Additional Information:	**Adverse Events Reporting Process** Cardinal Health has notified the U.S. Food & Drug Administration that we are taking this action. In the event you have experienced quality problems or adverse events related to the products listed above, please utilize the contact information above. The FDA can be contacted to report any adverse events experienced with these products: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or email) or call FDA 1-800-332-1088.

We apologize for any inconvenience this communication may cause. We know that you place high value in our products, and we appreciate your cooperation in this matter. Cardinal Health is committed to maintaining your confidence in the safety and quality of the products that we supply.

Respectfully yours,

Hector Rocha