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

CardinalHealth

URGENT MEDICAL DEVICE PRODUCT RECALL

Product Code	Product Description	Lot Numbers	UDI
See Attachment 1 (Affected Product Codes & Lot Numbers)			

May 2, 2025

Dear Valued Customer:

The purpose of this letter is to advise you that Cardinal Health has initiated a medical device product recall on several lots of Umbilical Vessel Catheters.

Description of the issue:	What is the issue? The attached list of affected product codes and lots are being recalled due to a possible packaging defect impacting the outer Tyvec pouch that protects the sterile product. This pouch is used on both the single-sterile Umbilical Vessel Catheters and the product within a finished insertion tray. This defect may allow for small holes to develop in the pouch which could potentially compromise the sterility of the product. These holes may be undetectable upon visual inspection, so none of the identified lots should be used. This recall is specific to the product codes, and lots listed on **Attachment 1 (Affected Product Codes & Lot Numbers)**. Other codes and lots are not impacted. What is the risk to health? If there is a breach in the sterile packaging, there is a risk that a non-sterile product could be used on a patient. Use of this device can increase the risk of unspecified infection. This infection would be severe in nature causing major health impacts to the patient as exposure would occur intravascular leading to widespread infection or potentially death in a high-risk patient population. If there are affected devices currently in use, we would recommend removal to help mitigate any risk to the patient. Cardinal Health has not received any reports of harm or adverse events. What other actions is Cardinal Health taking? Cardinal Health is currently notifying customers and will complete appropriate corrective actions.

Actions Required:	**1. REVIEW** your inventory for the affected product codes & lots listed on Attachment 1. Location of product code is shown on the labels below (Attachment 2). 2. **COMMUNICATE** with all personnel that utilize the attached list of products. **3. SEGREGATE** and quarantine all affected product upon review of your inventory. Affected product should not be used. Utilize return directions below to return product.

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	4. **DISSEMINATE** this notice to all departments, clinics and external campuses that handle the affected products. **5.** **DISTRIBUTORS** please notify any customers to whom you may have distributed/ forwarded affected product to or will send the product on to about this medical device product recall and share a copy of this notice. 6. **RETURN** the enclosed acknowledgment form via fax to 614-652-9648 or email directly to GMB-FieldCorrectiveAction@cardinalhealth.com, whether you have affected product or not.

Return of Product and Available Assistance:	**Please Contact** the appropriate Customer Service group to arrange for return and credit or questions regarding suitable alternative products. **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.**

Additional Information:	In the event you have experienced quality problems or adverse events related to the products listed on attachment 1, please utilize the contacts above: **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,

Kelley Moffett

SVP, Global Quality

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Attachment 1 – Affected Product Codes & Lot Numbers

Catalog Number	Description	Lot Number(s)	UDI (Each)	UDI (Box)
8888160119	Umbilical Vessel Catheter Insertion Tray with 3.5 and 5 French UVCs	2502400146	10192253040289	50192253040287
8888160325	Umbilical Vessel Catheter 2.5 French single lumen	2433100060 2433100059 2422700145 2422700139 2422700146 2422700142	10192253040296	50192253040294
8888160333	Umbilical Vessel Catheter 3.5 French single lumen	2431300157 2431300158 2431300156 2431300154 2431300153 2433300197 2431300152 2418100101 2433300200 2418300064 2432300069 2417000115 2431800139 2432200143 2432600251 2417000116 2433300199 2418100103 2432300066 2418300063 2433300195 2432600250 2430300087 2433300193 2430300085 2417000113 2433300201 2432200139 2429900138 2412300004 2430300083 2430300086 2430300084 2418100102 2431300155	10192253040302	50192253040300

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Attachment 1 – Affected Product Codes & Lot Numbers (continued)

Catalog Number	Description	Lot Number(s)	UDI (Each)	UDI (Box)
8888160341	Umbilical Vessel Catheter 5 French single lumen	2427700158 2425600066 2433000005 2427700160 2425600067 2425600070 2415100113 2425600071 2427700159 2415100110 2412100093 2433000095 2425600069 2425600077 2415100116 2425600063 2425600074 2415100115 2415100114 2412100096 2425600072 2425600075 2404400061 2425600064 2415100106 2425600076 2415100107 2415100112 2425600073 2425600065 2404400062 2404400065 2415100093 2415100109 2415100111 2433000094	10192253040319	50192253040317
8888160556	Umbilical Vessel Catheter 5 French dual lumen	2424900133 2424900134 2424900135 2435200126 2435200127 2435200129 2435200123 2435200124	10192253040364	50192253040362
8888160648	Umbilical Vessel Catheter 5 French triple lumen	2419800006 2335500149	10192253040371	50192253040379

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Attachment 2 – Product Code and Lot Location