URGENT MEDICAL DEVICE RECALL
Event-2021-04063 Monoject™ Flush Prefilled Syringes

Cardinal Health
15 Hampshire Street
Mansfield, MA 02048
800 292 9332 toll free
847 689 9101 fax

cardinalhealth com

CardinalHealth

RECALL: Monoject™ Flush Prefilled Syringes (0.9% Sodium Chloride)

August 4, 2021

Event-2021-04063 – Monoject™ Flush Prefilled Syringes

Attention: Patient Safety and Clinical Risk Departments, Director of Pharmacy, Director of Nursing

The purpose of this letter is to inform you that Cardinal Health has issued a Medical Device Recall for specific catalog numbers of Monoject™ Flush Prefilled Syringes (0.9% Sodium Chloride) manufactured and distributed between July 2019 and July 2021 due to the potential for the plunger to draw back after the air has been expelled and reintroduce air back into the syringe. Please see the Affected Product table below for the affected product codes.

Affected Product

Catalog #	Product Description	Lot #s
8881570121	12mL Syringe, 10 mL Saline Fill	ALL LOTS manufactured and distributed between July 1, 2019 and July 2021
8881570123	12mL Syringe, 3mL Saline Fill	
8881570125	12mL Syringe, 5mL Saline Fill	

Product Overview	Cardinal Health has initiated a medical device recall for the following Monoject™ Flush Prefilled Syringes (0.9% Sodium Chloride) due to the potential for the plunger to draw back after the air has been expelled and reintroduce air back into the syringe. Please see the Affected Product table above for a listing of the impacted products. Monoject™ Flush Prefilled Syringes (0.9% Sodium Chloride) contain preservative-free 0.9% Sodium Chloride Injection, USP in prefilled syringes of various sizes and fill volumes. They are disposable, single use only and are intended for use in flushing compatible intravenous tubing systems and indwelling intravascular access devices.

Why you are being contacted:	You are receiving this letter because our records indicate that you have purchased Monoject™ Flush Prefilled Syringes (0.9% Sodium Chloride).

Description of the problem:	Cardinal Health received customer complaints where users were experiencing a plunger drawback with Monoject™ Flush Prefilled Syringes (0.9% Sodium Chloride). After the user expels the air bubble prior to use, the plunger may draw back and reintroduce air into the syringe. If a clinician is not aware of air being reintroduced into the syringe, the clinician could inadvertently push air into the vascular system creating the potential for an air embolism. **Injection of air into the vascular system can cause air embolism which can result in serious adverse health consequences or death.** Cardinal Health has not received any reports of patient harm or injury related to this issue. What actions is Cardinal Health taking? At this time, Cardinal Health has ceased manufacturing and distributing these product catalog numbers.

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Product Availability Impact & Actions Requested on your part:	Cardinal Health recognizes the impact this product issue has on our customers in delivering patient care. • Immediately review your inventory and segregate and quarantine all on-hand affected product listed above. • As Cardinal Health does not have an alternative product, this may cause supply interruptions. In the interim, customers may look for an equivalent marketed flush prefilled syringe product. • If your facility does not have sufficient access to unaffected product, your facility may prepare flush syringes with preservative-free saline under sterile conditions, as described in CDC's guidance on Medication Preparation (https://www.cdc.gov/injectionsafety/providers/provider_faqs_med-prep.html) or according to your facility's policies and procedures, and coordinating with your pharmacy and nursing leadership.

Product Availability Impact & Actions Requested on your part:	1) **REVIEW** your inventory for affected product. 2) **SEGREGATE and QUARANTINE** all on-hand product per the Affected Product table above. 3) **COMMUNICATE** this notice to clinical staff through safety huddles to ensure awareness of this product issue. 4) **RETURN** the enclosed acknowledgment form via fax to 614-652-9648 or email to gmb-fieldcorrectiveaction@cardinalhealth.com, whether or not you have affected product. 5) **CONTACT** the appropriate Customer Service group to arrange for return and credit of any affected product Monday – Friday between 8:00am - 5:00pm EST: • Hospital—800-964-5227 • Federal Government—800-444-1166 • Distributor—800-635-6021 • All other Customers—888-444-5440 6) **CUSTOMERS** that did not receive product directly from Cardinal Health should contact the location where they purchased it.

Available Assistance:	Please contact the Customer Service group for any questions or to arrange for credit and return of any product: • Hospital—800-964-5227 • Federal Government—800-444-1166 • Distributor—800-635-6021 • All other customers—888-444-5440 For questions related to the 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.

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Additional Information	**Adverse Events Reporting Process** In the event you have experienced quality problems or adverse events related to the products listed in Attachment 1, please contact GMB-CAH-Dist-Domestic@cardinalhealth.com The FDA can be contacted to report any adverse events experienced with the use of these products: • Online @ 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,

Steven B. C de Baca

Steven B. C de Baca
Executive Vice President, Quality and Regulatory

CardinalHealth

CARDINAL HEALTH
DATE: August 4, 2021
FILE#: Event-2021-04063

URGENT MEDICAL DEVICE RECALL - RESPONSE REQUIRED

FAX COMPLETED FORM TO 614-652-9648 or email to gmb-fieldcorrectiveaction@cardinalhealth.com

1 Did you read and understand the product recall notice for Monoject™ Flush Prefilled Syringes (0.9% Sodium Chloride)?
____ YES ____ NO

2 Do you have any of the recalled product in your current inventory?
____ YES Indicate total quantity _____case/box (circle one)
____NO

3 Have you alerted any consignees that you may have distributed the product to? ____ YES ____NO

Name of facility _____

Address of Facility _____

_____

Name/Title of person completing form _____

Signature _____

Email address _____ Phone number _____

PLEASE FOLLOW INSTRUCTIONS ON THE ENCLOSED NOTICE