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

CardinalHealth

**EXPANSION NOTIFICATION**

# URGENT MEDICAL DEVICE PRODUCT RECALL

February 02, 2024

Dear Valued Customer:

| | |
|---|---|
| **Description of the issue:** | What is the issue?<br><br>In close coordination with the U.S. Food and Drug Administration (FDA), we are issuing a voluntary recall for product removal of all sizes of Cardinal Health brand Monoject™ sterile Syringe Luer-Lock Soft Packs (1, 3, 6, 12, 20, 35, and 60 mL) and Cardinal Health brand Monoject™ sterile Enteral Syringes with the ENFit® connection (1, 3, 6, 12, 35, and 60 mL), which are color-coded purple to denote enteral feeding only. This product removal applies to all sizes of sterile Cardinal Health brand lots of the products outlined below. Covidien brand Monoject™ syringes of all sizes are not impacted by this product action. Customers that purchase Presource custom kits with impacted components will be notified through a separate letter of this product removal . Please see Attachment 1 – Product Code and Lot Information for complete product code and lot information below.<br><br>We are issuing a recall for product removal of the lots listed below. Please follow the steps outlined in this letter to return the affected product.<br><br>This letter supersedes our previous communications dated September 20, 2023 and December 28, 2023 related to both Cardinal Health brand Monoject™ sterile Syringe Luer-Lock and Cardinal Health brand Monoject™ sterile Enteral Syringes with the ENFit® connection portfolios due to a change in manufacturing and rebranding efforts. In alignment with the FDA, we are expanding this recall action to a product removal of all sizes of Cardinal Health brand Monoject™ sterile Syringe Luer-Lock and Cardinal Health brand Monoject™ sterile Enteral Syringes with the ENFit® connection. It is our intention that this product recall will reduce confusion and create a simplified course of action for you, our customer.<br><br>We apologize for any frustration these changes and resulting issues have caused. Our goal, always, is to provide safe, high-quality products that you can rely on, as indicated by the product corrections initiated thus far.<br><br>We continue to work with the FDA, the syringe manufacturer and pump manufacturers to reintroduce Cardinal Health brand Monoject™ syringes.<br><br>This product recall is lot specific and other product codes, including Covidien branded product, are not impacted.<br><br>What is the risk to health?<br><br>If the Cardinal Health brand Monoject™ syringe is not recognized by the pump, it may result in delay of treatment or therapy. Conversely, if the syringe is recognized by pumps, it may result in volume and/or infusion rate discrepancies, which can lead to over- or under-infusion. As of January 25, 2024, Cardinal Health has received 32 complaints of syringe infusion pumps and 1 report of PCA pumps not recognizing the Cardinal Health brand Monoject™ sterile Luer-Lock syringe. There were 9 complaints where Cardinal Health brand Monoject™ sterile Enteral Syringes with the ENFit® connection were not recognized in the enteral syringe pump. While Cardinal Health has not received any reports of patient death for impacted syringes, there is a potential risk of serious injury or death. |

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

| | |
|---|---|
| **Actions Required:** | 1. **REVIEW** your inventory for the affected product codes and lots. Location of product code and lot are shown in below listed table (Attachment 1 – Product Code and Lot Information).<br>2. **COMMUNICATE** with all personnel that utilize the Cardinal Health Monoject™ Luer-Lock Tip syringes (1, 3, 6, 12, 20, 35 and 60 mL) and Cardinal Health Monoject™ sterile Enteral Syringes with the ENFit® connection (1, 3, 6, 12, 35, and 60 mL), which are color-coded purple that they should not be used.<br>3. **SEGREGATE** and quarantine all affected product upon review of your inventory. Product should not be used and cease using the product immediately. Utilize return directions below to return product.<br>4. **DISSEMINATE** this notice to all departments, clinics and external campuses that handle the affected syringes.<br>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.<br>6. **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. |

| | |
|---|---|
| **Return of Product and Available Assistance:** | **CONTACT** the appropriate Customer Service group to arrange return of product and with questions related to this notification. **Monday – Friday between 8:00am - 5pm EST**:<br>• Hospital – 800-964-5227<br>• Federal Government – 800-444-1166<br>• Distributor – 800-635-6021<br>• All Other Customers – 888-444-5440<br>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:<br>**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 above, please utilize the contacts below:<br>• Hospital—800-964-5227<br>• Federal Government—800-444-1166<br>• Distributor—800-635-6021<br>• All other customers—888-444-5440<br>**Adverse Events Reporting Process**<br><br>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.<br><br>The FDA can be contacted to report any adverse events experienced with these products:<br>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 understand the critical role our products play in providing safe, effective patient care, and we are committed to getting this right. Thank you for your ongoing patience and cooperation.

Respectfully yours,

Kelley Moffett

SVP Quality, Regulatory and Medical Affairs

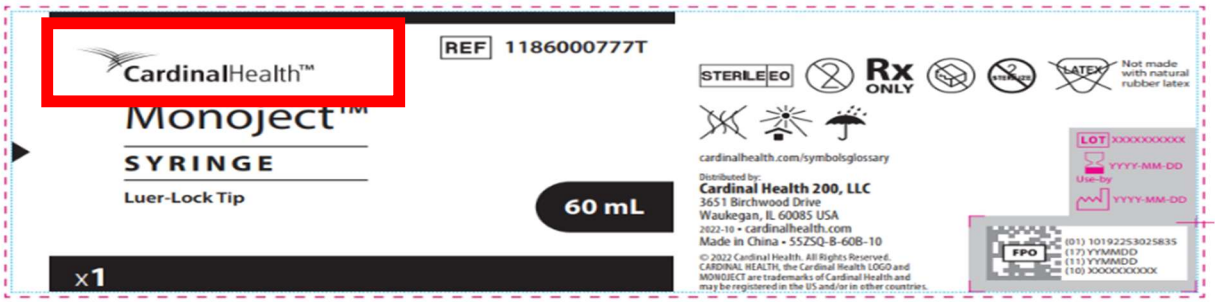
Cardinal Health 200, LLC
3651 Birchwood Drive
Waukegan, IL 60085
cardinalhealth.com

**Attachment 1 – Product Code and Lot Information**

| Product Code | Product Description | UDI | Lot Numbers |
|---|---|---|---|
| 1180100777 | Monoject™ 1 mL Tuberculin Syringe Luer-Lock Tip Soft Pack | 10192253034530 - each<br>20192253034537 - box<br>50192253034538 - case | 221201, 221202, 221203, 230201, 230202, 230203, 230204, 230205, 230601 |
| 1180300777 | Monoject™ 3 mL Syringe Luer-Lock Tip Soft Pack | 10192253033519 - each<br>20192253033516 - box<br>50192253033517 - case | 230201,230202,221201,221202,230203,230204,230205, 230206,230208,230209,230210,230211,230212,230213, 230214,230215,230216,230217,230218,230219,230207, 230602,230601,230602,230603,230701,230702,230703, 230704,230705,230706,230707 |
| 1180600777 | Monoject™ 6 mL Syringe Luer-Lock Tip Soft Pack | 10192253034608- each<br>20192253034605- box<br>50192253034606- case | 221201, 221202, 221203, 221204, 221205, 230201, 230202, 230203, 230204, 230205, 230206, 230207 |
| 1181200777T | Monoject™ 12 mL Syringe Luer-Lock Tip Soft Pack | 10192253025811- each<br>20192253025818- box<br>50192253025819- case | 221101, 221102, 221103, 221104 |
| 1182000777 | Monoject™ 20 mL Syringe Luer-Lock Tip Soft Pack | 10192253034677- each<br>20192253034674- box<br>50192253034675- case | 221201, 221202, 221203, 221204, 221205, 230201, 230202, 230203, 230204, 230205, 230206 |
| 1183500777 | Monoject™ 35 mL Syringe Luer-Lock Tip Soft Pack | 10192253034691- each<br>20192253034698- box<br>50192253034699- case | 221201, 230201, 230601, 230602 |
| 1186000777T | Monoject™ 60 mL Syringe Luer-Lock Tip Soft Pack | 10192253025835- each<br>20192253025832- box<br>50192253025833- case | 221101, 230601 |
| 401SE | Monoject™ 1 mL Purple Enteral Syringe with Enfit Connection Sterile | 06971564466202 - each<br>16971564466209 - box<br>26971564466206 - case | 230701, 230501 |
| 403SE | Monoject™ 3 mL Purple Enteral Syringe with Enfit Connection Sterile | 06971564466219 - each<br>16971564466216 - box<br>26971564466213 - case | 230501, 230701, 230601 |
| 406SE | Monoject™ 6 mL Purple Enteral Syringe with Enfit Connection Sterile | 06971564466226 - each<br>16971564466223 - box<br>26971564466220 - case | 230503 and 230701 |
| 412SE | Monoject™ 12 mL Purple Enteral Syringe with Enfit Connection Sterile | 06971564466233 - each<br>16971564466230 - box<br>26971564466237 - case | 230501, 230502 and 230601 |
| 435SE | Monoject™ 35 mL Purple Enteral Syringe with Enfit Connection Sterile | 06971564466240 - each<br>16971564466247 - box<br>26971564466244 - case | 230501, 230601 and 230602 |
| 460SE | Monoject™ 60 mL Purple Enteral Syringe with Enfit Connection Sterile | 06971564466257 - each<br>16971564466254 - box<br>26971564466251 - case | 230501, 230701 and 230702 |

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

Example Cardinal Health Product label impacted by this product removal (highlighted in red):




Example Product label NOT impacted by this product removal (highlighted in green):