PRODUCT ALERT NOTIFICATION

Advantus Health Partners

Do Not Use Certain Cardinal Health Monoject Luer-Lock and Enteral Syringes

NOTIFICATION DATE: 2/02/2024
LAST REVISED ON: 2/14/2024
SUPPLIER/CATEGORY: IV THERAPY PRODUCTS

SITUATION

The U.S. Food and Drug Administration (FDA) is warning consumers, health care providers, and health care facilities not to use certain Cardinal Health Monoject luer-lock and enteral syringes.

On February 2, 2024, Cardinal Health announced a recall for removal of all sizes of the following Cardinal Health brand Monoject syringes:

- Cardinal Health Monoject sterile Syringe Luer-Lock Tip Soft Packs (1, 3, 6, 12, 20, 35, and 60 mL) and
- Cardinal Health Monoject sterile Enteral Syringes with ENFit connection (1, 3, 6, 12, 35, and 60 mL), which are color-coded purple to denote enteral feeding only.

BACKGROUND

- These new syringes differ from the previously branded “Covidien” Monoject syringes as they have different dimensions and are made by a different contract manufacturer.
- The dimensional changes made to the Cardinal Health Monoject syringes, when used with syringe pumps, PCA pumps, or enteral syringe pumps, may result in recognition, compatibility, and pump performance issues, such as overdose, underdose, delay in therapy, delay in occlusion alarms, and delay in feeding.
- For any syringe, there is the potential that changes to dimensions could affect the performance of the device when used alone or with pumps.
- This product removal is lot-specific and applies to all Cardinal Health brand Monoject™ sterile syringes outlined below. Covidien brand Monoject™ syringes of all sizes are not impacted by this product action.

PRODUCT ALERT NOTIFICATION

ASSESSMENT

- The affected product and lot numbers are listed in the table below.
- Do not use Cardinal Health Monoject sterile Syringe Luer-Lock Tip Soft Packs (1, 3, 6, 12, 20, 35 and 60 mL).
- Do not use Cardinal Health Monoject sterile Enteral Syringes with ENFit connection (1, 3, 6, 12, 35, and 60 mL), which are color-coded purple.

Product Code	Product Description	UDI	Lot Numbers
1180100777	Monoject™ 1 mL Tuberculin Syringe Luer-Lock Tip Soft Pack	10192253034530 - each	221201, 221202, 221203, 230201, 230202, 230203, 230204, 230205, 230601
		20192253034537 - box	
		50192253034538 - case	
1180300777	Monoject™ 3 mL Syringe Luer-Lock Tip Soft Pack	10192253033519 - each	230201,230202,221201,221202,230203,230204,23020, 230206,230208,230209,230210,230211,230212,23021, 230214,230215,230216,230217,230218,230219,23020, 230602,230601,230602,230603,230701,230702,23070, 230704,230705,230706,230707
		20192253033516 - box	
		50192253033517 - case	
1180600777	Monoject™ 6 mL Syringe Luer-Lock Tip Soft Pack	10192253034608- each	221201, 221202, 221203, 221204, 221205, 230201, 230202, 230203, 230204, 230205, 230206, 230207
		20192253034605- box	
		50192253034606- case	
1181200777T	Monoject™ 12 mL Syringe Luer-Lock Tip Soft Pack	10192253025811- each	221101, 221102, 221103, 221104
		20192253025818- box	
		50192253025819- case	
1182000777	Monoject™ 20 mL Syringe Luer-Lock Tip Soft Pack	10192253034677- each	221201, 221202, 221203, 221204, 221205, 230201, 230202, 230203, 230204, 230205, 230206

		20192253034674-box	
		50192253034675-case	
1183500777	Monoject™ 35 mL Syringe Luer-Lock Tip Soft Pack	10192253034691-each	221201, 230201, 230601, 230602
		20192253034698-box	
		50192253034699-case	
1186000777T	Monoject™ 60 mL Syringe Luer-Lock Tip Soft Pack	10192253025835-each	221101, 230601
		20192253025832-box	
		50192253025833-case	
401SE	Monoject™ 1 mL Purple Enteral Syringe with Enfit Connection Sterile	06971564466202 - each	230701, 230501
		16971564466209 - box	
		26971564466206 - case	
403SE	Monoject™ 3 mL Purple Enteral Syringe with Enfit Connection Sterile	06971564466219 - each	230501, 230701, 230601
		16971564466216 - box	
		26971564466213 - case	
406SE	Monoject™ 6 mL Purple Enteral Syringe with Enfit Connection Sterile	06971564466226 - each	230503 and 230701
		16971564466223 - box	
		26971564466220 - case	

PRODUCT ALERT NOTIFICATION

Advantus Health Partners

412SE	Monoject™ 12 mL Purple Enteral Syringe with Enfit Connection Sterile	06971564466233 - each	230501, 230502 and 230601
		16971564466230 - box	
		26971564466237 - case	
435SE	Monoject™ 35 mL Purple Enteral Syringe with Enfit Connection Sterile	06971564466240 - each	230501, 230601 and 230602
		16971564466247 - box	
		26971564466244 - case	
460SE	Monoject™ 60 mL Purple Enteral Syringe with Enfit Connection Sterile	06971564466257 - each	230501, 230701 and 230702
		16971564466254 - box	
		26971564466251 - case	

RECOMMENDATIONS

- Circulate the notice to all who need to be aware.
- Check your inventory to find out if you have any of the recalled products at your facility.
- Do not use these recalled products and follow the recommendations in the company's recall announcement.
- The FDA will continue to work with Cardinal Health to help ensure that the public is notified to stop using the recalled products. If you think you had a problem with a syringe, or any medical device, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form. Reporting supply chain issues to the FDA helps inform actions to prevent shortages and protect patient health.

Please use the link below to view recent updates to the SBAR:
https://healthpartners.sharepoint.com/sites/Supply-Chain/SitePages/SBAR.aspx?ga=1