



California Device Recall Information Sheet

Cardinal Health Recalls Monoject Syringe For Changes In Manufacturing Efforts And Monoject Luer-Lock Tip For Problem With Syringe Compatibility

Recall Date	Product Description	Recalling Firm	Recall Reason
2/14/2024	Cardinal Health Monoject 1MI Purple Enteral Syringe With Enfit Connection Sterile, REF 401SE	CARDINAL HEALTH 200, LLC Waukegan, Illinois	Cardinal Health is expanding their previous product correction actions to a product removal of all sizes of Cardinal Health brand Monoject sterile Syringe Luer-Lock (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) due to a change in manufacturing and rebranding efforts.

2/14/2024	Cardinal Health Monoject 35ml Enteral Syringe (Purple) For Use with ENFit Connection System, REF 435SE	CARDINAL HEALTH 200, LLC Waukegan, Illinois	The listed lots of Cardinal Health Monoject Enteral Syringes with ENFit (6, 12, 35, 60 mL) have recognition and compatibility issues with certain syringe enteral feeding pumps. As a result, Cardinal Health recommends that they not be used with enteral syringe feeding pumps.
2/14/2024	Cardinal Health Monoject 20ml Syringe Luer-Lock Tip Soft Pack, REF 1182000777	CARDINAL HEALTH 200, LLC Waukegan, Illinois	Cardinal Health is expanding their previous product correction actions to a product removal of all sizes of Cardinal Health brand Monoject sterile Syringe Luer-Lock (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) due to a change in manufacturing and rebranding efforts.
2/14/2024	Cardinal Health Monoject 12ml Syringe Luer-Lock Tip Soft Pack, REF 1181200777T	CARDINAL HEALTH 200, LLC Waukegan, Illinois	Cardinal Health is expanding their previous product correction actions to a product removal of all sizes of Cardinal Health brand Monoject sterile Syringe Luer-Lock (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) due to a change in manufacturing and rebranding efforts.
2/14/2024	Cardinal Health Monoject 6ml Enteral Syringe (Purple) Low Dose (LDT) - For Use with ENFit Connection System, REF 406SE	CARDINAL HEALTH 200, LLC Waukegan, Illinois	The listed lots of Cardinal Health Monoject Enteral Syringes with ENFit (6, 12, 35, 60 mL) have recognition and compatibility issues with certain syringe enteral feeding pumps. As a result, Cardinal Health recommends that they not be used with enteral syringe feeding pumps.
2/14/2024	Cardinal Health Monoject 3ml Syringe Luer-Lock Tip Soft Pack, REF 1180300777	CARDINAL HEALTH 200, LLC Waukegan, Illinois	Cardinal Health is expanding their previous product correction actions to a product removal of all sizes of Cardinal Health brand Monoject sterile Syringe Luer-Lock (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) due to a change in manufacturing and rebranding efforts.
2/14/2024	Cardinal Health Monoject 1ml Tuberculin Syringe Luer-Lock Tip Soft Pack, REF 1180100777	CARDINAL HEALTH 200, LLC Waukegan, Illinois	Cardinal Health is expanding their previous product correction actions to a product removal of all sizes of Cardinal Health brand

			<p>Monoject sterile Syringe Luer-Lock (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) due to a change in manufacturing and rebranding efforts.</p>
2/14/2024	<p>Cardinal Health Monoject 12ml Enteral Syringe (Purple) For Use with ENFit Connection System, REF 412SE</p>	<p>CARDINAL HEALTH 200, LLC Waukegan, Illinois</p>	<p>The listed lots of Cardinal Health Monoject Enteral Syringes with ENFit (6, 12, 35, 60 mL) have recognition and compatibility issues with certain syringe enteral feeding pumps. As a result, Cardinal Health recommends that they not be used with enteral syringe feeding pumps.</p>
2/14/2024	<p>Cardinal Health Monoject 6ml Syringe Luer-Lock Tip Soft Pack, REF 1180600777</p>	<p>CARDINAL HEALTH 200, LLC Waukegan, Illinois</p>	<p>Cardinal Health is expanding their previous product correction actions to a product removal of all sizes of Cardinal Health brand Monoject sterile Syringe Luer-Lock (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) due to a change in manufacturing and rebranding efforts.</p>

2/14/2024	Cardinal Health Monoject 60ml Enteral Syringe (Purple) For Use with ENFit Connection System, REF 460SE	CARDINAL HEALTH 200, LLC Waukegan, Illinois	The listed lots of Cardinal Health Monoject Enteral Syringes with ENFit (6, 12, 35, 60 mL) have recognition and compatibility issues with certain syringe enteral feeding pumps. As a result, Cardinal Health recommends that they not be used with enteral syringe feeding pumps.
2/14/2024	Cardinal Health Monoject 3ml Purple Enteral Syringe With Enfit Connection Sterile, REF 403SE	CARDINAL HEALTH 200, LLC Waukegan, Illinois	Cardinal Health is expanding their previous product correction actions to a product removal of all sizes of Cardinal Health brand Monoject sterile Syringe Luer-Lock (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) due to a change in manufacturing and rebranding efforts.

Recall Class	Product Identification	Distribution	Affected Dates
I	Cardinal Health Monoject 1ml Purple Enteral Syringe UDI/DI 26971564466206 (Case), 16971564466209 (Box), 06971564466202 (Each), Lot Numbers: 230701, 230501	22985 Units in California	December, 2023 and prior
I	Cardinal Health Monoject 35ml Enteral Syringe (Purple) UDI/DI 26971564466244	78527 Units in California	December, 2023 and prior

	(Case), 16971564466247 (Box), 06971564466240 (Each), Lot Numbers: 230501, 230601 and 230602		
I	Cardinal Health Monoject 20ml Syringe Luer-Lock Tip UDI/DI 50192253034675 (Case), 20192253034674 (Box), 10192253034677 (Each), Lot Numbers: 221201, 221202, 221203, 221204, 221205, 230201, 230202, 230203, 230204, 230205, 230206	788396 Units in California	December, 2023 and prior
I	Cardinal Health Monoject 12ml Syringe Luer-Lock Tip UDI/DI 50192253025819 (Case), 20192253025818 (Box), 10192253025811 (Each), Lot Numbers: 221101, 221102, 221103, 221104	1708595 Units in California	December, 2023 and prior
I	Cardinal Health Monoject 6ml Enteral Syringe (Purple) UDI/DI 26971564466220 (Case), 16971564466223 (Box), 06971564466226 (Each), Lot Numbers: 230503 and 230701	35493 Units in California	December, 2023 and prior
I	Cardinal Health Monoject 3ml Syringe Luer-Lock Tip UDI/DI 50192253033517 (Case), 20192253033516 (Box), 10192253033519 (Each), Lot Numbers: 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	5879792 Units in California	December, 2023 and prior
I	Cardinal Health Monoject 1ml Tuberculin Syringe Luer-Lock Tip UDI/DI 50192253034538 (Case), 20192253034537 (Box),	161431 Units in California	December, 2023 and prior

	10192253034530 (Each), Lot Numbers: 221201, 221202, 221203, 230201, 230202, 230203, 230204, 230205, 230601		
I	Cardinal Health Monoject 12ml Enteral Syringe (Purple) UDI/DI 26971564466237 (Case), 16971564466230 (Box), 06971564466233 (Each), Lot Numbers: 230501, 230502 and 230601	81519 Units in California	December, 2023 and prior
I	Cardinal Health Monoject 6ml Syringe Luer-Lock Tip UDI/DI 50192253034606 (Case), 20192253034605 (Box), 10192253034608 (Each), Lot Numbers: 221201, 221202, 221203, 221204, 221205, 230201, 230202, 230203, 230204, 230205, 230206, 230207	1702454 Units in California	December, 2023 and prior
I	Cardinal Health Monoject 60ml Enteral Syringe (Purple) UDI/DI 26971564466251 (Case), 16971564466254 (Box), 06971564466257 (Each), Lot Numbers: 230501, 230701 and 230702	267028 Units in California	December, 2023 and prior
I	Cardinal Health Monoject 3ml Purple Enteral Syringe UDI/DI 26971564466213 (Case), 16971564466216 (Box), 06971564466219 (Each), Lot Numbers: 230501, 230701, 230601	32500 Units in California	December, 2023 and prior

For additional information, please visit the FDA website [1mL Purple](#), [35mL Enteral](#), [20mL Luer-Lock](#), [12mL Luer-Lock](#), [6mL Enteral](#), [3mL Luer-Lock](#), [1mL Tuberculin](#), [12mL Enteral](#), [6mL Luer-Lock](#), [60mL Enteral](#), [3mL Purple](#)