

**FIELD SAFETY NOTIFICATION**

April 9, 2024

Dear Valued McKesson Customer:

Cardinal Health has notified McKesson Medical-Surgical Inc. (MMS) of a Safety Communication regarding their plastic syringes made in China. The U.S. Food and Drug Administration (FDA) has issued a safety communication regarding their ongoing evaluation and performance issues related to the plastic syringes made in China. Cardinal Health has placed all impacted product on hold, aligning their process with the ongoing FDA evaluation. As a result, McKesson Medical-Surgical Inc. has placed all products listed in the table below on hold.

A review of our records indicates that your company may have purchased items included in the attached manufacturer's notification.

Refer to the table below for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description
414590	1180100555	SYRINGE, TB REG LUER TIP 1CC (100/BX) KENDAL
414601	1180300555	SYRINGE, REG LUER TIP 3CC (100/BX) KENDAL
414617	1180600555	SYRINGE, REG LUER TIP 6CC (10 0/BX) KENDAL
414630	1182000555	SYRINGE, REG TIP 20CC (40/BX)
414632	1183500555	SYRINGE, REG LUER TIP 35CC (40/BX) KENDAL
414634	1183500888	SYRINGE, CATH TIP 35CC (40/BX 4BX/CS)
414635	1186000444	SYRINGE, CATH TIP SOFT-PACK 60CC (30/BX) KENDAL
414597	1188100555	SYRINGE, INSULIN REG LUER TIP 1CC (100/BX) KENDAL
517305	1188100777	SYRINGE, INSULIN LL 1CC (60/BX4BX/CS) KENDAL
1026097	8881101015	SYRINGE, ENTERAL W/ENFIT CONN N/S PURP 1ML (3200/CS)
1026099	8881103015	SYRINGE, ENTERAL W/ENFIT CONN N/S PURP 3ML (2000/CS)
321869	8881103025	SYRINGE, REG LUER TIP N/S 3CC (250/BX 4BX/CS) KENDAL
915546	8881103066	SYRINGE, 3CC LL BULK (2000/CS)
512001	8881106010	SYRINGE, LL TIP 6ML (100/BX 5BX/CS)
1026101	8881106015	SYRINGE, ENTERAL W/ENFIT CONN N/S PURP 6ML (1200/CS)
57149	8881106028	SYRINGE, REG LUER TIP N/S 6CC (100/BX) KENDAL
1026103	8881112015	SYRINGE, ENTERAL W/ENFIT CONN N/S PURP 12ML (1000/CS)
30131	8881112059	SYRINGE, REG LUER TIP N/S 12CC(100/BX) KENDAL
512002	8881112083	SYRINGE, LL N/S 12CC (800/CS) KENDAL
63398	8881120037	SYRINGE, REG LUER TIP N/S 20CC(50/BX)
1026105	8881135015	SYRINGE, ENTERAL W/ENFIT CONN N/S PURP 35ML (300/CS)
321871	8881135084	SYRINGE, REG LUER TIP N/S 35CC(25/BX) KENDAL
1026107	8881160015	SYRINGE, ENTERAL W/ENFIT CONN N/S PURP 60ML (175/CS)

McKesson Medical-Surgical Inc.

**Table 1: Cardinal Health brand product SKUs currently on hold**

[Note: Covidien brand products with the same product codes are NOT on hold as they are not manufactured in China. This applies ONLY to Cardinal Health brand product manufactured in China with the SKUs below.]

SKU	Description
1183500888	MONOJCT 35ML SYR CATH TIP
1186000444	MONOJCT 60ML SYR CATH TIP
1186000555T	MONOJCT 60ML SYR LUER-SLIP
8881512852	12ML SYRINGE REGULAR LUER RP
8881112059	12ML SYRINGE REGULAR NS
8881112083	12ML SYRINGE LUER LOCK NS
8881512878	12ML SYRINGE LUER LOCK TIP RP
8881103025	MONOJCT 3ML SYR L-SLIP BNS
8881103066	MONOJCT 3ML SYR L-LOCK BNS
1180100555	MONOJCT 1ML TB SYR L-SLIP
1180600555	MONOJCT 6ML SYR L-SLIP
1188100555	MONOJCT 1ML INS SYR L-SLIP
1188100777	MONOJCT 1ML INS SYR L-LOCK TIP CAP
8881106010	MONOJCT 6ML SYR L-LOCK BNS
8881106028	MONOJCT 6ML SYR L-SLIP BNS
8881120037	MONOJCT 20ML SYR L-SLIP BNS
8881135084	MONOJCT 35ML SYR L-SLIP BNS
8881160629	MONOJCT 60ML SYR L-LOCK BNS
8881501400	MONOJCT 1ML TB SYR L-SLIP RP
8881501459	MONOJCT 1ML TRAY L-SLIP
8881516911	MONOJCT 6ML SYR L-SLIP RP
8881516937	MONOJCT 6ML SYR L-LOCK RP
8881520657	MONOJCT 20ML SYR L-LOCK RP
8881520673	MONOJCT 20ML SYR L-SLIP RP
8881535762	MONOJCT 35ML SYR L-LOCK RP
8881535770	MONOJCT 35ML SYR CATH TIP RP
8881535796	MONOJCT 35ML SYR L-SLIP RP
8881560125	MONOJCT 60ML SYR L-LOCK RP
8881560141	MONOJCT 60ML SYR CATH TIP RP
8881560224	MONOJCT 60ML SYR L-SLIP RP
1182000555	MONOJCT 20ML SYR L-SLIP
8881160405	MONOJCT 60ML SYR L-SLIP BNS
1180300555	MONOJCT 3ML SYR L-SLIP
1183500555	MONOJCT 35ML SYR L-SLIP
405ABE	AMBER ENFIT 0.5 ML SYRINGE NON-STER
405E	ENFIT 0.5 ML SYRINGE NON-STERILE
701ABE	AMBER ENFIT 1ML SYRINGE NON-STERILE
701ASE	AMBER ENFIT 1 ML SYRINGE STERILE
703ABE	AMBER ENFIT 3ML SYRINGE NON-STERILE
703ASE	AMBER ENFIT 3 ML SYRINGE STERILE

MMS #	MFG Catalog #	Description
541482	8881160405	SYRINGE, 60CC REG TIP N/S (100/CS) KENDAL
703080	8881160629	SYRINGE, LUER LOCK N/S 60CC (155/CS) KENDAL
56089	8881501400	SYRINGE, TB REG LS NOT FOR VETOR DENTAL KENDAL (100/BX)
209233	8881501459	PHARMACY TRAY, STR 1CC (25/TR 40TR/CS)
320281	8881512878	SYRINGE, LUER LOCK 12CC NOT F OR VET OR DENTAL
125563	8881516911	SYRINGE, REG LUER TIP 6CC NOT FOR VET OR DENTAL KENDAL
125564	8881516937	SYRINGE, LL 6CC NOT FOR VET ORDENTAL KENDAL
915638	8881520657	SYRINGE, LL 20CC NOT FOR VET OR DENTAL (50/BX 6BX/CS)
320287	8881520673	SYRINGE, REGULAR 20CC NOT FOR VET OR DENTAL
320293	8881535762	SYRINGE, LL 35CC NOT FOR VET OR DENTAL KENDAL
320292	8881535770	SYRINGE, CATH TIP 35CC NOT FORVET OR DENTAL KENDAL
320290	8881535796	SYRINGE, REG LUER TIP 35CC NOTFOR VET OR DENTAL KENDAL
1159851	8881560125	SYRINGE, LUER LOCK TIP 60ML (20/BX 5BX/CS)
875714	1186000555T	SYRINGE, REG TIP 60ML (30/BX 12BX/CS)
1019755	11812558	NEEDLE, SFTY MONOJECT 1ML 25GX5/8" (100/BX 12BX/CS)
1019753	11812705	NEEDLE, SFTY MONOJECT 1ML 27GX1/2" (100/BX 12BX/CS)
1019754	11813005	NEEDLE, SFTY MONOJECT 1ML 30GX1/2" (100/BX 12BX/CS)
1019723	11832010	NEEDLE, SFTY MONOJECT 3ML 20GX1" (100/BX 12BX/CS)
1019724	11832015	NEEDLE, SFTY MONOJECT 3ML 20GX1 1/2" (100/BX 12BX/CS)
1019725	11832110	NEEDLE, SFTY MONOJECT 3ML 21GX1" (100/BX 12BX/CS)
1019726	11832115	NEEDLE, SFTY MONOJECT 3ML 21GX1 1/2" (100/BX 12BX/CS)
1019727	11832210	NEEDLE, SFTY MONOJECT 3ML 22GX1" (100/BX 12BX/CS)
1019728	11832215	NEEDLE, SFTY MONOJECT 3ML 22GX1 1/2" (100/BX 12BX/CS)
1019729	11832310	NEEDLE, SFTY MONOJECT 3ML 23GX1" (100/BX 12BX/CS)
1019730	11832315	NEEDLE, SFTY MONOJECT 3ML 23GX1 1/2" (100/BX 12BX/CS)
1019731	11832510	NEEDLE, SFTY MONOJECT 3ML 25GX1" (100/BX 12BX/CS)
1019733	11832558	NEEDLE, SFTY MONOJECT 3ML 25GX5/8" (100/BX 12BX/CS)

**Please note:** This is *not* a recall. Carefully review the information in the attached Cardinal Health Notification.

If you have any questions regarding this notification, please contact Carinal Health Customer Service via phone at **(800) 964-5227**. If you have further distributed any of the items referenced in this notification, provide your accounts with a copy of this Field Safety Notice.

If your company would like to process a return and a credit in connection with an affected item listed above, please contact our Customer Service Department at [MMSSyringe@McKesson.com](mailto:MMSSyringe@McKesson.com).

McKesson Medical-Surgical provides additional information regarding the FDA communication and related matters on our microsite at [www.McKesson.com/syringe](http://www.McKesson.com/syringe). We sincerely apologize for any inconvenience this notification may have caused you and your staff.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

**McKesson Medical-Surgical Inc.**

706ABE	AMBER ENFIT 6ML SYRINGE NON-STERIL
706ASE	AMBER ENFIT 6 ML SYRINGE STERILE
712ABE	AMBER ENFIT 12ML SYRINGE NON-STERI
712ASE	AMBER ENFIT 12 ML SYRINGE STERILE
735ABE	AMBER ENFIT 35ML SYRINGE NON-STERIL
735ASE	AMBER ENFIT 35 ML SYRINGE STERILE
760ABE	AMBER ENFIT 60ML SYRINGE NON-STERIL
760ASE	AMBER ENFIT 60 ML SYRINGE STERILE
8881112015	MONOJCT ENTERAL 12ML SYR NS
8881103015	MONOJCT ENTERAL 3ML SYR NS
8881101015	1ML ENTERAL BULK NS
8881106015	6ML ENTERAL BULK NS
8881135015	35ML ENTERAL BULK NS
8881160015	MONOJECT 60mL Enteral Syringe, Bulk



March 28<sup>th</sup> 2024

Dear Valued Customer,

On March 19, 2024, the U.S. Food and Drug Administration (FDA) issued an updated safety communication regarding their ongoing evaluation of quality and performance issues related to plastic syringes made in China. Within the communication, the FDA announced additional recommendations and actions to address these issues.

Cardinal Health is committed to ensuring the safety and quality of our products, and as a manufacturer of standard plastic syringes, we take FDA's recommendation seriously. As a result, we have expanded our previous product hold beyond what was communicated in our February 2, 2024, field action to include additional China-manufactured plastic syringes in deference to the FDA's recommendation. While we have not had increased complaints on the China-made plastic syringes in this expanded scope, we are aligning our process with the ongoing FDA evaluation and the subsequent response of our suppliers. *The complete list of China-made Cardinal Health brand SKUs currently on hold are in Table 1 below.*

While some of our syringe portfolio has been manufactured in China for many years to ensure supply resiliency, we also manufacture in the U.S. and in regions outside of China. We currently have two Cardinal Health-owned U.S. manufacturing plants producing Cardinal Health and Covidien brand needle and syringe products, including plastic syringes. In response to FDA's recent recommendation, we are expanding upon our U.S. production and actively evaluating alternate manufacturing options outside of China. We are committed to increasing plastic syringe supply as quickly as possible.

We will keep you informed as we work with urgency to increase production and engage with the FDA and our suppliers to ensure you have the quality products you need.

If you have any product or inventory-related questions, feel free to contact your local Cardinal Health rep or our customer service at 800-964-5227.

Thank you,

A handwritten signature in black ink that reads "Kelley Moffett".

Kelley Moffett  
Senior Vice President  
Quality, Regulatory and Medical Affairs  
Cardinal Health



Cardinal Health  
SHARPS SAFETY  
3651 Birchwood Dr  
Waukegan, IL 60085

cardinalhealth.com

April 1, 2024

Dear Valued Customer,

On March 19, 2024, the U.S. Food and Drug Administration (FDA) issued an updated safety communication regarding their ongoing evaluation of quality and performance issues related to plastic syringes made in China. Within the communication, FDA shared a Warning Letter sent to Sol-Millennium Medical, Inc. (Sol-Millennium), which supplies a small portion of Cardinal Health's Monoject™ Needle and Syringe combination portfolio.

As a result of these events, we implemented a product hold on Monoject™ Hypodermic Safety Needles with Syringe combination products sourced from Sol-Millennium. **Monoject™ Magellan™ Hypodermic Safety Needle with Syringe combination products are manufactured in the U.S. and are not impacted by this product hold.** *A list of Cardinal Health Monoject™ Hypodermic Safety Needle with Syringe combination SKUs sourced from Sol-Millennium currently on hold are in Table 1 below.*

In response to FDA's recent recommendations, we are expanding our U.S. production and actively evaluating alternate manufacturing options outside of China. We are committed to increasing supply as quickly as possible. During this period, we recommend substituting our U.S.-manufactured Monoject™ Magellan™ Hypodermic Safety Needles with Syringe combination products (more detail is within Table 2 below).

We will keep you informed as we work with urgency to increase production and engage with the FDA and our suppliers to ensure you have the quality products you need.

If you have any product or inventory-related questions, feel free to contact your local Cardinal Health rep or our customer service at 800-964-5227.

Thank you,

A handwritten signature in black ink that reads "Kelley Moffett".

Kelley Moffett  
Senior Vice President  
Quality, Regulatory and Medical Affairs  
Cardinal Health

**Table 1: Cardinal Health brand Monoject™ Needle and Syringe combination product currently on hold**

SKU	Description
11812558	MONOJECT SAFETY 1ML, 25 X 5/8
11812705	MONOJECT SAFETY 1ML, 27 X 1/2
11813005	MONOJECT 1ML 30 X 1/2
11832010	MONOJECT SAFETY NEEDLE 3ML 20 X 1
11832015	MONOJECT SAFETY NEEDLE 3ML 20 X 1.5
11832110	MONOJECT SAFETY NEEDLE 3ML 21 X 1
11832115	MONOJECT SAFETY NEEDLE 3ML 21 X 1.5
11832210	MONOJECT SAFETY 3ML, 22 X 1
11832215	MONOJECT SAFETY 3ML, 22 X 1.5
11832310	MONOJECT SAFETY 3ML, 23 X 1
11832315	MONOJECT 3ML 23 X 1 1/2
11832510	MONOJECT SAFETY NEEDLE 3ML 25 X 1
11832558	MONOJECT SAFETY 3ML, 25 X 5/8

**Table 2: Recommended best alternatives to Monoject™ Safety Hypodermic Magellan™ Safety Hypodermic Video**

**Monoject™ Safety Hypodermic Needles and Syringes** **Monoject™ Magellan™ Safety Hypodermic Best Alternatives**

Product	Description	Product	Description
		8881811310	Monoject™ Magellan™ 1mL 23G x 1"
11812558	Monoject™ Hypodermic Safety Needle and Syringe 1mL 25G x 5/8"	8881811558	Monoject™ Magellan™ 1mL 25G x 5/8"
		8881811510	Monoject™ Magellan™ 1mL 25G x 1"
11812705	Monoject™ Hypodermic Safety Needle and Syringe 1mL 27G x 1/2"		
11813005	Monoject™ Hypodermic Safety Needle and Syringe 1mL 30G x 1/2"		
		8881833810	Monoject™ Magellan™ 3mL 18G 1"
11832010	Monoject™ Hypodermic Safety Needle and Syringe 3mL 20G x 1"	8881833010	Monoject™ Magellan™ 3mL 20G x 1"
11832015	Monoject™ Hypodermic Safety Needle and Syringe 3mL 20G 1-1/2"	8881833015	Monoject™ Magellan™ 3mL 20G x 1-1/2"
11832110	Monoject™ Hypodermic Safety Needle and Syringe 3mL 21G x 1"	8881833110	Monoject™ Magellan™ 3mL 21G x 1"
11832115	Monoject™ Hypodermic Safety Needle and Syringe 3mL 21G x 1-1/2"	8881833115	Monoject™ Magellan™ 3mL 21G x 1-1/2"
11832210	Monoject™ Hypodermic Safety Needle and Syringe 3mL 22G x 1"	8881833210	Monoject™ Magellan™ 3mL 22G x 1"
11832215	Monoject™ Hypodermic Safety Needle and Syringe 3mL 22G x 1-1/2"	8881833215	Monoject™ Magellan™ 3mL 22G x 1-1/2"
11832310	Monoject™ Hypodermic Safety Needle and Syringe 3mL 23G x 1"	8881833310	Monoject™ Magellan™ 3mL 23G x 1"
11832315	Monoject™ Hypodermic Safety Needle and Syringe 3mL 23G x 1-1/2"		
11832558	Monoject™ Hypodermic Safety Needle and Syringe 3mL 25G x 5/8"	8881833558	Monoject™ Magellan™ 3mL 25G x 5/8"
11832510	Monoject™ Hypodermic Safety Needle and Syringe 3mL 25G x 1"	8881833510	Monoject™ Magellan™ 3mL 25G x 1"