PRODUCT DISRUPTION BRIEF

Potential plastic syringe device failures (reviewed September 12)

The FDA potential device failure safety communication remains in effect for plastic syringes made in China. Providers should continue transition from plastic syringes manufactured by multiple manufacturers and evaluate all other syringes for manufacturing location prior to use.

Current conditions

Please note, that the potential plastic syringe device failure information contained in this brief details information related to potential safety concerns for plastic syringes manufactured in China.

This situation is not related to the tariff increases raised by the Biden Administration on May 14. For more information related to China tariffs, view the disruption brief here.

September 2024 update for standard, safety and flush syringes: As most of Vizient's contracted suppliers (5 of 6) manufacture domestically, supply remains stable but tightly managed. Manufacturing has been prioritized for these products and plants are operating 24/7 to meet demand.

On May 16, the U.S. Food and Drug Administration (FDA) updated its recommendations and added that providers should immediately transition away from using plastic syringes manufactured by the following China-based manufacturers, unless use of these syringes is absolutely necessary until you can complete the transition to syringes that are not manufactured in China:

- Jiangsu Caina Medical Co Ltd.
- Jiangsu Shenli Medical Production Co Ltd.
- Shanghai Kindly Enterprise Development Group Co Ltd.
- Zhejiang Longde Pharmaceutical Co Ltd.

On April 24, the issued an additional warning letter that describes violations related to the sale and distribution of unauthorized plastic syringes made in China that have not been cleared or approved by the FDA for sale or distribution in the U.S. to the following firm:

- Cardinal Health (firm marketing and distributing plastic syringes made in China within the U.S.)

The warning letter also describes violations related to quality system regulations for syringe products. The FDA expects this firm to fully address the violations described in the warning letter.

On April 10, the FDA announced expanded actions for Jiangsu Shenli Medical Production Co. Ltd. with an additional import alert for not meeting device quality system requirements, to prevent ALL plastic syringes by this manufacturer from entering the United States.

On March 18, the FDA provided an update to their ongoing evaluation of quality and performance issues related to plastic syringes made in China, and announced additional recommendations and actions the FDA is taking to address these issues. The FDA has issued warning letters that describe violations related to the sale and distribution of unauthorized plastic syringes made in China that have not been cleared or approved by the FDA for sale or distribution in the U.S. to the following three entities:

- Jiangsu Shenli Medical Production Co. Ltd. (China-based manufacturer of plastic syringes)
- Medline Industries, LP (firm marketing and distributing plastic syringes made in China within the U.S.)
- Sol-Millennium Medical, Inc. (firm marketing and distributing plastic syringes made in China within the U.S.)

The warning letters for Medline Industries, LP and Sol-Millennium Medical, Inc. also concern violations related to quality system regulations for syringe products. The FDA expects these entities to fully address the violations described in the

To learn more, please contact:
Beth Grimsley, Director,
beth.grimsley@vizientinc.com.

warning letters. In addition, they are actively evaluating quality issues and performance testing failures with plastic syringes made by Jiangsu Shenli Medical Co Ltd, a China-based manufacturer cited in the warning letter issued to Medline Industries, LP. The FDA will take additional steps as appropriate.

On November 30, the FDA informed consumers, health care providers, and health care facilities that the FDA is evaluating the potential for device failures (such as leaks, breakage, and other problems) with plastic syringes manufactured in China, that are used for injecting fluids into, or withdrawing fluids from, the body. We had received information about quality issues associated with several China-based manufacturers of syringes. The issue does not include glass syringes, pre-filled syringes, or syringes used for oral or topical purposes.

Supplier communications

Becton Dickinson syringes are manufactured in the US and are increasing capacity in support of the potential market constraints caused by these warnings.

Medline will issue a safety notice for impacted syringes in surgical procedure kits and packs to inform providers of product alerts without immediately stopping shipment nor disrupting the critical supply of surgical packs. Affected syringes will no longer be used in future production runs of kits and packs. Medline will voluntarily recall the below syringes:

Item	Description	Recalled lots	Suggested alternatives
DNSC91881	Control Syringe lOmL, Luer Lock	All lots	DYNJSYR10C, B-D309695, 70085003
DYNJPOLYCONl	Control Syringe lOmL Luer Lock	All lots	DYNISYR10C, B-D309695, 70085003
DYNJSYRPP20R	Syringe l0mL Luer Lock, Red	All lots	DYNJSYRPC20R
DYNJSYRPPlOR	Syringe l0mL Luer Lock, Red	All lots	DYNJSYRPClOR
DYNJSYRPPlOW	Syringe l0mL Luer Lock, White	All lots	DYNJSYRPCl0W, B-D301029
DYNJSYRPPSW	Syringe SmL Luer Lock, White	All lots	DYNJSYRPC6W
SYR10 1020	1mL Luer Slip Syringe	Only lot numbers in format: 97YYMMXXXX	SYR103020,SYR101010LD, B-D309659
SYR1010 10	1mL Luer Lock Syringe	Only lot numbers in format: 897YYMMXXXX	SYR101010LD

Medline's recall team will reach out to providers impacted by above recalls with details and next steps. Additional details for recalled item substitutions are available here.

Cardinal Health has expanded their previous product hold to include additional China-manufactured plastic syringes. A list of Cardinal products on hold is available here. In response to FDA recommendation, Cardinal is expanding US production and actively evaluating alternative manufacturing options outside of China.

Mitigation strategy

Until further notice, the FDA recommends that health care providers and facilities:

- **Immediately transition away from using plastic syringes manufactured by Jiangsu Shenli Medical Co Ltd, unless use of these syringes is absolutely necessary until you can complete the transition.**
- **Immediately transition away from using unauthorized plastic syringes manufactured by Jiangsu Shenli Medical Production Co Ltd, which includes all models other than the 5 mL luer lock syringe, unless use of these syringes is absolutely necessary until you can complete the transition.**

For all other plastic syringes made in China, while evaluations remain ongoing, the FDA recommends the following:

- Check the manufacturing location for syringe inventory by reviewing the labeling, outer packaging, or contacting the supplier or group purchasing organization.
- Consider using syringes not manufactured in China, if possible. At this time, glass syringes, pre-filled syringes, or syringes used for oral or topical purposes are not included.
- If providers have syringes manufactured in China, then continue to use them as needed until transitioning to alternative syringes and closely monitor for leaks, breakage, and other problems.
- Report any issues with syringes to the FDA.

Vizient maintains a Category Resource Guide for safety needles and syringes which provides details on the landscape of the market, manufacturing insights, logistic insights, utilization insights and advice on building supply assurance. Within the

category resource guide, for our contracted suppliers, in addition to further information curated, we have highlighted relevant information for our contracted suppliers:

- Becton Dickinson (BD) – The supplier has the largest market share and only standard needles and syringes are on contract. Needles and syringes are produced domestically. The syringes are composed of polycarbonate with a rubber stopper and a metal siliconized needle. BD released a statement that the FDA safety communication does not impact BD syringes. BD has placed all syringe codes on manual allocation to help ensure continuity to current customers.
- Cardinal (Covidien Monojet) – Needles and syringes are produced primarily in Norfolk, Neb., and Deland, Fla. However, late summer 2023, Cardinal shifted some manufacturing to China. We are working closely with Cardinal to understand any potential impact. The syringes are composed of polypropylene, and the needle is metal.
- Smiths Medical (purchased by ICU Medical) – Needles and syringes are produced in Olive Branch, Miss. The syringes are made of polypropylene, and needles are stainless steel.
- Retractable Technologies – The needles and syringes are manufactured for the U.S. market in Little Elm, Texas. For the Asian market, the supplier has a new partnership with Double Dove to manufacture in Pudong (near Shanghai), China.
- Terumo – The needles and syringes are manufactured in the Philippines. The syringes are made of polypropylene, and the needles are stainless steel and silicone lubricant.

Additional resources

Supply assurance webpage; Vizient Newsroom

Want to receive weekly Supply Assurance updates?
Update your preferences through our Subscription Manager by selecting Supply Assurance Weekly Digest.

Questions? Contact disasterresponse@vizientinc.com, pharmacyquestions@vizientinc.com, novaplus@vizientinc.com.

Cardinal products on hold

Note: Covidien products with the same product codes are not on hold; this applied to only Cardinal brand products manufactured in China.

SKU	Description
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
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
1180100555	MONOJCT 1ML TB SYR L-SLIP
1180300555	MONOJCT 3ML SYR L-SLIP
1180600555	MONOJCT 6ML SYR L-SLIP
1182000555	MONOJCT 20ML SYR L-SLIP
1183500555	MONOJCT 35ML SYR L-SLIP
1183500888	MONOJCT 35ML SYR CATH TIP
1186000444	MONOJCT 60ML SYR CATH TIP
1186000555T	MONOJCT 60ML SYR LUER-SLIP
1188100555	MONOJCT 1ML INS SYR L-SLIP
1188100777	MONOJCT 1ML INS SYR L-LOCK TIP CAP
8881101015	1ML ENTERAL BULK NS
8881103015	MONOJCT ENTERAL 3ML SYR NS
8881103025	MONOJCT 3ML SYR L-SLIP BNS
8881103066	MONOJCT 3ML SYR L-LOCK BNS
8881106010	MONOJCT 6ML SYR L-LOCK BNS
8881106015	6ML ENTERAL BULK NS
8881106028	MONOJCT 6ML SYR L-SLIP BNS
8881112015	MONOJCT ENTERAL 12ML SYR NS
8881112059	12ML SYRINGE REGULAR NS
8881112083	12ML SYRINGE LUER LOCK NS
8881120037	MONOJCT 20ML SYR L-SLIP BNS
8881135015	35ML ENTERAL BULK NS
8881135084	MONOJCT 35ML SYR L-SLIP BNS
8881160015	MONOJECT 60mL Enteral Syringe, Bulk
8881160405	MONOJCT 60ML 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
8881512852	12ML SYRINGE REGULAR LUER RP
8881512878	12ML SYRINGE LUER LOCK TIP RP
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