



March 2024

BD Increases Domestic Production to Support U.S. Health Care Need for Syringes

Dear Valued Customer,

BD is aware that the U.S. FDA issued an updated [Safety Communication](#) on March 19, 2024, regarding its ongoing evaluation of quality and performance issues related to plastic syringes made in China.

BD syringes are not implicated by this FDA safety communication. The hypodermic syringes BD provides to the U.S. health care system are primarily manufactured in the United States in Nebraska and Connecticut.

New information included in the FDA communication

- FDA's updated safety communication indicates that warning letters have been sent to: [Jiangsu Shenli Medical Production Co. Ltd.](#), [Medline Industries, LP](#) and [Sol-Millennium Medical, Inc.](#)
- The FDA warning letters describe violations related to unauthorized plastic syringes made in China that have not been cleared or approved by the FDA for sale or distribution in the United States. The warning letters for Medline Industries, LP and Sol-Millennium Medical, Inc. also concern violations related to quality system regulations for syringe products.
- FDA is also actively evaluating quality issues and performance testing failures with plastic syringes made by Jiangsu Caina Medical Co Ltd, that supplies several U.S. private label distributors.

BD has a longstanding legacy of manufacturing in the United States. BD controls its local manufacturing facilities, its quality and reporting systems, and ensures that all BD products are appropriately cleared for sale in the United States (see Figure A).

Recommended customer actions

FDA recommends that customers check the manufacturing location for plastic syringes that they use or have in their inventory by reviewing the labeling, outer packaging, or contacting their supplier or group purchasing organization. FDA also recommends that customers use syringes not manufactured in China, if possible. Customers are also encouraged to review the SKU lists provided in the FDA warning letters where FDA inspections revealed that product is adulterated, misbranded, and does not have valid regulatory clearance or approval for commercial distribution.

BD actions to support U.S. market

Since FDA issued its initial safety communication last November, BD has increased manufacturing output by more than 25%. BD has capacity to help support heightened U.S. syringe demand and plans to further increase production to meet the market need. To help maintain a consistent supply of devices, we ask customers to place orders in line with normal utilization.

Ensuring the safety and quality of our products is the top priority at BD. BD remains committed to supporting the U.S. health care system to help supply those providers who currently purchase syringes impacted by the FDA safety communication. BD clinical staff are prepared to support customers with any clinical questions they may have regarding our products. For clinical questions, please contact MDS-US-MedicalAffairs@bd.com.

Please reach out to your local BD representative or call BD customer service at 844.823.5433 with any questions. Thank you for your continued support of BD and its products and services.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michelle Cunningham", with a stylized flourish at the end.

Michelle Cunningham
BD Medical – Medication Delivery Solutions
VP/GM, Medication Delivery and Vascular Care Solutions

Figure A- Syringe Design-to-Delivery Ownership

		01	02	03	04	05	06
		Design  BD owned proprietary design	510K Clearance  BD owned 510K(s)	Supply Chain  BD controlled sourcing of raw materials	Manufacturing  BD owned manufacturing locations in the US.	Quality Control  BD owned FDA compliant Quality Management Systems	Logistics  Truckload shipping in the United States
	<i>Brands identified in safety communication</i>	Who owns the design?	Who owns the 510K(s)?	Reliant on 3 rd party manufacturers' sourcing practices	Outsourced China based production and manufacturing	Reliant on 3 rd party manufacturers' quality process	Imported from China