

BD Medical
1 Becton Drive
Franklin Lakes, NJ 07417
USA
tel: 201-847-8800
www.bd.com



Helping all people
live healthy lives

FOR U.S. CUSTOMERS USING BD PLASTIC SYRINGES

September 1, 2015

Dear Sir / Madam,

This letter is being provided in follow-up to our July 31, 2015, communication¹ regarding BD plastic sterile syringes. These syringes are FDA-cleared for use in general purpose fluid aspiration / injection only, and the concerns addressed in this communication do not relate to that cleared use.

We have become aware that these syringes are being used for purposes for which they were not designed or cleared. More specifically, compounding facilities and repackagers are using these syringes as closed containers, in which medications are stored prior to administration. **We have received reports of decreased potency when drugs are compounded or repackaged and stored in these syringes. Because of the potential public health impact when the syringes are used in this way, we are issuing this communication to assist in identifying affected syringes.**

We have determined that the cause of the reported decreased potency is an interaction with a rubber stopper used in certain product lots. To date, decreased potency has been reported for the following drugs: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanyl. ***Decreased drug potency has only been reported when drugs are stored in these syringes.***

We have now confirmed that certain lots of 1mL, 3mL, 5mL, 10mL, 20mL and, 30mL BD syringes contain the rubber stopper associated with decreased drug potency after storage. Please note, this list includes BD Oral Syringes. (The attached Appendix I provides a quick reference of the affected syringes by size and catalog number)

To check whether you have syringes affected by this issue:

1. *Determine the Catalog Number and Lot Number of your syringes.* The Catalog Number is a six digit number and the lot number is a seven-digit number that are both shown on the product packaging. For assistance in identifying these numbers, refer to the document that is available on the BD.com website on the "Alert: Drug Storage & BD Syringes" webpage by clicking on the link "Instructions for Identifying Catalog and Lot Numbers".

¹ <http://www.bd.com/hypodermic/pdf/07-31-15-letter.pdf>

2. *Determine whether your syringes come from an affected lot.*
- a. Visit the BD webpage dedicated to this issue by navigating to www.bd.com and clicking on "Alert: Drug Storage & BD Syringes," or by typing www.bd.com/alerts-notices into your web browser.
 - b. Scroll to the bottom of the page and look for the search box.
 - c. You can search by Catalog Number (six digits) or Lot Number (seven digits). You may enter one Catalog Number or multiple Lot Numbers. Remember, if you would like to check more than one lot number, separate your entries with a comma. The search function will return any results containing either search term.
 - d. Please make sure to **double-check** the Lot Number(s) or Catalog Number you enter to ensure that you have typed the number correctly.
 - e. If the Catalog or Lot Number you entered is affected by this issue, a report containing "Catalog No.", "Syringe Description", and "Lot No." will appear along with a list of the affected Lot(s). If the Catalog or Lot Number(s) you entered are not affected (i.e. catalog number and/or lots were not made with the alternate stopper), then the following messages will appear: "You searched for: [the search terms you entered]" and "The lot or catalog numbers you entered were NOT produced using the alternate stopper". If you receive these messages, be sure to check that you entered the correct numbers.
 - f. BD will continue to manufacture syringes using both the primary and alternate stopper, as both work properly when the syringes are used as intended. Accordingly, the list of lots containing the affected alternate stopper will continue to be updated on a weekly basis.

BD is concerned that abrupt withdrawal from use of general purpose syringes for compounding and repackaging would result in increased risk to patients and disruption in the health care system. Because BD continues to manufacture and distribute syringes that contain the affected stoppers, compounding facilities and repackagers should use the contact information below to ensure they receive syringes with stoppers that have not been associated with reports of decreased potency.

Please remember that if you are using BD syringes for their intended use of general purpose fluid aspiration / injection, and not for storage before administration, you can continue to safely use any lot of these products. We also note that, in the U.S., BD Insulin Syringes, BD PosiFlush Saline and Heparin Syringes, BD Pharmaceutical Systems' prefillable syringes, and 60mL BD general use syringes do not use the rubber stopper associated with this issue; and, therefore, are not impacted.

To help answer any questions you may have as quickly and efficiently as possible, BD has created a dedicated phone number (201-847-4500) and email address (drug_potency@bd.com) for inquiries related to this matter.

Sincerely,



Alex Wesolowski
VP, Corporate Regulatory Operations

APPENDIX I—U.S. Alternate Stopper Quick Reference Guide

Syringe Size	Product	Catalog No.	Produced with Alternate Stopper	
			Dates (MM/YYYY)	Lot Details
1mL	Luer-Lok™ syringe	309659	07/2012	Only two lots produced
	All Others	Various	Never	
3mL	Pharmacy Convenience Trays	309702	06/2014-05/2015	Refer to bd.com/alerts-notices
	Blunt Fill Needle + Syringe Combo	305060	01/2014-07/2015	Refer to bd.com/alerts-notices
	Bulk non-sterile syringe	301078, 301077	10/2014-06/2015	Refer to bd.com/alerts-notices
	Oral syringe	305210	03/2014-05/2015	Refer to bd.com/alerts-notices
	Enteral syringe	305855, 305854	07/2014-07/2015	Refer to bd.com/alerts-notices
	Luer-Lok™ syringe (Eurographics)	309658	Never	
	Luer-Lok™ syringe	All (excl. 309658)	8/2012-Present	Refer to bd.com/alerts-notices
	SafetyLok™ syringe	309592, 309593, 309594, 309596, 309606	03/2015-Present	Refer to bd.com/alerts-notices
All Others	Various	Never		
5mL	Pharmacy Convenience Trays	309703	08/2013-04/2015	Refer to bd.com/alerts-notices
	Blunt Fill Needle + Syringe Combo	305062	01/2015-07/2015	Refer to bd.com/alerts-notices
	Bulk non-sterile syringe	301027, 301028	08/2012-07/2015	Refer to bd.com/alerts-notices
	Oral syringe	305208, 303086, 305218	07/2014-07/2015	Refer to bd.com/alerts-notices
	Enteral syringe	305855, 305856	07/2014-07/2015	Refer to bd.com/alerts-notices
	SafetyLok™ syringe	305558, 305561	03/2014-Present	Refer to bd.com/alerts-notices
	Luer-Lok™ syringe (Eurographics)	309649	Never	
	Luer-Lok™ syringe	All (excl. 309649)	08/2012-Present	Refer to bd.com/alerts-notices
All Others	Various	Never		
10mL	Bulk non-sterile syringe	301029	04/2015	Only one lot produced
	SafetyLok™ syringe	305559, 305564, 305462, 305482	03/2014-06/2015	Refer to bd.com/alerts-notices
	All Others	Various	Never	
20mL	Eccentric Tip syringe (120 Pack)	300613	07/2013-Present	Refer to bd.com/alerts-notices
	Luer-Lok™ syringe	302830	11/2012	Only three lots produced
	All Others	Various	Never	
30mL	Bulk non-sterile syringe	301033, 301034, 301118	02/2013-02/2014	Refer to bd.com/alerts-notices
	Luer-Lok™ syringe	302832, 305618	01/2013-07/2014	Refer to bd.com/alerts-notices
	Slip Tip syringe	302833	09/2013-12/2013	Refer to bd.com/alerts-notices
	Enteral syringe	302836, 305862	09/2013-02/2014	Refer to bd.com/alerts-notices
	All Others	Various	Never	