

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-notice 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 | 301073, 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 | 305853, 305854 | 07/2014-07/2015 | Refer to bd.com/alerts-notices |
| | Luer-Lok™ syringe (Eurographics) | 309658 | Never | Refer to bd.com/alerts-notices |
| | Luer-Lok™ syringe | All (excl. 309658) | 8/2012-Present | |
| | SafetyLok™ syringe | 309592, 309593, 309594, 309596, 309606 | 03/2015-Present | |
| | 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 | Refer to bd.com/alerts-notices |
| | Luer-Lok™ syringe | All (excl. 309649) | 08/2012-Present | |
| | 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 | |