Becton Dickinson GmbH
Tullastr. 8-12 · 69126 Heidelberg
Postfach 10 16 29 · 69006 Heidelberg
Tel.: 06221 3050
Fax: 06221 305216
www.bd.com/de

Helping all people live healthy lives

Becton Dickinson GmbH · Postfach 10 16 29 · 69006 Heidelberg

URGENT: FIELD SAFETY NOTICE – MSS-15-637 FA

Medical Device Safety Advisory Notice
BD Plastipak Syringes / BD Oral Syringes

Date: <<insert date here>>

Syringe Size	Product Type	Catalog No.	Produced with Alternate Stopper	
			Dates (MM/YYYY)	Lot Details
3 ml	Luer-Lok™ syringe	309658	8/2012-Present	Refer to bd.com/alerts-notices
	Bulk non-sterile syringe	301073	10/2014-06/2015	Refer to bd.com/alerts-notices
	With BD SafetyGlide™ needle	305904	09/2012 - Present	Refer to bd.com/alerts-notices
	Oral syringe	305210 305220 305853	03/2014-05/2015	Refer to bd.com/alerts-notices
5mL	Luer-Lok™ syringe	309649	08/2012-Present	Refer to bd.com/alerts-notices
	Bulk non-sterile syringe	301027	08/2012-07/2015	Refer to bd.com/alerts-notices
	With BD Eclipse™ needle	305785	03/2012 - Present	Refer to bd.com/alerts-notices
	With BD SafetyGlide™ needle	305907	03/2011 - Present	Refer to bd.com/alerts-notices
	Oral syringe	305855 305218	07/2014-07/2015	Refer to bd.com/alerts-notices
20mL	Eccentric Tip syringe	300613 301183 301190	01/2015-Present	Refer to bd.com/alerts-notices
	Bulk non sterile Eccentric Tip syringe	300220	07/2013-Present	Refer to bd.com/alerts-notices
30mL	Luer-Lok™ syringe	302832	01/2013-07/2014	Refer to bd.com/alerts-notices
50mL	Catheter Tip	300867	06/2013 - Present	Refer to bd.com/alerts-notices
	Bulk non sterile catheter tip	300228	08/2014- Present	Refer to bd.com/alerts-notices

For the Attention of:

- Customers who use BD hypodermic syringes listed above not for immediate use.
- Procurement, Medical Director, Risk Manager, Head of Pharmacy, Medical Device Safety Officer

These syringes are cleared for use in general purpose fluid aspiration / injection only and the concerns addressed in this Field Safety Notification do not relate to that cleared use.

Description of the problem:

We have received reports from US customers of decreased potency when drugs are compounded or repackaged and stored in BD Plastipak 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.

Potential Root Cause Analysis

We have determined that the reported decreased potency is caused by 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.

Potential hazard and potential risk to patients

Any potential risk associated with storage of drugs in syringes and potential decreased drug potency is dependent on the specific drug and the application. There is no risk if the drug is not stored in the syringe which is not recommended.

Details of affected devices

Certain lots of BD Plastipak™ syringes, containing the rubber stopper associated with decreased drug potency after storage have been distributed in Europe. Please note this list includes BD™ Oral Syringes. **Appendix I presents 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."

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 digit). 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 message will appear: " You searched for: (the search terms you entered)" and "the lot or catalog number 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 the 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.

Please remember that if you are using BD syringes for their intended use of medical fluid aspiration/injection and not for storage before administration, you can continue to safely use any lot of these products.

BD is not in a position to immediately revert back to the use of the primary stoppers. 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. BD is not aware about similar ready to use hypodermic syringes which are cleared for long term storage of drugs.

Because BD continues to manufacture and distribute syringes that contain the affected stoppers, compounding facilities and repackagers should contact BD Customer Support or their local BD Sales Representative to ensure they receive syringes with stoppers that have not been associated with reports of decreased potency. In addition, compounding pharmacies and repackagers should regularly check the web site to identify newly affected lots that may have been added to the web site.
The storage or pre-filling is an off-label use for the subject syringes, and therefore BD does not evaluate these products for drug compatibility or stability.

Transmission of this Field Safety Notice

Please maintain awareness of this notice and resulting actions to ensure effectiveness of the corrective action in case you intend to further use the syringe for compounding and storage. BD willl update customers once we have a resolution to this component issue.

Contact Reference Person

If you have any questions, please feel free to contact your local BD Sales Consultant and they will be able to connect you with our Clinical and Regulatory Affairs professionals to discuss further. Alternatively, you may send a message to drug_potency@bd.com or call our us at <**add contact details**.>

We confirm that the appropriate regulatory agency have been informed of these actions.

Yours sincerely,

[redacted]
Regulatory Compliance Manager
BD Medical EEMA

APPENDIX I

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ACKNOWLEDGEMENT FORM

Please read in conjunction with Field Safety Notice MSS-015- 637 FA & return form to insert appropriate e-mail address or by fax to: insert fax number as soon as possible or no later than the xxx

☐ I have read and understood this Field Safety Notice and have distributed the information to all possibly impacted departments within my organization.

Organisation / Hospital / Clinic :	
Department (*if applicable*) :	
Address :	
Postcode :	City :
Contact Name :	
Job Title :	
Contact Telephone Number :	
Contact E-mail Address :	
Signature :	Date :

This form must be returned to BD Medical before this action can be considered closed for your account