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CZECH REPUBLIC

URGENT: FIELD SAFETY NOTICE
Medical Device Safety Advisory Notice and Product Recall

Date: 10.04.2013

BD Product Reference	Description
300223	BD Plastipak™ 50ml Luer Lok Syringe – Non Sterile
300865	BD Plastipak™ 50ml Luer Lok Syringe - Sterile
300869	BD Plastipak™ 50ml Luer Lok Syringe Amber - Sterile

For the Attention of:

- **Distributors supplying BD Plastipak™ 50ml Luer Lok Syringes**

Please be advised that this Field Safety Notice supercedes any prior BD communication regarding this issue (please discard any prior communications that you may have received).

Product Advisory Notice

BD launched a new syringe stopper design in April 2012. Syringes with the new stopper design (reference enclosed picture) may exhibit higher plunger forces when used in pumps.

The higher pump forces may increase the likelihood of triggering a false occlusion alarm for the current setting of occlusion level for some pumps. Please contact your BioMedical Engineering Department (EBME) to assess the pump and syringe system and make adjustments if necessary.

Product Recall

While most of the syringes in the product distribution/usage chain have the new design stopper, there may be limited inventory of syringes with the previous design stopper. If syringes with the previous design stopper are used in syringe pumps that have been adjusted



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for the new stopper, there may be a delay in initiating an occlusion alarm. In order to minimize the potential for this occurrence, **BD is recalling syringes with the previous design stopper**. The recalled product (with the previous stopper design, i.e. larger stopper) can be identified as detailed in appendix 1. Please note that only previous design (larger stopper) product is being recalled.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Please check your inventory for the three BD products listed. Lot numbers are identified in appendix 1. Return any affected products to BD in accordance with the instructions on the attached packing list.

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2. Please ensure that a copy of this letter is provided to any organizations to which the affected devices have been transferred or distributed.
3. Please complete the Customer Advisory Notice and Recall Response Card below and return by fax immediately to the number on the Customer Response Card.

Note: THIS FORM MUST BE COMPLETED AND FAXED TO BD MEDICAL.

4. If you have any questions regarding this communication, please contact the following telephone number **+421 918599899**

Please accept our apologies for the inconvenience caused by this advisory and recall notice. We know that you share in our desire to provide superior quality products and services to both our customers and their patients.

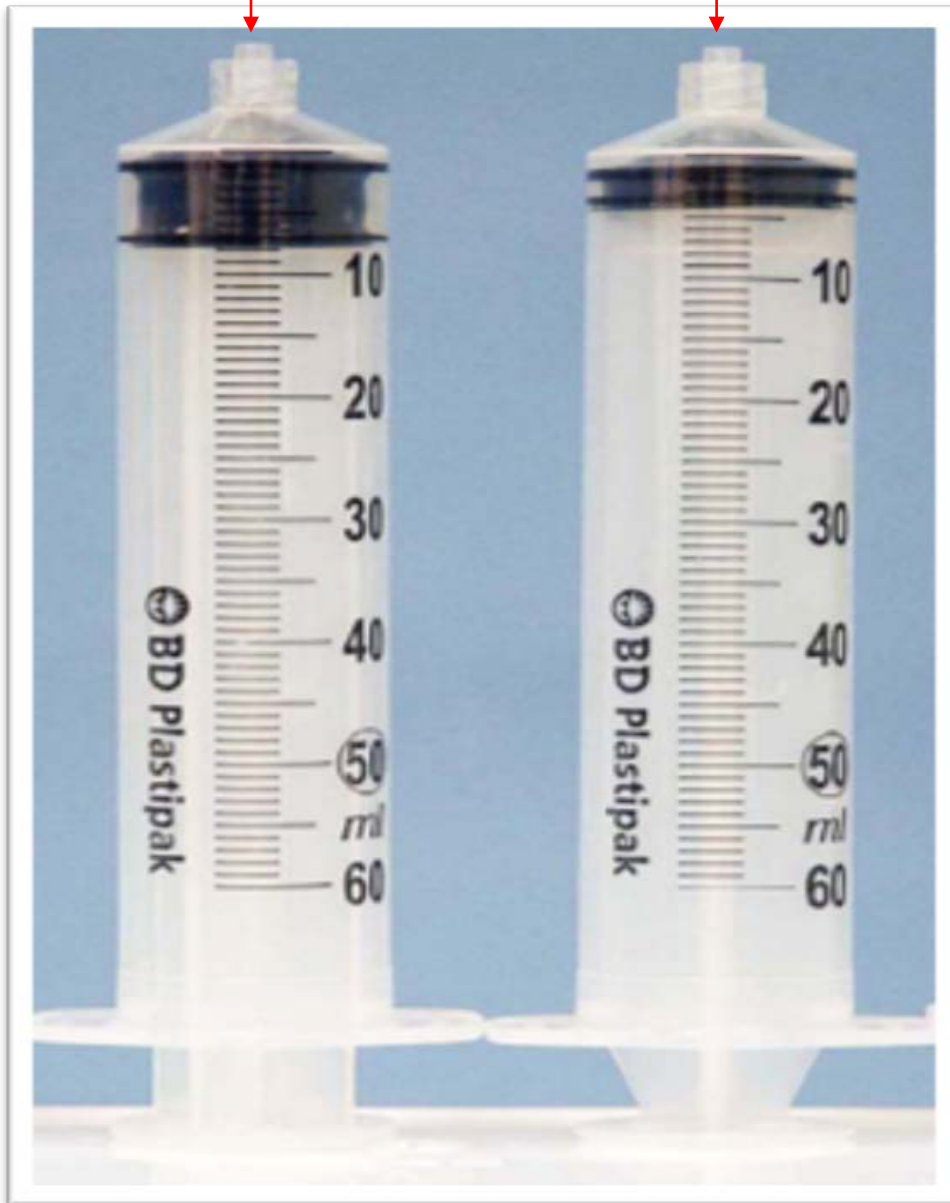
Yours sincerely,

Patrick Karvan
Sales Manager CEE

BD Plastipak™ 50ml Luer Lok Syringe Pictures

PREVIOUS DESIGN (being recalled)

CURRENT DESIGN



CUSTOMER RESPONSE CARD for:

BD Plastipak™ 50ml Luer Lock Syringes Reference Numbers: 300223, 300865, 300869

Please complete by checking the boxes below.

- This BD Advisory and Recall Notice has been read and understood by the undersigned and has been communicated within the referenced organisation.
- We do not have any of the stock of the products listed in the Recall Notice
- We do have stock of the products listed in the Recall Notice that we will be returning to BD or destroying locally (please provide a destruction certificate to BD if destroying locally) and require replacement products.

REF	LOT NUMBER	QUANTITY

Please fax to Zuzanna Uścimiak at +48 651 75 89.

If you have any questions concerning this, please contact Zuzanna_Uscimiak@europe.bd.com between 8:00 am – 4:00 pm, Monday – Friday

Contact Name (please print)

Title

Signature and date

Facility Name

Address

Phone Number

Fax Number



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Appendix 1

300865	BD Plastipak™ 50ml Luer Lok Syringe - Sterile
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All lot numbers prior to **1202294**. Please read the lot number as follows using 1202294 as an example.

12	Year
02	Month
294	Sequential Number

300869	BD Plastipak™ 50ml Luer Lok Syringe Amber - Sterile
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All lot numbers prior to **1203307**. Please read the lot number as follows using 1203307 as an example.

12	Year
03	Month
307	Sequential Number

300223	BD Plastipak™ 50ml Luer Lok Syringe – Non sterile
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All lot numbers prior to **1202273**. Please read the lot number as follows using 1202273 as an example.

12	Year
02	Month
273	Sequential Number