



Date 2 March 2017
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Urgent Field Safety Notice MSS-16-730-FA

Dear Sir or Madam,

we would like to inform you about a voluntary call-back of the manufacturer BD. The syringe

BD Plastipak™ Syringe 100 ml with catheter neck

is affected by an urgent field safety notice. The manufacturer BD calls back all LOT numbers with an expiration date of 5 years.

Actual situation

BD conducts a voluntary safety measure for the BD Plastipak™ Syringe 100 ml with catheter neck. All LOT numbers with an expiration date of 5 years are affected. The reason for the call-back is that after 2 years after manufacturing the occurrence of a leakage at the plunger seal is possible. Until now, no such incidents have been reported to BD.

Even though the product can be used safely during the first 18 month after manufacturing, BD calls back all LOT numbers with a expiration date of 5 years. Users of the product are kindly asked not to use these syringes anymore with immediate effect.

Potencial risks for patients

As described above, after the course of 18 months after manufacturing there is a higher risk of leakages at the plunger seal. In rare cases this can lead to lower doses delivered to the patient and thus prolongate the duration of therapy. For both patients and medicinal personnel there is a risk of unintended contact with medicinal products.



We have provided you with kits in which the syringe is used. An overview about the affected kits is attached in the Annex.

Please do not use the BD Plastipak™ Spritze 100 ml with catheter neck and exchange the product before the use in the OP.

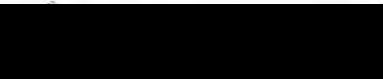
Other components of the set are not affected and may still be used. Please do not use the BD Plastipak™ Syringe 100 ml with catheter neck until all necessary measures have been taken. Please provide all employees and involved persons with this information.

Please fill in the customer response form until Mar 03rd 2016. You will receive sterile replacements for the affected syringes.

If you have questions regarding future set production, please contact your customer service agent.

We apologize for the inconvenience and thank you in advance for your support. If you have any questions, please feel free to contact us.

Best regards,



Sandra Höppner
Quality & Regulatory Affairs Manager