

Urgent Field Safety Notice

Address

Sales Division

Sales Division

Lohmann & Rauscher GmbH & Co.KG
Westerwaldstr. 4 D-56579 Rengsdorf

Kurzz. Tel.: 99-XXXX/ Fax: 99-XXXX

Email: xxxx.xxxx@de.LRmed.com

Date

Urgent Field Safety Notice due to increased potential of leakage past the stopper

BD Plastipak™ Syringe, Catheter tip with Luer slip adapter, 100ml

Dear Sir or Madam,

Today, in terms of patient safety, we would like to inform you about following Field Safety Corrective Action (FSCA) of Becton-Dickinson (BD) for the following product:

BD Plastipak™ Syringe, Catheter tip with Luer slip adapter, 100ml

BD is conducting a voluntary field safety corrective action for all lots of BD Plastipak™ Catheter Tip (CT) syringe 100ml labeled with a 5yr expiration date. The syringes are being recalled due to leakage past stopper failures during internal routine real time stability tests, with failures beginning at the 2yr time point. No adverse event has been reported for this issue at this time. Although the product can safely be used for 18 months after manufacturing, to avoid mistakes, BD is recalling all lots labelled with a shelf life of 5 years. Users should stop using these lots immediately.

Potential hazard and potential risk to patients:

As mentioned, there is an increased risk of leakage past the stopper starting at 18 months after production. In exceptional cases, this might result in delay in therapy, underdosing of the patient or exposure of clinicians or patients to drugs..

The products were integrated in our KitPack® OP-Setsystems.

In terms of patient safety, not to stop the work in the operation theatre as well as to guarantee the patient care following corrective actions has to be performed:

- Do not use the BD Plastipak™ Syringe 100ml in the KitPack. Please discard it before you start your surgery.
- We will add on our setsystems in our warehouses following additional label:
“Attention! Do not use the BD Plastipak™ Syringe 100ml with Luer adapter. Discard it.”
-

The other components of KitPack® OP-Setsystems are not affected and can be used as usual. Of course, we will recommend you alternatives to the BD Plastipak Syringe 100ml if necessary, in order to best bridge a possible supply bottleneck.

Our responsible authority agreed with this procedure.

Please ensure within your organization that all users of the above mentioned products and other relevant persons are aware of this **Urgent Field Safety Notice** and send the enclosed confirmation back to us.

If you have delivered the product to third parties, please forward a copy of that information to them.

We thank you in advance for your cooperation and apologize for any inconvenience.

Yours truly,
Lohmann & Rauscher GmbH & Co KG
i.V. / On behalf of i.V. / On behalf of

XXXXYY
Sales department

XXXXYY
Regional Vigilance Officer

Attachment:
Urgent Field Safety Notice – due to increased potential of leakage past the stopper

Urgent Field Safety Notice!

Date

due to increased potential of leakage past the stopper

(via Fax to 02634 - 99 xxxx)

Sender: Lohmann & Rauscher GmbH & Co. KG
Westerwaldstr.4
D-56579 Rengsdorf

Addressee: Adresse
Xxx
xxx
& all users who use the below mentioned products.

Description: Urgent Field Safety Notice – due to increased potential of leakage past the stopper

BD Plastipak™ Syringe, Catheter tip with Luer slip adapter, 100ml

Product	REF	Lot
KitPack XXXX	XXX	XXXXX

If necessary please add a L&R contact person

Corrective Actions:

We ask you not to use the contained BD Plastipak™ Syringe 100ml anymore.

Please **discard** the contained BD Plastipak™ Syringe 100ml in the KitPack® OP-Setsystems.

Please inform your employees who use the product of this Field Safety Notice and confirm to us that the product is not used anymore.

The undersigned confirms (please tick):

- that he does not use the BD Plastipak™ Syringe 100ml
- that he has informed all involved persons about this urgent field safety notice
- that he does not possess the above mentioned products anymore,
- that he has not given the above mentioned products to third parties,
- that if he has given the above mentioned products to third parties, he has informed the third parties about this urgent field safety notice not to use the BD Plastipak™ Syringe 100ml,

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____