

## **Urgent Field Safety Notice**

**Urgent Field Safety Notice – Follow-up Product recall** of CombiSets® containing Becton Dickinson 100ml Plastipak™ Catheter Tip syringe with Luer slip adaptor according to attachments.

---

April 12, 2017

Sender: PAUL HARTMANN AG  
Paul-Hartmann-Str. 12  
89522 Heidenheim

Recipient: „affiliate / authorized distributor“

### **Affected product:**

Affected CombiSets® with BD 100ml Plastipak™ Catheter Tip syringe **see attachment 1a + 1b**

Other not mentioned LOTs are not affected.

### **Description of the problem and Product Advisory Notice:**

We have been informed by our supplier Becton Dickinson and Company regarding their 100ml Plastipak™ Catheter Tip syringe with Luer slip adaptor about an Urgent Field Safety Notice as per attachment 2.

These 100ml Plastipak™ Catheter Tip syringe are used as a component in HARTMANN CombiSets®.

Becton Dickinson and Company informed that affected lots of 100ml Plastipak™ Catheter Tip syringe “are being recalled due to leakage past stopper failures during internal routine real time stability tests, with failures beginning at the 2yr time point. Although the product can safely be used for 18 months after manufacturing, to avoid mistakes”, they are recalling all lots labelled with a shelf life of 5 years.

They pointed out, that no adverse events have been reported for this issue at this time. So far, we have also not received any reports of incidents related to this issue in connection with our CombiSets®.

All CombiSets®, containing the BD Plastipak™ syringe 100 ml exceeding 18 months after manufacturing in February / March have been recalled at that time point (Annex 1a extended 10.03.2017).

As already announced, we are now recalling all further CombiSets® (see **attachment 1b**) and thus all CombiSets® containing affected lots of BD 100ml Plastipak™ Catheter Tip syringe.

**Advise on actions:**

Please examine your inventory and do not use the affected products with BD 100ml Plastipak™ Catheter Tip syringe ***of list 1b*** any longer.

We kindly ask you to confirm the receipt of this notification and return attachment 3 (Response form 1 Affiliate Reception & Transmission **12.04.2017**) until **Friday 21.04.2017**.

For confirmation of closure please complete and return attachment 4 (Response form 2 Affiliate Closure) until **Wednesday 10.05.2017**.

Your contact for further information is [REDACTED], telephone: (+49) 7321 – 36 [REDACTED]

**Transmission of this Urgent Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the affected products have been transferred to. Therefore please take adequate measures. A template for a customer letter is enclosed. Customers are requested to confirm receipt of the Urgent Field Safety Notice to the local HARTMANN affiliates / authorised distributor.

We do require your written confirmation of implementation and closing of the actions above.

This Urgent Field Safety Notice has been submitted to the Competent Authorities of the concerned countries within the European Economic Area (EEA).

Heidenheim, April, 12 2017  
PAUL HARTMANN AG

Attachments:

1. Lists of affected HARTMANN products  
a CombiSets® with BD 100ml Plastipak™ Catheter Tip syringe extended 10.03.2017  
***b CombiSets® with BD 100ml Plastipak™ Catheter Tip 15.02.2017***
2. Urgent Field Safety Notice Becton Dickinson
3. Response form 1 Affiliate Reception & Transmission **12.04.2017**
4. Response form 2 Affiliate Closure **12.04.2017**

Hiermit bestätigen wir, dass der komplette Bestand dieser Artikel (alle CombiSets® mit BD Plastipak™ Spritze 100 ml) gesperrt wurde und an die PAUL HARTMANN AG retourniert wird.

Es sind somit keine weiteren vom Rückruf betroffenen Artikel laut in **Anlage 1b 15.02.2017** im Lagerbestand vorhanden.

Datum:

Stempel:

Unterschrift: