

BD · Postfach 10 16 29 · 69006 Heidelberg

**URGENT: FIELD SAFETY NOTICE**  
**MPS-18-1254-FA****Voluntary Product Recall**

June 2018

Product Name	Catalogue (Ref) No.	Lot No.	Expiration Date
PhaSeal™ Secondary Set (C61)	515302	1005465	2021-04-30
		1005466	2021-04-30
		1005467	2021-04-30

**For the Attention of:**

Procurement, Medical Director, Risk Manager, Head of Pharmacy, Medical Device Safety Officer

**Description of the problem and health hazard(s):**

BD is conducting a voluntary field safety corrective action for the lots of PhaSeal™ Secondary Set (C61), Cat (Ref) 515302, listed on the table above. The recall is being conducted due to reports of leakage which could result in the exposure of the healthcare worker potentially to hazardous drugs during preparation, transport and administration. BD distributed the affected recalled lots from Nov 3, 2017 to Apr 23, 2018. The root cause has been identified and corrections are being implemented.

**You Need to Take the Following Actions:**

- Immediately review your inventory for the specific Catalogue (Ref) and lot numbers listed above, and quarantine product subject to the recall. This recall only affects the Catalogue (Ref) and lot numbers listed on the table above.
- Complete the attached Acknowledgement Form and fax it back to BD at XXX-XXX-XXXX or email the completed form to [yyy@yy.com](mailto:yyy@yy.com).

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Sitz: Heidelberg  
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IBAN: BE78 0017 9083 2386  
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Die Becton Dickinson GmbH gehört zur BD-Unternehmensgruppe.

**Actions Taken by BD:**

Upon receipt of the Acknowledgement Form, BD will contact you to organize the replacement of the recalled product at no charge.

**Transmission of this Field Safety Notice**

Please distribute this communication to all users of the PhaSeal™ Secondary Set (C61) affected.

**Contact Information**

If you have questions or require further assistance, please feel free to contact your local BD Account Manager [add contact details](#).

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

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We thank you in advance for helping us to assure patient safety by compliance with this Field Safety Notice as quickly and effectively as possible.

Yours sincerely,

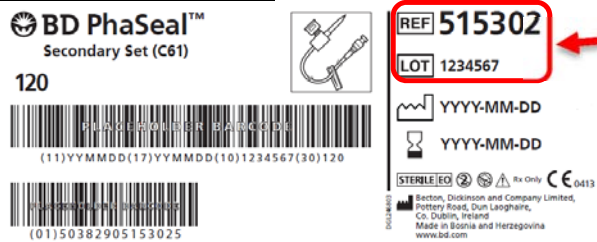


Dr. Bernd Peschke  
Director Regulatory Compliance  
BD Medical MPS - EEMA

**(Name & Signature of Local  
Contact)**

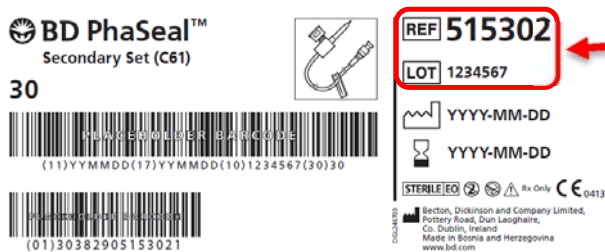
## Location of Product Identification (Example):

### Case Carton Label:



Catalogue (Ref)  
and Lot Number

### Shelf Box Label:



Catalogue (Ref)  
and Lot Number

### Unit Label:



Catalogue (Ref)  
and Lot Number

## ACKNOWLEDGEMENT FORM

**MPS-18-1254-FA**

**PhaSeal™ Secondary Set (C61)**

**Catalogue Number: 515302**

**Please assist BD by promptly returning this form to:**

**BD**

**{Contact Name}**

**Email: (BD country contact email)**

**Fax No.: {Fax Number}**

**Facility:** \_\_\_\_\_

Please use full, current facility name. Do not use initials.

**Street Address:** \_\_\_\_\_

**Postcode / City:** \_\_\_\_\_

**Contact Person:** \_\_\_\_\_

**Telephone No.:** \_\_\_\_\_ **Email Address:** \_\_\_\_\_

**Fax No.:** \_\_\_\_\_

Name:	
Title:	
Signature/Date:	

☐ I have read and understood the contents of this Field Safety Notice and confirm that our product inventory has been checked. Please select one of the following:

☐ We do not have any of the affected product(s) on hand.

☐ We have the following affected product in our inventory:

Product Name	Catalogue (Ref) No.	Lot No.	Expiration Date	Product in our Inventory
PhaSeal™ Secondary Set (C61)	515302	1005465	2021-04-30	
		1005466	2021-04-30	
		1005467	2021-04-30	

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