

URGENT: FIELD SAFETY NOTICE
MPS-17-1087-FA

Voluntary Product Recall

Date: <<insert date here>>

| Product Name | Catalogue (Ref) No. | Lot No. | Expiration Date |
|------------------------------|---------------------|---------|-----------------|
| PhaSeal™ Secondary Set (C61) | 515302 | 1004522 | 2021-02-28 |
| | | 1004523 | 2021-02-28 |
| | | 1004524 | 2021-02-28 |
| | | 1004525 | 2021-02-28 |

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 and separation of the Connector from the junction on the IV set spike, which could result in the exposure to the healthcare worker to hazardous drugs potentially during preparation, transport or administration. BD distributed the affected recalled lots from July 25, 2017 to September 05, 2017.

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 Notice of Return form and fax it back to BD at XXX-XXX-XXXX or email the completed form to yyyy@yy.com.

Actions Taken by BD:

Upon receipt of the Notice of Return, 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,

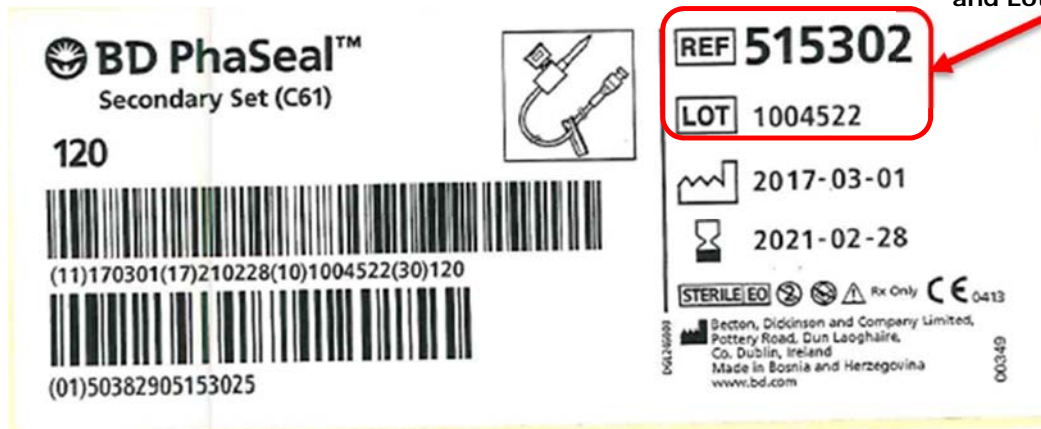
ppa Dr. Bernd Peschke
Director Regulatory Compliance
BD Medical MPS - EEMA

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

Location of Product Identification:

Case Carton Label:

Catalogue (Ref)
and Lot Number



Shelf Box Label:

Catalogue (Ref)
and Lot Number



NOTICE OF RETURN

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. | Total Units |
|------------------------------|---------------------|---------|-------------|
| PhaSeal™ Secondary Set (C61) | 515302 | 1004522 | |
| | | 1004523 | |
| | | 1004524 | |
| | | 1004525 | |

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