

URGENT: FIELD SAFETY NOTICE – PAS-016-841

BD Vacutainer® Push Button Blood Collection Set
Catalogue Number: 367342, Lot Numbers: 5355533 and 5356681

16th August 2016

Attention: Medical Device Safety Officer, Risk Manager, Laboratory Director, Head of Supply Chain, Phlebotomy Manager, Clinical Studies Director, Researchers, Clinical Pathologists.

This letter contains important information which requires your **immediate** attention.

Details of affected devices and description of the problem:

BD Life Sciences – Preanalytical Systems is issuing a recall for catalogue code 367342, BD Vacutainer® Push Button Blood Collection Set, lot numbers 5355533 and 5356681.

Through customer feedback, BD has become aware that the lot numbers listed in Table 1 do not perform as intended upon activation of the safety feature of the device which retracts the needle. Reports have indicated that the front and rear barrel of the device separate upon activation, which could potentially expose the needle and could cause an accidental needlestick injury or leakage of blood. The cause of this failure has been attributed to a manufacturing defect.

Table 1 – Affected product details

Catalogue Number	Product Description	Lot number	Expiry date
367342	BD Vacutainer® Push Button Blood Collection Set	5355533	2017-12
		5356681	2017-12

**This Field Safety Notice only affects the catalogue and lot numbers in Table 1.
To locate the catalogue and lot number, refer to Appendix 1.**

Advice on action to be taken:

- Stop use of the affected product immediately and quarantine all stock.
- Inform appropriate personnel in your organisation to discontinue the use of the affected lots.
- Complete and return the acknowledgement form (page 3) as soon as possible or **no later than the 25th of August 2016** following the instructions, in exchange for replacement product or credit.
- If you destroy affected product, the certificate of destruction form (page 4), should also be sent.

Transmission of this Field Safety Notice

Please maintain awareness of this notice in your organisation for an appropriate period to ensure effectiveness of the corrective action.

Contact Reference Person

If you have any questions about the product please contact your local BD representative or the BD office on (01865) 781666 or BDUK_customerservice@bd.com.

BD Life Sciences – Preanalytical Systems is committed to providing quality products to our customers and we have undertaken appropriate internal corrective actions. We apologise for the inconvenience this situation may cause.

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

Yours sincerely,



Lorna Darrock
European Regulatory Affairs Manager
BD Life Sciences - Preanalytical Systems



Advancing the
world of health

Field Safety Notice Acknowledgement Form

BD Vacutainer® Push Button Blood Collection Set
Catalogue number 367342

Please read in conjunction with Field Safety Notice PAS-016-841 and return form to BDUK_customerservice@bd.com or by fax to: (01865) 781528 / 717313 as soon as possible or **no later than the 25th of August 2016**.

Option 1

- **YES**, I have affected product in inventory and will return in exchange for replacement product or credit (tick appropriate box below).
- This notice has been read and understood and distributed to all appropriate personnel.
(Fill out and return this form to BD at fax/e-mail above and return the product with a copy of this form to FAO Returns Team, ref. PAS-016-841, BD, DC3, Laagstraat 57, B- 9140 Temse, Belgium)

Option 2

- **YES**, I have affected product in inventory and I confirm that this has been destroyed on site in exchange for replacement product or credit (tick appropriate box below).
- This notice has been read and understood and distributed to all appropriate personnel.
(Fill out and return this form along with the Certificate of Destruction form, **and provide evidence of destruction**, to BD at fax/e-mail above)

Option 3

- I have **NO** affected product left in inventory.
- This notice has been read and understood and distributed to all appropriate personnel.
(Fill out and return this form to BD at fax/e-mail above)

Organisation / Hospital / Clinic :	
Department (if applicable) :	
Address :	
Postcode :	City :
Contact Name :	
Job Title :	
Contact Telephone Number :	Contact E-mail Address :
Quantity Returned / Destroyed :	<input type="checkbox"/> Credit <input type="checkbox"/> Replacement
Signature :	Date :

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

CERTIFICATE OF DESTRUCTION

**BD Vacutainer® Push Button Blood Collection Set
Catalogue Number 367342**

If you choose to destroy impacted product, you are requested to complete and return this form to BDUK_customerservice@bd.com or by fax to: (01865) 781528 / 717313 as soon as possible or **no later than the 25th of August 2016.**

Dependent on your choice, replacement product or credit processes will be initiated.

Date of Destruction :	
Lot number :	
Quantity :	
Evidence attached :	
Signature :	Date :

This form, along with evidence, must be returned to BD PAS in order for replacement product or issue of credit processes to be initiated.

Appendix 1: Location of Catalogue and Lot Number Information

1. Unit



2. Shelf Carton



3. Shipping Case

