

URGENT: FIELD SAFETY NOTICE – PAS-18-1162

BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes
Catalogue Number: 368879, Lot Number: 6319963

15th January 2018

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

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 368879, BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes, lot number 6319963.

BD has received feedback from customers that the fill line is in the incorrect position (see below image) for tubes associated with this lot number. During investigation of these complaints, BD has become aware that the labelling for this lot of tubes has the incorrect shelf life. The shelf life is listed as 18 months, as opposed to the correct shelf life, 10 months.

Product associated with this lot expired in September 2017, but the label indicates the product has remaining shelf life, through May 2018. The use of an expired tube can result in lower draw volume due to the loss of vacuum in the tube. Furthermore, because the fill line is incorrectly located on the tube, a lower draw volume (e.g. under filled tube) would be difficult to detect prior to clinical testing. A lower draw volume could affect the blood to additive ratio, with the potential for erroneous results. Results should be correlated with the patient's clinical picture and repeat testing may be required.



Table 1 – Affected product details

Catalogue Number	Product Description	Lot number	Incorrect expiry date on Labelling	Correct Expiry Date
368879	BD Vacutainer® SST™ II <i>Advance</i> Plus Blood Collection Tubes	6319963	2018-05	2017-09

**This Field Safety Notice only affects the catalogue and lot number 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 and quarantine all stock as soon as possible.
- Inform appropriate personnel in your organisation to discontinue use of the affected lot.
- BD recommends discussing the content of this letter with your laboratory director regarding the need to review previous test results associated with this lot of product. Our records indicate your organisation received this product on <XXX> date.
- Complete and return the acknowledgement form (page 3) as soon as possible or **no later than the 1st February 2018** 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 **tel no.** or **email.**

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
EMEA Regulatory Affairs and Compliance Manager
BD - Preanalytical Systems

Field Safety Notice Acknowledgement Form
BD Vacutainer® SST™ II Advance Plus Blood Collection Tubes
Catalogue number 368879

Please read in conjunction with Field Safety Notice PAS-18-1162 and return form to **e-mail** or by fax to: **fax no.** as soon as possible or **no later than the 1st February 2018.**

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-18-1162, 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® SST™ II Advance Plus Blood Collection Tubes
Catalogue number 368879

PAS-18-1162

If you choose to destroy impacted product, you are requested to complete and return this form to **e-mail** or by fax to: **fax number** as soon as possible or **no later than the 1st February 2018.**

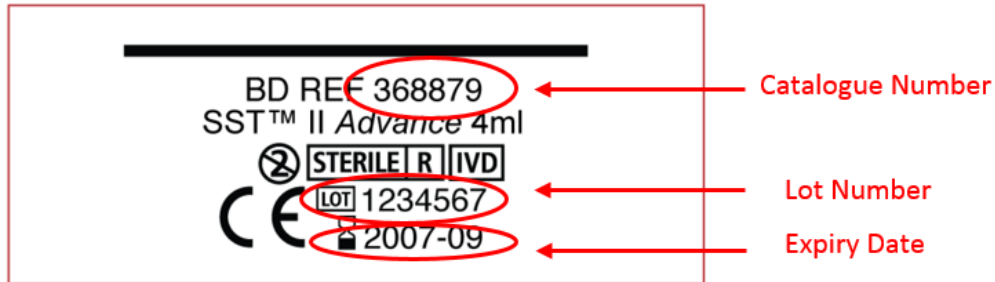
Dependent on your choice, replacement product or credit processes will be initiated.

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

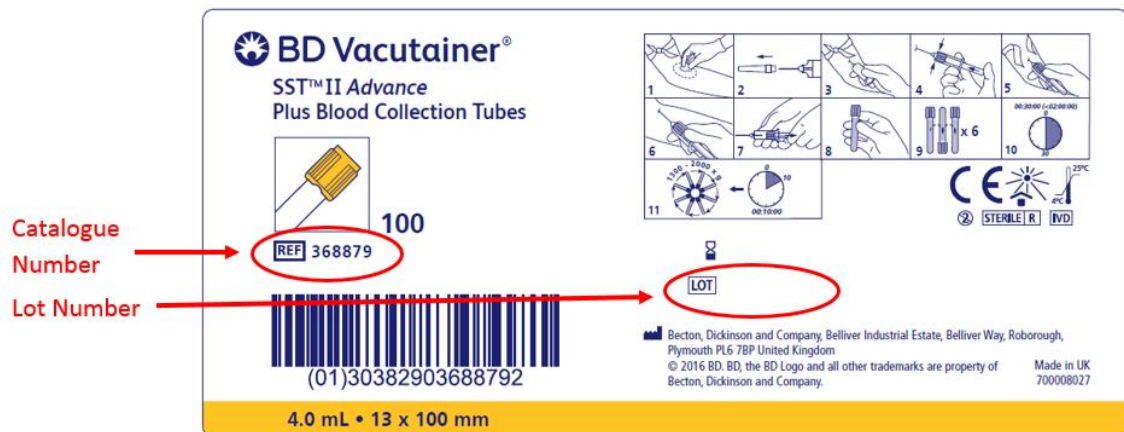
This form, along with evidence, must be returned to BD PAS in order for replacement product or issue of credit processes to be initiated.

Appendix 1: Location of Catalogue and Lot Number Information

1. Unit



2. Shelf Carton



3. Shipping Case

