

URGENT: FIELD SAFETY NOTICE – PAS-17-959

BD Vacutainer® SST™ II *Advance* Plus Blood Collection Tubes
 Catalogue Number: 366882, Lot Number: 6309990

24th February 2017

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 366882, BD Vacutainer® SST™ II *Advance* Plus Blood Collection Tubes, lot number 6309990.

Through internal checks, BD has become aware that the labelling for the tube, shelf and case packs for this lot number have been incorrectly printed with a shelf life of 18 months, as opposed to the correct 12 month shelf life.

Note: Due to the nature of the issue, there is no impact on patient results obtained with this device, as it is within its correct 12 month expiry date of the 30th October 2017 and the defect is related to labelling and not to the performance of the device.

Correct date should read 2017-10-30

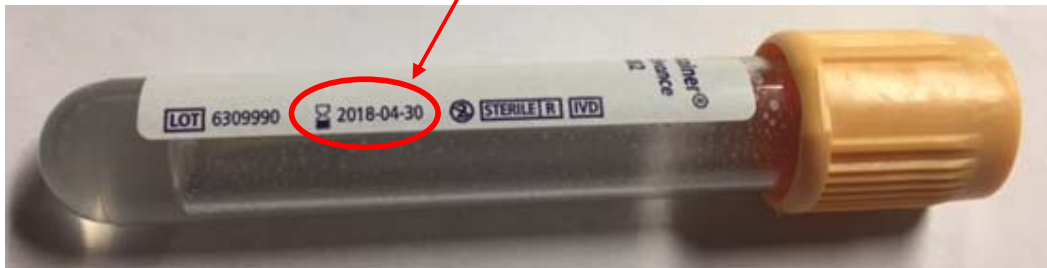


Table 1 – Affected product details

Catalogue Number	Product Description	Lot number	Incorrect expiry date on Labelling	Correct Expiry Date
366882	BD Vacutainer® SST™ II <i>Advance</i> Plus Blood Collection Tubes	6309990	2018-04-30	2017-10-30

**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 the use of the affected lot.
- Complete and return the acknowledgement form (page 3) as soon as possible or **no later than the 10th of March 2017** 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 366882

Please read in conjunction with Field Safety Notice PAS-17-959 and return form to **e-mail** or by fax to: **fax no.** as soon as possible or **no later than the 10th of March 2017.**

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-17-959, 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 <i>(if applicable)</i> :	
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 366882

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 10th of March 2017.**

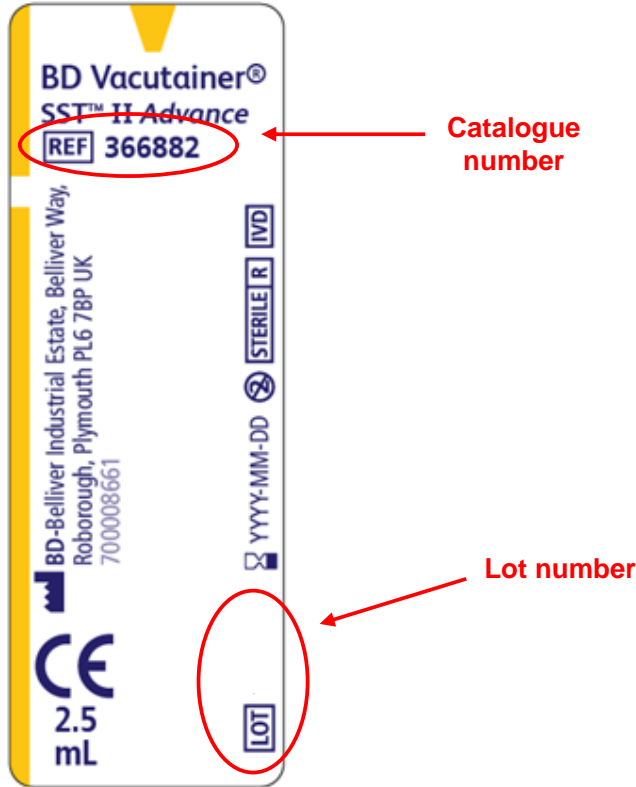
Dependent on your choice, replacement product or credit processes will be initiated.

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

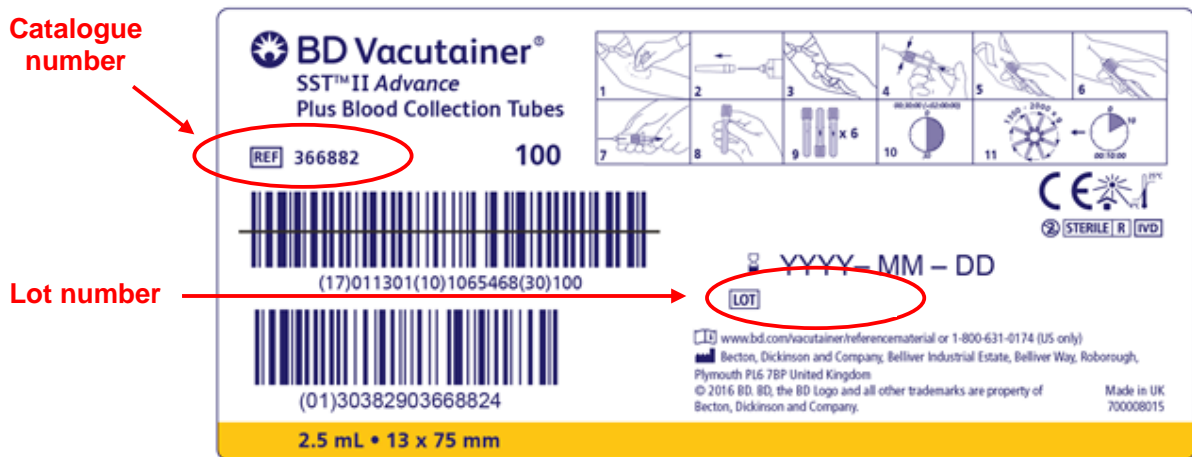
This form, along with evidence, must be returned to BD PAS in order for replacement product or issue of credit processes to be initiated.

Appendix 1: Location of Catalogue and Lot Number Information

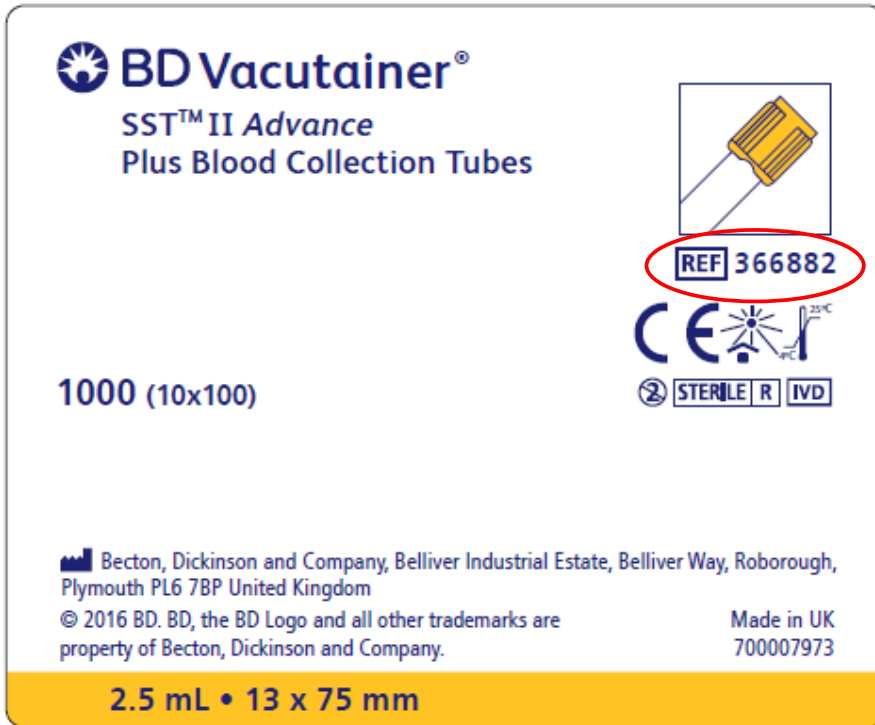
1. Unit



2. Shelf Carton



3. Shipping Case



Catalogue
number