

URGENT: FIELD SAFETY NOTICE – PAS-15-608 FA

BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder

Catalogue Numbers: 368835 and 368836

<<insert date here>>

Attention: Medical Device Safety Officer, Risk Manager, Laboratory Director, Head of Supply Chain, Phlebotomy Manager, Occupational Health Manager

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

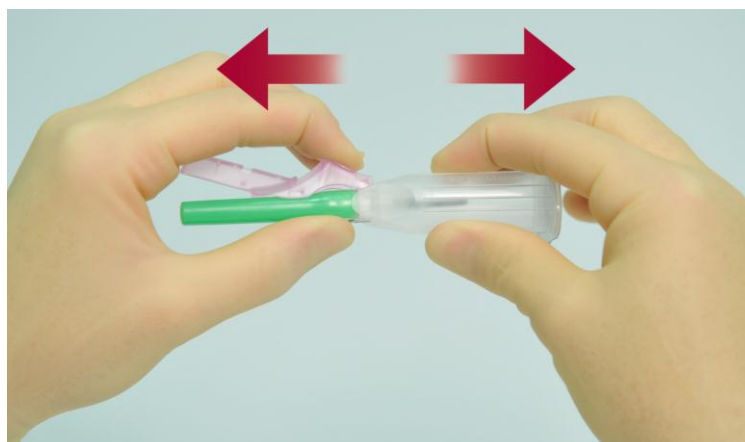
Details of affected devices & description of the problem:

BD Life Sciences – Preanalytical Systems is issuing this product advisory notice for the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder (catalogue code 368835 and 368836). Through customer feedback, BD has become aware that some lots of the BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder have the potential for the integrated holder to become detached from the needle. This detachment can lead to possible sample collection failure and in exceptional circumstances have the potential to cause a needlestick injury.

This Field Safety Notice only affects the catalogue and lot numbers listed in the table in attachment 1. To locate the catalogue and lot numbers refer to attachment 2.

By following the advice below, impacted lots of the BD Vacutainer® Eclipse™ Signal™ with Integrated Holder can continue to be used and distributed within your organisation.

- Prior to use, ensure that the pink Eclipse Shield is positioned over the green or black IV shield (as per picture below).
- Grasp the IV shield and the Eclipse Safety Shield together and the holder in the other hand and pressing firmly down on the Eclipse Safety Shield pull in a straight direction (as per picture below). Do not bend the device whilst pulling.
- If the holder becomes detached, dispose of the device in an appropriate sharps container.



Advice on action to be taken by Healthcare Professionals using the BD Vacutainer® Eclipse™ Signal™ with Integrated Holder:

- Undertake an assessment within your healthcare establishment using the modified instructions for use and of the impacted lot numbers (attachment 1);
- If your assessment concludes that you wish to continue use of the impacted devices:
 - Inform appropriate personnel in your organisation of this Field Safety Notice and instructions for use;
 - Complete Option 1 on the acknowledgement form (page 4) and return as soon as possible or no later than the 1st September 2015.
- If your assessment concludes that you wish to return impacted lots to BD in exchange for a credit note:
 - Inform appropriate personnel in your organisation of this Field Safety Notice;
 - Complete Option 2 on the acknowledgement form (page 4) and return as soon as possible or no later than the 1st September 2015..

Transmission of this Field Safety Notice

Please maintain awareness of this notice and resulting actions 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 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 agency have been informed of these actions.

Yours sincerely,

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

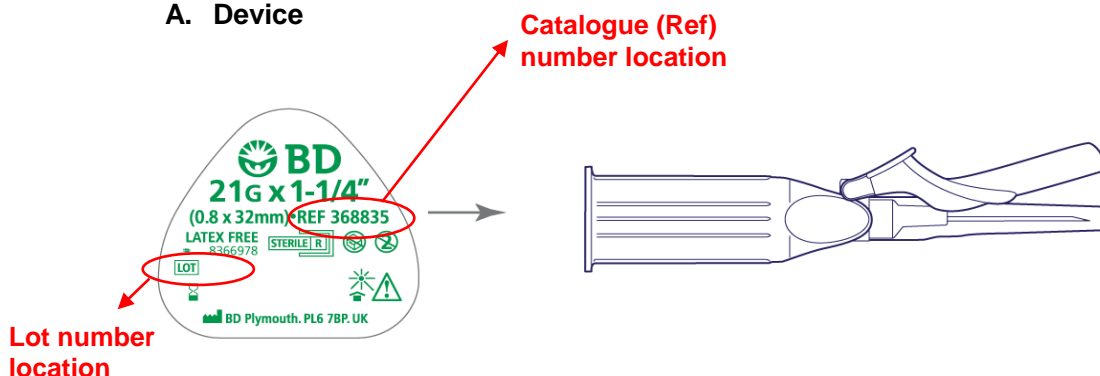
Attachment 1: Impacted Lot Numbers

BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder 21G Catalogue Number: 368835			
Impacted Lot Numbers:			
4182127	4337456	4276343	5041109
4206029	4346490	4323052	5057410
4239482	4252010	4344023	5072433
4302105	4259413	4346070	5072434
4302106	4266252	5034053	5086165
			5086166

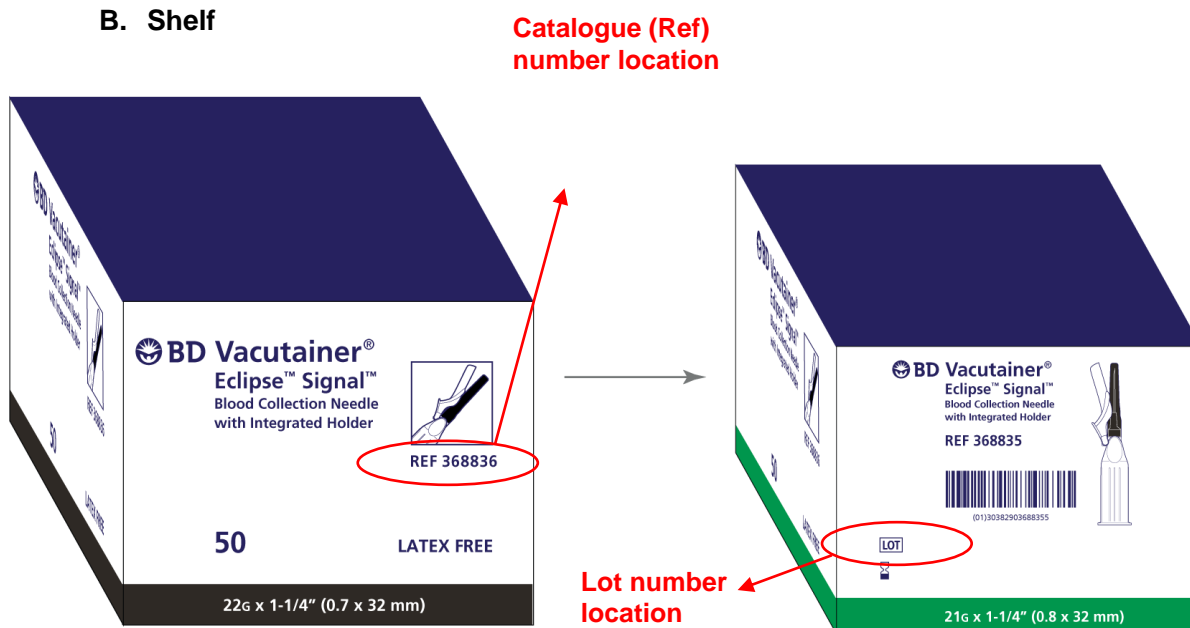
BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder 22G Catalogue Number: 368836			
Impacted Lot Numbers:			
4189358	4268488	4336228	5027368
4198214	4302103	4346062	5072462
4231358	4329078	4346068	5114342
4245288			

Attachment 2: Guidance on the location of Lot Number and Catalogue Number

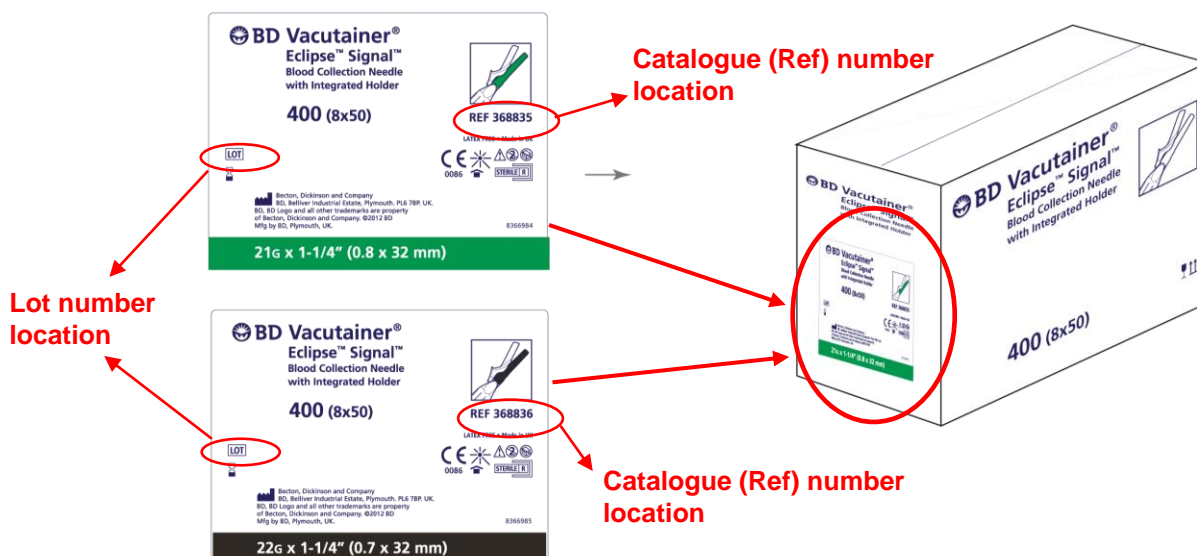
A. Device



B. Shelf



C. Case



ACKNOWLEDGEMENT FORM

Please read in conjunction with Field Safety Notice PAS-015-608 FA & return form to BDUK_customerservice@bd.com or by fax to: (01865) 781528 / 717313 as soon as possible or no later than the 1st September 2015.

Option 1 **YES**, I have impacted product and will continue to use the device in line with the instructions provided by BD. 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).

Option 2 **YES**, I have impacted product and I confirm that this will be returned in exchange for credit.

(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-015-608 FA, BD, DC3, Laagstraat 57, B- 9140 Temse, Belgium)

Organisation / Hospital / Clinic :	
Department (<i>if applicable</i>) :	
Address :	
Postcode :	City :
Contact Name :	
Job Title :	
Contact Telephone Number :	
Contact E-mail Address :	
Signature :	Date :

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