Delivering Efficiency to Healthcare

FAX COVER

From: *National Distribution & Contracting, Inc.* *Djana Milliken – Compliance* ***URGENT*** ****This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.**** **To:** *Purchasing or Regulations Department*	**Date:** *3/16/2018*
Pages: *6* *(Including cover page)*	
Regarding: *BD Urgent: Medical Device Recall* *BD Vacutainer Plus SST Tube with Hemogard Closure* *Item # 367983 & 367986*	

Comments:

Dear Distributor,

Attached is a letter we received from BD regarding the recall on the Economy BD Vacutainer Plus SST Tube with Hemogard Closure. Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. ***Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.*** *Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you.*

Thanks,

Djana Milliken

Djana Milliken

407 New Sanford Road, La Vergne, TN 37086
compliance@ndc-inc.com / Phone: 615-324-6375 / Fax: 615-229-6801

BD Life Sciences – Preanalytical Systems
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

URGENT: MEDICAL DEVICE RECALL

Date: March 12, 2018

Dear Distributor,

BD is issuing a Medical Device Recall for the above product catalog and lot numbers, which our records indicate you may have been shipped previously. Additional details are provided below.

For the Attention of: Medical Director, Risk Manager, Medical Device Safety Officer, Lab Manager

Product Name	UDI	Catalog (Ref) No.	Lot/Ser. No.	Expiration Date	Product Package Size
BD VACUTAINER® PLUS SST Tube with HEMOGARD closure 13x75mm 3.5ml PLBL Gold	DI(01)50382903679831 PI(17)180531(10)7135828(30)1000	367983	7135828	5/31/2018	1,000 units per case (10 shelf packs of 100 units each)
	DI(01)50382903679831 PI(17)180430(10)7125692(30)1000		7125692	4/30/2018	
BD VACUTAINER® PLUS SST Tube with HEMOGARD closure 13x100mm 5.0ml PLBL Gold	DI(01)50382903679862 PI(17)180531(10)7146901(30)1000	367986	7146901	5/31/2018	

Description of the problem and health hazard(s):

BD has confirmed that a limited number of tubes associated with the above lots of BD VACUTAINER® PLUS SST tubes which are currently in the market may exhibit stopper creep-out/pull-out/pop-off, where the stopper dissociates from the tube. An example of stopper creep-out/pull-out/pop-off is demonstrated in **Figure 1** below. BD has received reports of

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1 Becton Drive
Franklin Lakes, NJ 07417
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this issue occurring during collection and processing (including centrifugation, transportation and testing). Stopper creep-out/pull-out/pop-off can result in potential user exposure to blood resulting from an unstoppered tube, which may result in exposure to blood borne pathogens.

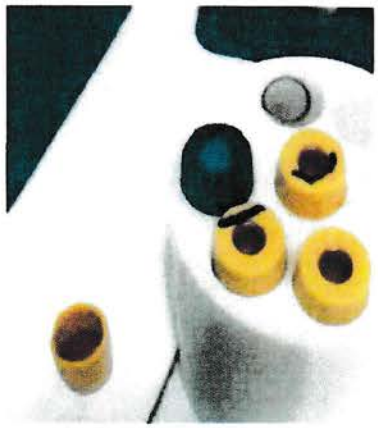

Figure 1. Stopper creep-out/pull-out/pop-off in centrifuge

Our records indicate you may have been shipped the above-referenced lots of product. BD distributed the potentially affected lots beginning June 2, 2017.

Affected lot numbers can be found on the individual unit and shelf pack labels. Sample graphics showing the location of the catalog and lot number on the unit and shelf pack labels are included on page 4 of this notification to assist you in identifying if the lots are within your control.

Please Take the Following Actions:

1. Immediately review your inventory for the subject lots and quarantine the product subject to the recall.
2. If you have distributed this product, please identify your customers and notify them of this Medical Device Recall. A copy of the BD Customer Medical Device Recall Notice is included with this communication.
3. If you would like BD to conduct the notification to your customers, please email your customer list within 3 business days to **BDPASRC@bd.com**. Please include the contact name, address, phone number, email address, and/or fax numbers for each customer. BD will notify these customers of the Medical Device Recall.
4. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification and process your product credit.

   Return all affected products using the enclosed packaging instructions and include the completed Recall Response Form with the product.

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5. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program.

   Web: Medwatch website at www.fda.gov/medwatch
   Phone: 1-800-FDA-1088 (1-800-332-1088)
   Mail: MedWatch, HF-2, FDA 5600 Fisher's Lane, Rockville, MD 20853-9787

Actions Taken by BD:

Upon receipt of the returned product, BD will issue credit.

Contact Information:

If you require further assistance, please contact:

BD Contact	Contact Information
BD Preanalytical Systems	1-877-870-4486 Monday – Friday between 8:00am and 5:00pm (EST) in the United States

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Aparna Ahuja, MD
PG cert Hospital Management, IF CAP
WW Vice President, Medical Affairs
BD Life Sciences - Preanalytical Systems

Gail Griffiths
Sr. Director, Regulatory Compliance
US Region

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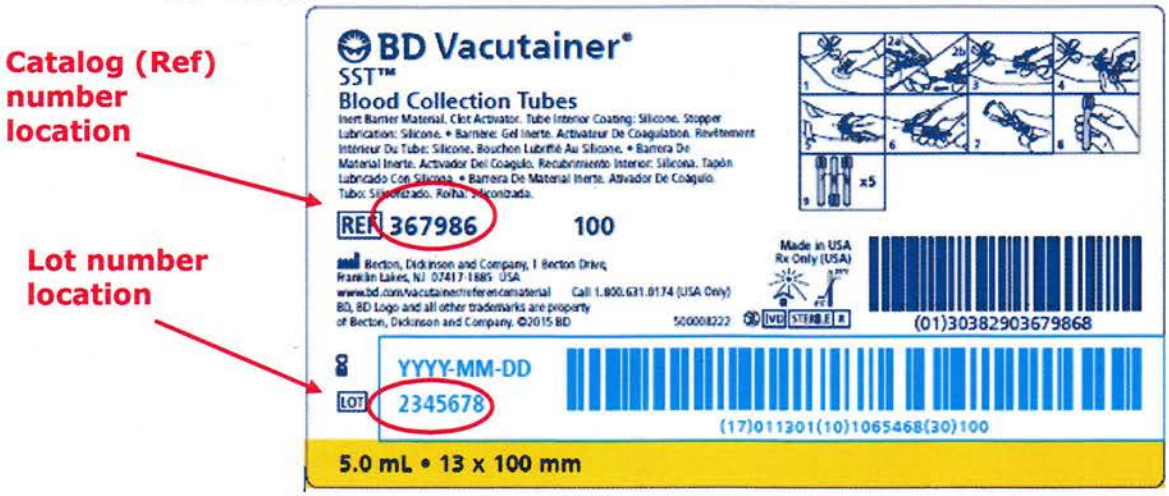
Medical Device Recall Catalog (Ref) / Lot Identification Sample
(Catalog number 367986 provided as an EXAMPLE)

A. Unit (Tube):

B. Shelf:



Advancing the world of health

3/16/2018

BD Medical - Vacutainer Plus SST Tube with Hemogard closure

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 or email to: compliance@ndc-inc.com

REQUEST FOR RETURN FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item number	Lot number	Expiration date	Quantity to return

☐ I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.

☐ We have inspected our inventory and have no product related to this recall

_____

Completed by: (Print Name /Signature/Date)

Returned Completed form to: Djana Milliken
Fax #: 615.229-6801
Email: compliance@ndc-inc.com