NDC™

Delivering Efficiency to Healthcare

A facsimile from

NDC, INC.

Djana Milliken Compliance Specialist

Phone: 615-366-3225

Fax 615-229-6801

To: Purchasing or Regulations Department

*****URGENT*****

Date: 03/23/2016

7 pages + Cover

*****This is being faxed to the "bill to" account for your company. Please distribute to any/all branches.**

Regarding: BD Angiocath Autoguard Shielded IV Catheter Recall

Comments:

Dear Distributor, attached is a letter we received from BD regarding the recall on their item 381700 and 381720 (please see attached for Lot Numbers). 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 them return any affected product to you.

Thanks,

Djana Milliken

Djana Milliken
Compliance Specialist
NDC, Inc.

1 Becton Drive
Franklin Lakes, NJ 07417

bd.com

URGENT VOLUNTARY PRODUCT RECALL

Catalog (Ref) #	Product Description
381700	24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter (0.7 mm x 19 mm) made of FEP polymer
381720	24 G x 0.56 in. BD Angiocath-N™ Autoguard™ shielded IV catheter (0.7 mm x 14 mm) made of FEP polymer

March 18, 2016

Dear Distributor:

BD is conducting a voluntary recall of the **24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter** and the **24 G x 0.56 in. BD Angiocath-N™ Autoguard™ shielded IV catheter** since the device may have a defect in the catheter. In some instances this defect could result in catheter separation or breakage. One adverse event has been reported for this issue that did not result in harm. BD is actively working on implementing corrective actions to address this issue.

This recall only affects the Catalog (Ref) # and lot numbers listed on the table included in Attachment A: List of Recall Catalogs and Lots. BD distributed the affected recalled lots from January 2013 to February 2016. A copy of the label showing the location of the catalog (Ref) and lot number is attached to the letter to assist you in identifying the recalled lots in your control.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed above, and quarantine product subject to the recall. Immediately discontinue the shipment of the affected product.
2. Complete the Recall Response Card form and fax it back to BD at 1-866-809-6038 or email the completed form to **BD3918@stericycle.com**.
3. Return all affected products with the completed Recall Response Card form following the instruction on the enclosed packing instruction. Upon receipt of the returned product, BD will issue a credit. BD estimates that Cat (Ref) # 381700 and 381720 will become available in the next 90 to 180 days. During this time, BD will be offering Cat (Ref) # 381412, 24 G x 0.75 in. BD Insyte™ Autoguard™ shielded IV catheter, and Cat (Ref) # 381411, 24 G x 0.56 in. BD Insyte-N™ Autoguard™ shielded IV catheter as replacement product. Attachment B provides a reference table for the product replacement.
4. If you have distributed this product, please identify your customers and notify them immediately of this product recall. If you would like BD to notify your customers, please email your customer list within 3 business day to Becky_Saggau@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 recall.

   NOTE: If you do not have any of the affected lots in your inventory, please complete the Recall Response Card form indicating you have zero (0) quantity and fax the completed form back to BD at 1-866-809-6038 or email the completed form to BD3918@stericycle.com.

If you have any questions or require assistance with the return of the recalled product, please contact 1-866-800-2920 between 8AM and 5 PM ET Monday through Friday.

The safety and well-being of patients and healthcare workers is the primary objective for BD and we aim to ensure that only the highest quality product is used by our customers. 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.

1 Becton Drive
Franklin Lakes, NJ 07417

bd.com

Sincerely,

Randall Jones, MD
WW Medical Director
Infusion Therapy, BD Medical

Sergio Gadaleta
Sr VP Regulatory Affairs
Medical Segment, BD Medical

1 Becton Drive
Franklin Lakes, NJ 07417

bd.com

Attachment A: List of Recall Catalogs and Lots

Catalog (Ref) #	Product Description	Lot Number	Expiration Date
381700	24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter (0.7 mm x 19 mm) made of FEP polymer	3121951	5/2016
		3143801	6/2016
		3190895	7/2016
		3254585	9/2016
		3303872	11/2016
		4051735	3/2017
		4133600	5/2017
		4177944	7/2017
		4219570	8/2017
		4289603	10/2017
		4317642	11/2017
		5063833	3/2018
		5106687	4/2018
		5125665	5/2018
		5230884	8/2018
		5300771	11/2018
381720	24 G x 0.56 in. BD Angiocath-N™ Autoguard™ shielded IV catheter (0.7 mm x 14 mm) made of FEP polymer	3045792	2/2016
		3106688	4/2016
		3289840	10/2016
		4059581	6/2017
		4203557	8/2017
		5002915	1/2018
		5063827	6/2018
		5125565	5/2018
		5300772	11/2018

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Attachment B: Replacement Product Reference

Recall Product		Replacement Product*	
381700	24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter made of FEP polymer	381412	24 G x 0.75 in. BD Insyte™ Autoguard™ shielded IV catheter made of BD Vialon™ biomaterial
381720	24 G x 0.56 in. BD Angiocath-N™ Autoguard™ shielded IV catheter made of FEP polymer	381411	24 G x 0.56 in. BD Insyte-N™ Autoguard™ shielded IV catheter made of BD Vialon™ biomaterial

*The primary difference between the two devices is the type of catheter material (Angiocath is made of FEP Polymer and Insyte is made with BD Vialon™ biomaterial). The BD Vialon™ biomaterial may give a slightly different tactile feedback during the insertion process.

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Franklin Lakes, NJ 07417

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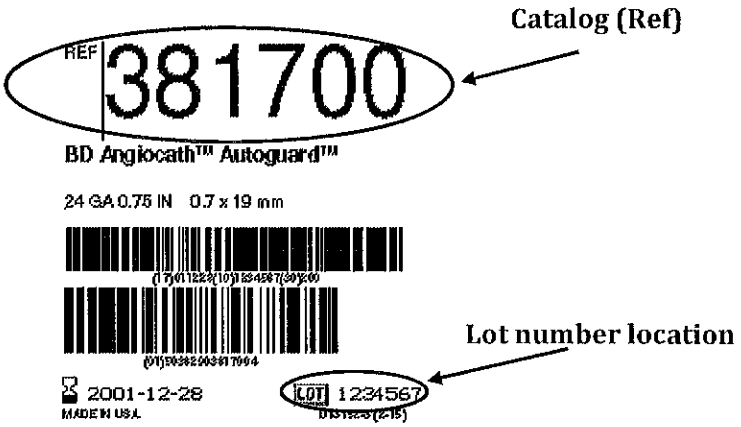
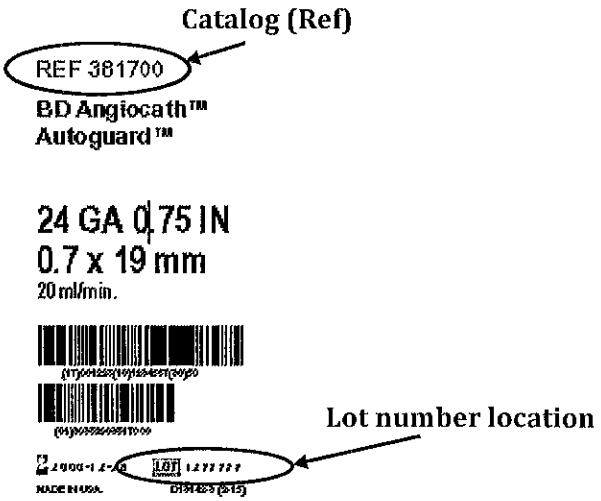
24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter Voluntary Recall
Catalog (Ref) / Lot Identification Sample

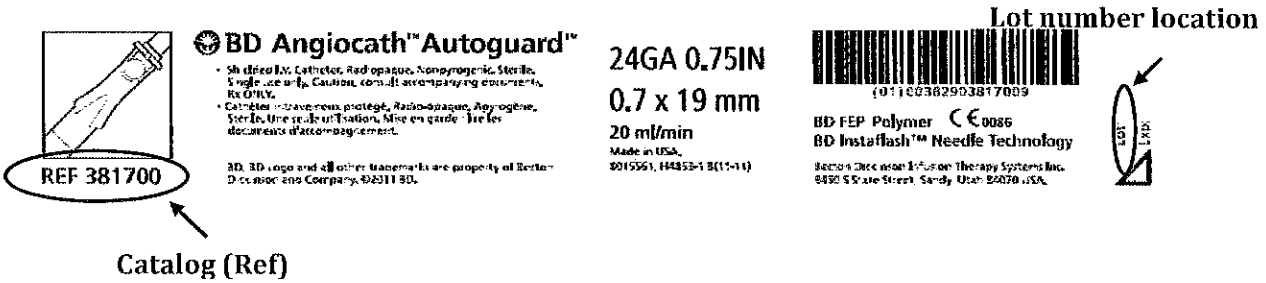
A. Case/Shipper:



B. Shelf:



C. Unit:



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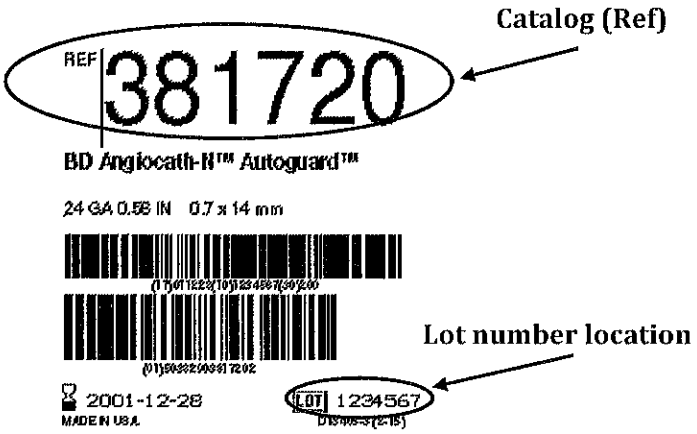
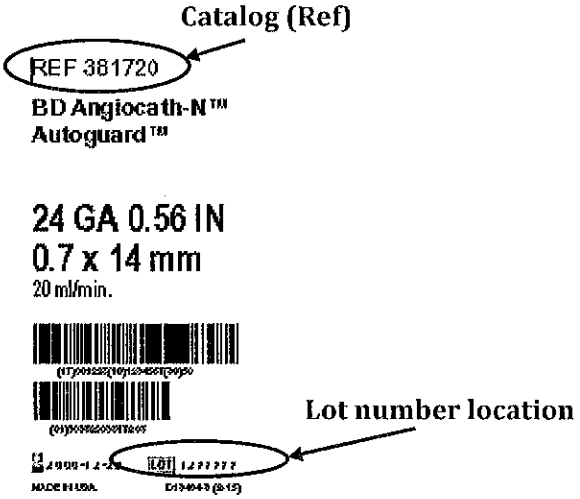
24 G x 0.56 in. BD Angiocath-N™ Autoguard™ shielded IV catheter Voluntary Recall
Catalog (Ref) / Lot Identification Sample

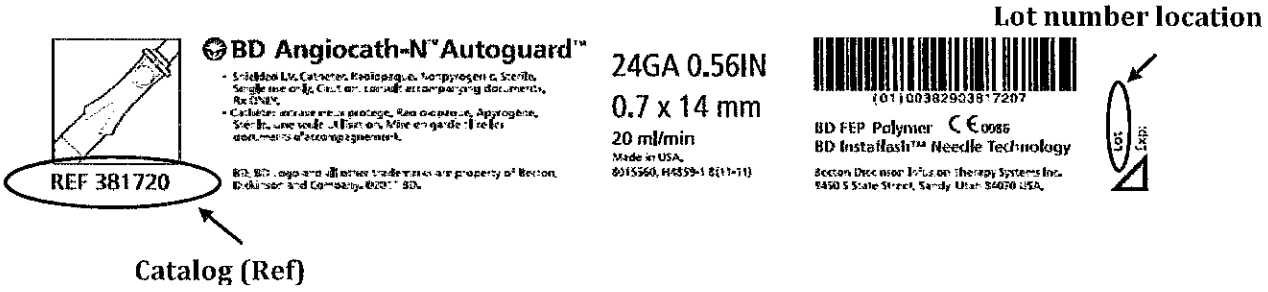
A. Case/Shipper:



B. Shelf:



C. Unit:



March 23, 2016

Please respond by April 6, 2016

BD

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	Quantity to return	Expiration date
BEC 381700			

☐ 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.

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

Returned Completed form to:

Djana Milliken
Fax #: 615.229.6801
Email: compliance@ndc-inc.com