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 Customer:

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 product replacement. 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.

   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.

Sincerely,

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

Sergio Gadaleta
Sr VP Regulatory Affairs
Medical Segment, BD Medical

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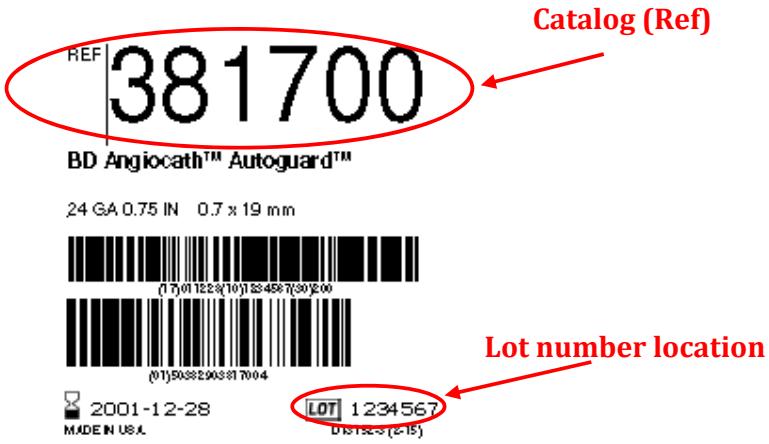
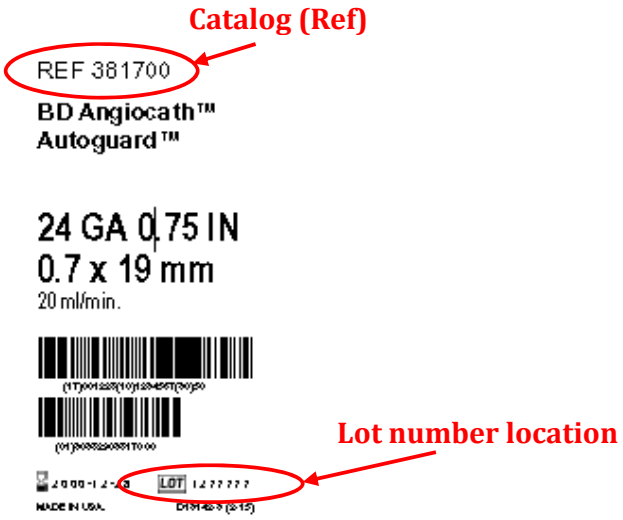
24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter Voluntary Recall
Catalog (Ref) / Lot Identification Sample

A. Case/Shipper:



B. Shelf:



C. Unit:

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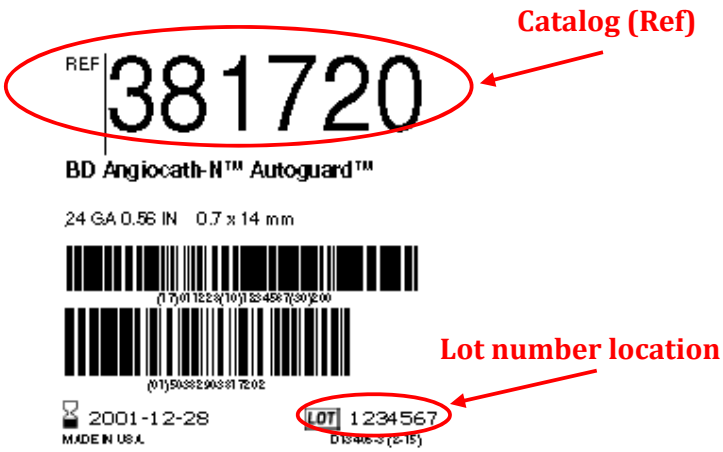
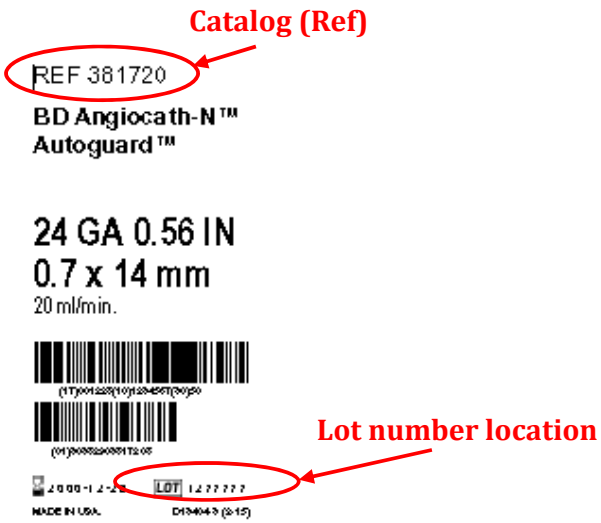
24 G x 0.56 in. BD Angiocath-N™ Autoguard™ shielded IV catheter Voluntary Recall
Catalog (Ref) / Lot Identification Sample

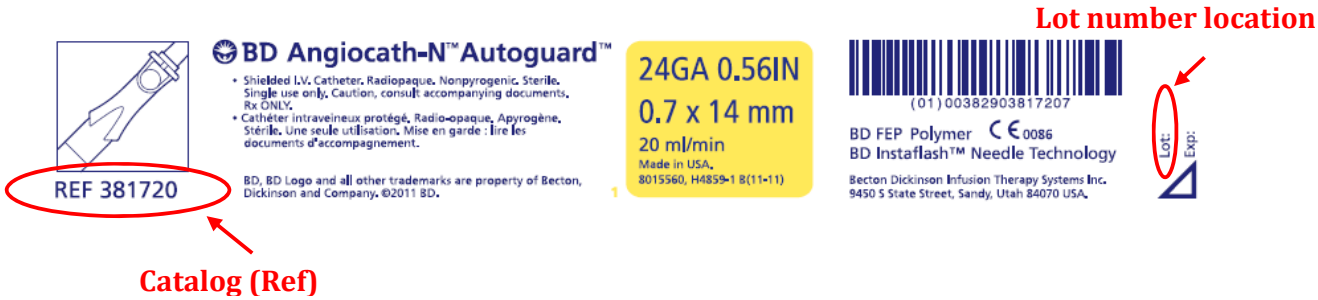
A. Case/Shipper:



B. Shelf:



C. Unit:



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Recall Response Card

24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter and 24 G x 0.56 in. BD Angiocath-N™ Autoguard™ shielded IV catheter Voluntary 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

Check inventory and complete the information below, even if you do not have the affected product. Failure to complete all sections of this page may result in improper or delayed product replacement.

Fax the completed form to BD at 1-866-809-6038 or email the completed form to **BD3918@stericycle.com**.

Please return only product from the lots referenced in the recall letter, you will only receive product replacement for recalled product that you return.

Required Information:

_____ _____
Business Name: Phone Number:

_____
Address/City/State/Zip :

_____
Lot Number and Quantity Returned (units) :

_____
Completed by: (Print Name/Signature/Date

BD Office Use Only:

_____
Lot Number and Quantity Returned (units) :

☐ I have NO affected product (Fill out and return this form to BD at fax above).

☐ YES, I have affected product (Fill out and return this form to BD at fax above and return the product per the packing instruction.)

Please enclose the completed form with the return product shipment.

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PACKING INSTRUCTIONS

24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter and 24 G x 0.56 in. BD Angiocath-N™ Autoguard™ shielded IV catheter Voluntary Recall

Product Return Instructions:

1.Please enclose the complete Recall Response Card with the shipment.

2.The simplest way to return product would be to access the following UPS website: http://returns.upsrow.com
login: bdapi, Password: bdapi

When you access the site, you can select among 3 UPS shipping options. If you select the initial option, "Display Return Label Only", you can give the package to a UPS person who stops at your site or drop it off at a UPS location. If you select either of the remaining two options, a UPS person will stop by your location specifically to pick up the package. You need to enter the returned product reorder number, lot number and quantity on the website.
Note: If you are not returning product, also indicate this on the website.

3.If you do not have access to the internet you can call UPS at 1-800-PICK-UPS (742-5877) and arrange for a pick-up using the following charge number specific to this recall: 0ER739.

Product should be returned to:

Returns Team
BD Distribution Center
DOOR #2
130 Four Oaks Parkway
Four Oaks, NC 27524

For shipments over 150 pounds - utilize UPS Ground Freight. UPS Freight Customer Service can be contacted at 1-800-333-7400. When arranging the pick-up of freight, please specify 3rd party billing as follows:

Returns Team
BD c/o Cass Info Systems
PO Box 67
St. Louis, MO 63166-0067

4. Upon receipt of returned product BD will provide product replacement. A returned goods authorization is NOT required for this recall return process.

DO NOT SHIP FREIGHT COLLECT
Our warehouse cannot receive products shipped "freight collect".