Becton Dickinson GmbH
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Tel.: 06221 3050
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URGENT: FIELD SAFETY NOTICE

VOLUNTARY PRODUCT RECALL

BD Angiocath ™ Autoguard™ shielded IV Catheter
Catalog Number 381700

March 17, 2016

Dear Customer,

BD is conducting a voluntary recall of the **24 G x 0.75 in. BD Angiocath™ Autoguard™ shielded IV catheter** (Catalogue number 381700) 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 Catalog 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:

- Immediately review your inventory for the specific Catalog (Ref) and lot numbers listed in Attachment A, and quarantine product subject to the recall. Immediately discontinue the shipment of the affected product.
- **Completed the Notice of Return form and fax it back to BD at (BD office contact fax. number).**

Upon receipt of the Notice of Return BD will contact you to organize the replacement of the recalled product at no charge.

NOTE: If you do not have any of the affected lots in your inventory, please complete the Notice of Return form indicating you have zero (0) quantity and return the completed form back to BD at **(BD office contact fax. number).**

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If you have any questions or require assistance with the return of the recalled product and/or availability of replacement product, please contact (BD office contact tel. number)..

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,

Dr. Bernd Peschke **(Name & Signature of Local Contact)**

Director Regulatory Compliance Europe / EMA
BD Medical

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Lot Number Enclosure

BD Angiocath ™ Autoguard™ shielded IV Catheter, Catalog Number 381700

Attachment A: List of Recall Catalog 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	3143801	6/2016
		3190895	7/2016
		3303872	11/2016
		4051735	3/2017
		4133600	5/2017
		4289603	10/2017
		5063833	3/2018

Attachment B: Replacement Product Reference

Recall Product		Replacement Product*	
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 is designed to soften up to 70% once in the vessel and provide kink resistance, which may give a slightly different tactile feedback during the insertion process.

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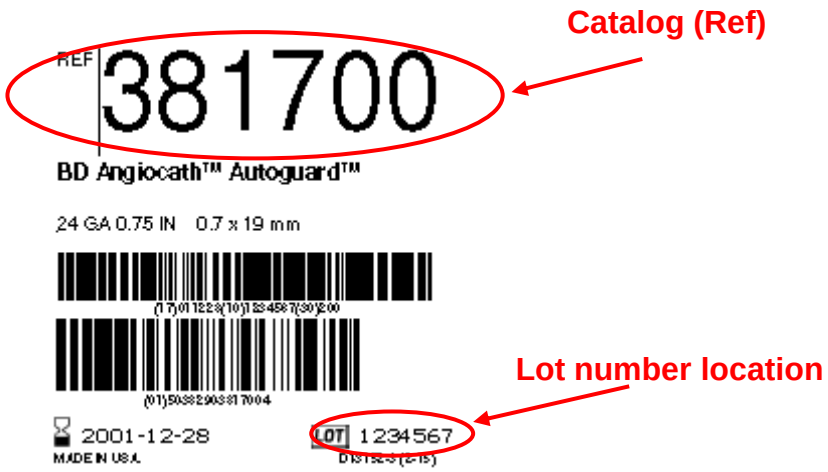
Label Enclosure

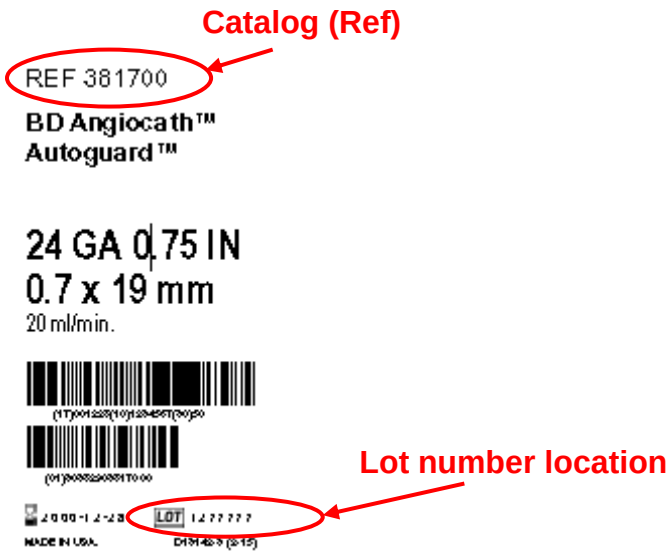
BD Angiocath™ Autoguard™ shielded IV catheter

Catalog (Ref) / Lot Identification Sample

A. Case/Shipper:



B. Shelf:



C. Unit:

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NOTICE OF RETURN

BD Angiocath ™ Autoguard™ shielded IV Catheter; Catalog Number 381700

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

Fax the completed form to{ Contact Name} at {Fax Number} **or email the completed form to (BD country contact email).**

Upon receipt of the Notice of Return BD will contact you to organize the replacement of the recalled product at no charge.

Please check your return carefully and complete the contact information below. Only return product from the lots referenced in the recalled letter, you will only receive replacement for recalled product that you return.

Required Information:

_____ _____
Establishment 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) :