



February 11, 2010

## **URGENT: MEDICAL DEVICE RECALL**

### **BD Nexiva I.V. Catheters with Q-Syte**

Attention Pharmacy Managers / Material Managers

Attached is a copy of the expanded BD Q-Syte recall dated February 8, 2010. Our records show that you purchased Nexiva Catheters from MSD. Please check your stock and remove any affected lots from your inventory.

Fill out the BD RECALL RESPONSE CARD and fax to BD even if you do not have affected stock on hand.

This recall is being conducted with the knowledge of the Food and Drug Administration. We apologize for any inconvenience this action may cause.

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February 8, 2010

### URGENT: MEDICAL DEVICE RECALL

**Subject: Expansion of BD Q-Syte™ Luer Access Split-Septum Recall of October 28, 2009 to include BD Nexiva™ Closed IV Catheter System**

**Attention Customers:**

On October 28, 2009 Becton Dickinson Infusion Therapy Systems Inc. determined that some lots of BD Q-Syte™ Luer Access Split Septum and MPS Acacia with BD Q-Syte™ had a manufacturing deviation which could cause the product to not function properly and initiated a voluntary recall. The recall did not include BD Q-Syte™ devices on the BD Nexiva™ Closed IV Catheter System. After further analysis, we have extended the recall to include BD Nexiva™ Closed IV Catheter Systems with BD Q-Syte™ units that may have been affected by this deviation. We have isolated the risk associated with the manufacturing deviation to specific REF (catalog) numbers and lots listed below and ask that you return any inventory from those lots. All other lot numbers of BD Q-Syte™ Luer Access Split Septum, BD Nexiva™ Closed IV Catheter Systems and MPS Acacia with BD Q-Syte™ are NOT affected.

The product in the table directly below is representative of affected BD Q-Syte™ Luer Access Split Septum units:

REF Number	Lot Number
385100	8268863
385100	8269020
385100	8275798
385100	8308321
385100	8308323
385100	8309553
385100	8331937
385100	8331940
385100	8354558
385100	9007921
385100	9009643
385100	9009646

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385100	9028838
385100	9035029
385100	9035032
385101	8305510
385101	8331944
385102	8305511
385102	8308330
385102	8354561
385102	9012072
385108	9007918
385108	9035042
385108	9035044

The product in the table directly below is representative of BD Nexiva™ units with affected BD Q-Syte™ Luer Access Split Septum units:

REF Number	Lot Number
383530	8238450
383530	8319936
383530	8345957
383530	9013868
383531	8284049
383531	8284050
383531	8305438
383531	8308349
383531	8345951
383531	9013867
383531	9026722
383532	8248349
383532	8259950
383532	8295761
383532	8296792
383532	8296793
383532	8309299
383532	8309662
383532	8311150
383532	8319961
383532	8322609
383532	8331771
383532	8338737
383532	8338738
383532	8358628
383532	9020033
383533	8291980
383533	8330279
383534	8331763
383536	8248355
383536	8249034
383536	8249035
383536	8269338
383536	8270576

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383536	8274565
383536	8275207
383536	8275210
383536	8283964
383536	8311167
383536	8312211
383536	8319016
383536	8347056
383536	9007360
383536	9015539
383536	9022039
383537	8263294
383537	8270579
383537	8347058
383537	9013864
383538	8312220
383539	8263293
383539	8274555
383539	8275429
383539	8290311
383539	8340308
383539	9016819
383540	8340302
383647	9034319
383649	9041552

The product below is manufactured by MPS Acacia and distributed in the US by BD:

REF Number	Lot Number
385150	A1967
385150	A1979
385150	A2056
385151	A1950
385151	A2399
385164	A1951

**Please read the following information for an explanation of this request.**

BD Q-Syte™ product is a luer access split septum needleless access device used to access central venous catheters. BD Nexiva™ is a closed IV catheter system used for peripheral IV access.

A small number of complaints have been received describing the observation of air bubbles leaking into the infusion system through the BD Q-Syte™ luer access split septum needleless access device. This may result in a possible air embolism in a patient with a central venous catheter. During the investigation a manufacturing deviation was identified and corrected. BD Nexiva™ is a peripheral IV catheter system with two BD Q-Syte™ devices contained within the packaging (one attached to the catheter system and one packaged loose to be attached post insertion). After further

with two BD Q-Syte™ devices contained within the packaging (one attached to the catheter system and one packaged loose to be attached post insertion). After further analysis of BD Q-Syte™'s original voluntary recall notification (10/28/09), it was deemed that there was a potential risk of end-users inadvertently taking a BD Q-Syte™ device from the BD Nexiva™ product or package, and placing it on a central venous catheter.

**YOU NEED TO TAKE THE FOLLOWING ACTIONS:**

1. Please review your list of potential customers who have purchased any of the affected lots above. BD Medical will be communicating directly to the end customers and will work with them to coordinate any returns and product replacement. If you believe that a customer may have purchased product but not received communication of this recall please call BD at the number below. BD is currently working to ensure that replacement products are readily available.
2. Immediately review your inventory of **BD Q-Syte™, BD Nexiva™ and MPS Acacia with BD Q-Syte™** for REF numbers and lot numbers listed above and remove them from all inventory locations. Recalled products can be identified by the REF and **Lot** numbers printed on the unit, shelf box and shipper containers.
3. Complete the Distributor Recall Response Card (Attachment 1) and return by fax immediately to the number on the Distributor Recall Response Card for product in your facility at the time of receipt of this letter. ***THIS FORM MUST BE COMPLETED AND FAXED TO BD MEDICAL EVEN IF THERE IS NO PRODUCT IN INVENTORY.***
4. Please call BD Medical Systems Customer Complaints at 1-800-453-4538, option 2, extension 2585 or 2860 to arrange for replacement of product currently in your inventory, between 8:00 AM and 5:00 PM Mountain Standard Time, Monday - Friday.

Please accept our apologies for the inconvenience caused by this action. We know that you share in our desire to provide superior quality products and services to both our customers and their patients.

Yours sincerely,



Brett Wilko  
Regulatory Compliance Manager

Attachment 1



**RECALL RESPONSE CARD for:**

**BD Q-Syte™, BD Nexiva™ and MPS Acacia with BD Q-Syte™**

Please complete by checking the appropriate box. Even if you have no inventory of listed product lots, please indicate this below and return this card by fax. If you currently have stock, complete the form noting quantity in units next to the lot number and return this card immediately by fax.

- We do not have any of the stock listed below on hand.
- We have the following stock that we will be returning:

REF	LOT NUMBER	QUANTITY

Please fax to Complaint Department at 801-304-3954.

If you have any questions concerning this, please call at 1-800-453-4538, opt. 2, ext. 2585 or 2860 between 8:00am – 5:00pm MST, Monday – Friday to arrange for product replacement.

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Contact Name (please print)	Title	Signature and date
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Facility Name	Address	Phone Number	Fax Number
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