



Delivering Efficiency to Healthcare



# FAX COVER

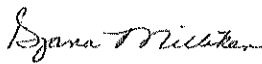
**From:** National Distribution & Contracting, Inc.  
 Djana Milliken – Compliance  
 \*\*\*URGENT\*\*\*  
 \*\*\*This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.\*\*\*

**To:** Purchasing or Regulations  
 Department

**Date:** 8/8/2016

**Pages:** 6 (Including cover page)

**Regarding:**  
 BD Spinal Anesthesia Trays Recall

**Comments:**  
 Dear Distributor,  
 Attached is a letter we received from BD Medical regarding the recall on the spinal anesthesia trays. 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



## URGENT PRODUCT RECALL

Cat (Ref) #	Cat (Ref) #	Cat (Ref) #
405612	405641	405694
405622	405648	405704
405623	405649	405737
405624	405682	405829
405634	405684	
405636	405685	

August 2, 2016

Dear Valued Distributor:

BD is conducting a recall for the specific catalog and lot numbers of **BD™ Spinal Anesthesia Trays** listed in **Attachment A**. Hospira, Inc. initiated a drug recall for some lots of 5% Lidocaine Hydrochloride and 7.5% Dextrose Injection, USP, NDC 0409-4712-01. These BD™ Spinal Trays contain the 5% Lidocaine Hydrochloride and 7.5% Dextrose Injection, USP, 2mL Ampul (NDC Number 0409-4712-01) being recalled by Hospira, Inc. As a result, BD is recalling the BD Spinal Trays affected by this recall.

*As stated in the Hospira recall notification letter, "Hospira, Inc., a Pfizer company, is voluntarily recalling three lots of 5% Lidocaine Hydrochloride and 7.5% Dextrose Injection, USP, NDC 0409-4712-01 ( Lot No.: 34-547-DK, 34-548-DK and 39-372-DK) to the **Hospital/Retail level**. Hospira initiated this recall because product from these lots does not meet the specification for color throughout shelf life. Lot 34-547-DK also does not meet the specification for pH throughout shelf life. Please note that use of, or exposure to, product from these lots is not likely to cause adverse health consequences."*

BD distributed the affected BD™ Spinal Anesthesia Trays from March 2014 through May 2016. A copy of the recall letter communicated by Hospira, Inc. is available upon request.

[bd.com](http://bd.com)

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

1. Immediately review your inventory for the specific catalog (ref) and lot numbers listed on **Attachment A**, and quarantine product subject to the recall. Immediately discontinue the shipment of the affected product.
2. Complete the Business Response Card (BRC) form and fax it back to BD at **1-877-551-7148** or email the completed form to **BD7821@stericycle.com**.
3. Return all affected products with the completed Business Response Card (BRC) form following the instruction on the enclosed packing instruction. Upon receipt of the returned product, BD will issue a credit.
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 days 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. BD regrets to inform you that there is no replacement product available for the recalled BD trays. As a result, customers that have purchased the recalled product from a wholesaler/distributor have been instructed to return the recalled product to BD and to contact BD at **1-877-410-5554** to receive further instructions.

**NOTE:** If you do not have any of the affected lots in your inventory, please complete the Business Response Card (BRC) form indicating you have zero (0) quantity and fax the completed form back to BD at **1-877-551-7148** or email the completed form to **BD7821@stericycle.com**.

If you have any questions or require assistance with the return of the recalled product, please contact **1-877-410-5554** between 8AM and 5 PM ET Monday through Friday. For **medical questions** regarding the drug, please contact Medical Information (Hospira) at 1-800-615-0187 or via e-mail at [medcom@hospira.com](mailto:medcom@hospira.com).

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

Advancing the world of health

Attachment A: List of Recall Catalogs and Lots

Catalog No.	Product Description	Lot No.	Expiration Date
405612	BD Spinal Anesthesia Tray 22G x 3.5 in. BD™ Quincke Spinal Needle Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B01H119D	1-Jun-2015
405622	BD Spinal Anesthesia Tray 25G x 3.5 in. BD™ Quincke Spinal Needle Bupivacaine HCL (0.75%) with Dextrose (8.25%), 2 mL (Marcaine) Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B01H178D	1-Oct-2015
		B01H216D	1-Jan-2016
		B02H064D	1-Jun-2015
		B02J264D	1-Oct-2016
		B03H055D	1-May-2015
		B03H167D	1-Sep-2015
405623	BD Spinal Anesthesia Tray 25G x 3.5 in. BD™ Quincke Spinal Needle Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B02H075D	1-Sep-2016
405624	BD Spinal Anesthesia Tray 25G x 3.5 in. BD™ Quincke Spinal Needle Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B01H031D	1-May-2015
		B01J189D	1-Oct-2016
		B03H209D	1-Jan-2016
405634	BD Spinal Anesthesia Tray 26G x 3.5 in. BD™ Quincke Spinal Needle Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B03J258D	1-Oct-2016
		B03J260D	1-Oct-2016
405636	BD Spinal Anesthesia Tray 26G x 3.5 in. BD™ Quincke Spinal Needle Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B01J364D	1-Oct-2016
		B02H239D	1-Jan-2016
		B02J364D	1-Oct-2016
		B02K049D	1-Oct-2016
		B03H030D	1-May-2015
		B03J196D	1-Oct-2016
		B03K012D	1-Oct-2016
		B04H030D	1-May-2015
405641	BD Spinal Anesthesia Tray 24G x 3.5 in. Sprotte® Needle Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B01H134D	1-Sep-2015
		B01H167D	1-Sep-2015
		B01H181D	1-Oct-2015
		B01J365D	1-Oct-2016
		B01K050D	1-Oct-2016
		B02K006D	1-Oct-2016
405648	BD Spinal Anesthesia Tray 22G x 3.5 in. BD™ Whitacre Spinal Needle Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B03H031D	1-May-2015
		B04H097D	1-Jun-2015
405649	BD Spinal Anesthesia Tray 22G x 3.5 in. BD™ Whitacre Spinal Needle 25G x 3.5 in. BD™ Quincke Spinal Needle Bupivacaine HCL (0.75%) with Dextrose (8.25%), 2 mL (Marcaine) Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B01H099D	1-Oct-2016

Attachment A: List of Recall Catalogs and Lots (Continuation)

bd.com

Catalog No.	Product Description	Lot No.	Expiration Date
405682	BD Spinal Anesthesia Tray 25G x 3.5 in. BD™ Whitacre Spinal Needle, TW Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B03H034D	1-May-2015
		B04J262D	1-Oct-2016
405684	BD Spinal Anesthesia Tray 25G x 3.5 in. BD™ Whitacre Spinal Needle, TW Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B01H034D	1-May-2015
		B01H238D	1-Jan-2016
		B01H259D	1-Jan-2016
		B02J229D	1-Oct-2016
		B03J364D	1-Oct-2016
		B03K006D	1-Oct-2016
		B03K048D	1-Oct-2016
		B04H136D	1-Sep-2015
405685	BD Spinal Anesthesia Tray 25G x 3.5 in. BD™ Whitacre Spinal Needle, TW Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B01H035D	1-May-2015
		B01H036D	1-May-2015
		B01H070D	1-Jun-2015
		B01H091D	1-Jun-2015
		B01H138D	1-Sep-2015
		B02H031D	1-May-2015
405694	BD Spinal Anesthesia Tray 25G x 3.5 in. BD™ Quincke Spinal Needle 25G x 3.5 in. BD™ Whitacre Spinal Needle, TW Bupivacaine HCL (0.75%) with Dextrose (8.25%), 2 mL (Marcaine) Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B04H119D	1-Jun-2015
		B01H191D	1-Oct-2016
		B02H135D	1-Oct-2016
		B03H050D	1-Jul-2016
		B03H114D	1-Oct-2016
405704	BD Spinal Anesthesia Tray 27G x 3.5 in. BD™ Whitacre Spinal Needle Lidocaine HCL (5%) with Dextrose (7.5%), 2 mL	B02H034D	1-May-2015
405737	BD Spinal Anesthesia Tray 25G x 3.5 in. BD™ Whitacre Spinal Needle, TW Bupivacaine HCL (0.75%) with Dextrose (8.25%), 2 mL (Marcaine)	B03H153D	1-Sep-2015
405829	BD Spinal Anesthesia Tray 27G x 3.5 in. BD™ Quincke Spinal Needle 25G x 3.5 in. BD™ Whitacre Spinal Needle, TW	B02H077D	1-Jun-2015
		B03H106D	1-Jun-2015



Please respond by  
August 23, 2016

8/9/2016

BD Medical - Spinal Anesthesia Trays

**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:**

Fax #:  
Email:

Djana Milliken  
615.229-6801  
[compliance@ndc-inc.com](mailto:compliance@ndc-inc.com)

*Delivering Efficiency to Healthcare\**

402 BNA Drive, Suite 600 | Nashville, TN 37217  
[www.ndc-inc.com](http://www.ndc-inc.com) | 615.229.3700