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# FAX COVER

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|---|---|
| **From:** *National Distribution & Contracting, Inc.*<br>*Djana Milliken – Compliance*<br>***URGENT***<br>****This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.****** | |
| **To:**<br>*Purchasing or Regulations Department* | **Date:**<br>*4/27/2017* |
| **Pages:** *3* *(Including cover page)* | |
| **Regarding:**<br>*B. Braun Medical Inc.*<br>*Urgent Medical Device Recall* | |

**Comments:**

*Dear Distributor,*

*B. Braun is issuing a voluntary recall of CytoGuard Closed Luer Connector- item # 456081. B. Braun distributed affected recalled product from November 7, 2012 through May 19, 2015. 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.* ***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 letter.*

*Thanks,*

Djana Milliken

*Djana Milliken*

*407 New Sanford Road, La Vergne, TN 37086*
*compliance@ndc-inc.com / Phone: 615-324-6375 / Fax: 615-229-6801*

**B. Braun Medical Inc.**
901 Marcon Blvd.
Allentown, PA 18109
Telephone: (800) 227-2862
Fax: (610) 849-1197
Email: PA_QualityAssurance.BBMUS_Service@bbraun.com

April 19, 2017

# URGENT MEDICAL DEVICE RECALL

Dear Valued Customer:

This is to inform you that B. Braun Medical Inc. (B. Braun) is issuing a voluntary recall of CytoGuard™ Closed Luer Connector (Item #456081), which is manufactured by Elcam Medical. Through in-house testing, Elcam has identified the potential for some blisters to be punctured resulting in a compromised sterility barrier.

**Affected Product and Distribution Information:**
The following product catalog number and suspect lot numbers are affected:

| Product Catalog Number | Lot Number | Product Description | B. Braun Distribution Date Range |
|---|---|---|---|
| 456081 | 1240156001<br>1240156002<br>1240156003<br>1240156004<br>1370249001<br>1370251101<br>1370257101<br>1370259201<br>1370268401<br>1370270401<br>1370273801<br>1470311101<br>1570315301 | CytoGuard™ Closed Luer Connector | November 7, 2012 – May 19, 2015 |

**Our records indicate that you are in receipt of affected product and further distribution or use should be discontinued immediately.** Please review the below information and actions required.

**Actions Required By B. Braun Medical Customer/User:**

1. Review the Product Recall Notification in its entirety and ensure that all users in your organization of the above mentioned product and other concerned persons are informed about this voluntary product recall. If you are a distributor, please forward this recall notification to your customers.
2. Determine your current inventory of the affected lots within your facility. Do not destroy any affected product. Further use of this product should be discontinued immediately and quarantined.
3. Using the attached "Product Removal Acknowledgement" form, record the total number of individual units (within partial cases) and the number of full-unopened cases. If you have no inventory remaining, please enter zero (0) on the form.

4/27/2017

# B. Braun Medical - CytoGuard Closed Luer Connector

**Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.**

**Please complete and fax to: 615-229-6801 Or email to: Compliance@ndc-inc.com**

## Acknowledgment of Receipt

***Customer Information***

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

***Inventory Information***

| Item # | LOT # |
|---|---|
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☐ 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:*** Djana Milliken
Fax #: 615.229-6801
Email: compliance@ndc-inc.com