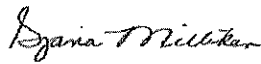




# FAX COVER

<b>From:</b> NDC Homecare dba Preferred Medical Djana Milliken – Compliance ***URGENT*** ***This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.***	
<b>To:</b> Purchasing or Regulations Department	<b>Date:</b> 1/23/2019
<b>Pages:</b> <u>3</u> (Including cover page)	
<b>Regarding:</b> Urgent Medical Device Recall Notification Teleflex - Rusch Drainage Bags Item # 390000 & 390060	
<b>Comments:</b> Dear Distributor, Attached is a letter we received from Teleflex regarding the recall on the Rusch Drainage Bags. 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. <u>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.</u> 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 Medical Device Recall Notification

## Rüsch® Drainage Bags

EIF-000308

[Date]

To: Risk Manager

Teleflex has voluntarily issued a recall for the following product:

Product Name	Product Code	Lot/Batch Number		GTIN
Rüsch® Premium Drain Bag	390000	20161005	20170701	14026704645708
		20161120	20170801	
		20161125	20170902	
		20170105	20170904	
		20170210	20171001	
		20170301	20171101	
		20170401	20171201	
		20170402	20180101	
		20170501	20170802	
		20170601		
Rüsch® Urinary Drainage Bag	390060	20161005	20170701	14026704645715
		20161120	20170801	
		20161125	20170901	
		20170105	20170902	
		20170210	20170903	
		20170401	20170904	
		20170402	20171101	
		20170501		

Teleflex is voluntarily recalling these products because the device labels are not UDI compliant. The missing UDI compliance information on the labeling would not affect the function/performance of the device itself. Other label information and warnings are unaffected by this labeling.

No patient injury has been reported.

Product code and lot combinations not referenced above are not impacted by this field action.

Our records indicate you have received products that are subject to this recall. We are notifying our customers to take the following actions:

1. Immediately discontinue use and quarantine any products with the product codes and lot numbers listed above.
2. Complete the enclosed Recall Acknowledgement Form and fax to **[distributor fax number]**.
3. Once the fax is received, we will provide instructions on how to return any affected product directly to **[distributor name]**.
4. If you have no affected stock, please complete the enclosed Recall Acknowledgment Form and fax it to **[distributor fax number]**. This will allow us to document your receipt of this letter.

The U.S. Food and Drug Administration has been notified of this action.

We apologize for any inconvenience this action may cause you or your patients, and remain committed to providing high quality, safe and effective products.

Sincerely,

**[Distributor Representative]**



1/23/2019

## Teleflex - Rusch Drainage Bags

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](mailto:compliance@ndc-inc.com)

### 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	Quantity to return
390000		
390060		

- 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®*

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