

## **URGENT MEDICAL DEVICE RECALL**

### **BD Connecta™ Plus**

June XX, 2019

Product Name	Cat. No.	Lot No.	Exp. Date
BD CONNECTA PLUS 3 WHITE 360DEG	394600	8278804C	2021-09-30

#### **For the Attention of:**

- Medical Director, Risk Manager, Medical Device Safety Officer, Nurse Manager

#### **Description of the problem and health hazard(s):**

BD is conducting a voluntary medical device recall for the one lot of BD Connecta Plus Stopcocks. The recall is being conducted due to a potential for contamination of a small number of units within the sealed packaging. While the contamination would likely be identified prior to use, if a contaminated BD Connecta Plus Stopcock were to be used it could result in contamination of the fluid path and/or exposure to biohazardous material.

Our records indicate that your facility may have received affected product.

#### **Please Take the Following Actions:**

1. Immediately review your inventory for the specific catalog and lot numbers listed above. Instruct customer to either destroy or return product based on regional requirements.
2. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.
3. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification and process your product replacement / credit.
4. Report any adverse health consequences experienced with the use of this product to BD.

#### **Actions to be Taken by BD:**

1. BD will provide a credit/replacement for all discarded/returned inventory.
2. Corrective actions have been initiated to prevent recurrence of the identified root cause.

#### **Contact Information**

**If you require further assistance, please contact:**

BD Contact	Contact Information
<b>Customer/Technical Support</b>	<b>Please insert regional contact information here.</b>

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. 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,

Applicable Regional Signatory

## CUSTOMER RESPONSE FORM

### **MDS-19-1529-FA**

**Please assist BD by promptly returning this form to: BD Regional Recall Contact**

**Email:** provide applicable email address

**Fax No.:** provide applicable fax number

**Facility:** \_\_\_\_\_

Please use full, current facility name. Do not use initials.

**Street Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip:** \_\_\_\_\_

**Contact Person:** \_\_\_\_\_

**Telephone No.:** \_\_\_\_\_ **Fax No.:** \_\_\_\_\_

**Email Address:** \_\_\_\_\_

☐ I have read and understood the attached notice.

Name/Title:	
Signature/Date:	

☐ We do not have any of the affected product(s) on hand.

☐ We have the following units on hand and request credit/replacement.

Product Name	Catalog No.	Lot No.	Units (Qty.)
BD CONNECTA PLUS 3 WHITE 360DEG	394600	8278804C	

☐ I certify that I have destroyed all affected product indicated above as available inventory at the time of receipt of this notification.