

12 May 2022

# **URGENT: FIELD SAFETY NOTICE - MDS-22-4419**

BD Connecta™ Stopcock and BD Nexiva™ with BD Connecta™

REF / Lot Numbers: See Attachment 1

Type of Action: Product Removal

### Attention: Clinical Personnel, Risk Managers, Purchasing Managers

This letter contains important information which requires your immediate attention.

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of **BD Connecta™** Stopcocks and **BD Nexiva™ with BD Connecta™**, as identified in Attachment 1. According to our distribution records, your organisation may have received the impacted product.

#### **Description of the problem**

BD has confirmed through customer feedback that the specific lots of BD Connecta™ Stopcock and BD Nexiva™ with BD Connecta™ listed in Attachment 1 may have the potential for leakage at the housing component of the stopcock (refer to Figure 1).



Figure 1: Potential site of the leakage at the housing component of the stopcock

This product removal is limited to the product code and lot numbers listed in Attachment 1. No other product codes or lot numbers are affected by this product field action.

#### **Clinical risk**

The specific product code and lot numbers of BD Connecta™ Stopcocks and BD Nexiva™ with BD Connecta™ (listed in Attachment 1) have the potential to leak and may result in delay or interruption in treatment, exposure to infusate and biohazardous material, under dosing or under infusion, contamination and/or air ingress.

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1030 Eskdale Road Winnersh Triangle Wokingham RG41 5TS www.BD.com

BD has identified that this issue is related to a specific molding cavity used in manufacturing and corrective actions have been implemented to prevent reoccurrence.

#### **Actions for Clinical Users**

For Clinical Users:

- 1. For devices *in situ*, check to see if the device is listed in Attachment 1 of this Field Safety Notice and, if so, replace immediately.
- 2. If you are unable to determine if the device is within scope, replace the device or continue to monitor for leakage and/or other complications.

### **Actions for customers to take:**

BD requires that the following actions are taken:

- 1. Inspect your inventory, locate and quarantine any units of the impacted lot numbers and destroy all affected product (as listed in Attachment 1).
- 2. If you have further distributed the product, identify those facilities, notify them at once of this product removal and have them destroy the affected product.
- 3. If you experience any issues with the BD Connecta™ Stopcock or the BD Nexiva™ with BD Connecta™, report as a complaint as per your normal process.
- 4. Complete and sign the Customer Response Form on page 3 and return it to <a href="mailto:BDUKFieldAction@bd.com">BDUKFieldAction@bd.com</a> as soon as possible or no later than 20<sup>th</sup> June 2022, indicating the following:
  - the quantities destroyed OR
  - o that your organisation does not have any impacted units left in inventory

For units destroyed, replacement devices will be sent. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

#### Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office. We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

Lorna Darrock

Sr. Manager, Post Market Quality

Harrock

**EMEA Quality** 

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# **Customer Response Form - MDS-22-4419**

# BD Connecta™ Stopcock and BD Nexiva™ with BD Connecta™

REFs/Lot Numbers: See Attachment 1

Please read in conjunction with Field Safety Notice MDS-22-4419 and return the completed and signed form as soon as possible or **no later than 20<sup>th</sup> June 2022** to BDUKFieldAction@bd.com.

ionn as soon as possible of <u>inc</u>	Diater than 20 " June 2022 to b	DUKFIEIDACIION	<u>vou.com</u> .				
I confirm this notice has been read, understood and that all recommended actions have been implemented as required.							
Tick the appropriate box below:							
<ul> <li>☐ We do not have any of the affected product as listed in Attachment 1 in our possession.</li> <li>OR</li> <li>☐ We have units of the affected product as listed in Attachment 1 and we confirm that the units have been destroyed.</li> <li>(Please complete Attachment 1 with the quantity of units destroyed. Then complete the table below with your contact information and return both documents to the email address listed above)</li> </ul>							
Name of Trust / Organisation							
Your Facility Address							
Postcode							
Telephone number		E-mail address					
Name of your supplier for this product (if not direct from BD)							
	Facility / Hospital Name			Postcode			
Please list <u>all</u> Facilities / Hospitals covered by your							
response*							
(e.g. other sites within your Trust / organisation.)							
*Please note that you may still receive reminder notifications if you cover multiple impacted sites but do not declare these above.							
Your Name		Job Title					
Signature		Date					

This form must be returned to <a href="mailto:BDUKFieldAction@bd.com">BDUKFieldAction@bd.com</a> before this action can be considered closed for your account. If you were forwarded this Field Safety Notice via a distributor/3<sup>rd</sup> party, please return your completed form to that organisation for reconciliation purposes.

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# Attachment 1: MDS-22-4419 List of impacted product codes/lot numbers

## Stopcock Without Extension  ## Tube  ## BD Connecta™ Stopcock Without Extension	REF	Product Description	Lot	GTIN	Expiry Date (DD/MM/YYYY)	Quantity Destroyed
394602  X 1.00IN    1719988   382903856826   31107/2024     1082422   382903856826   31107/2024     1082422   382903856871   31103/2024     1082422   382903856871   31103/2024     1126368   382903856871   31103/2024     1126368   382903856871   31103/2024     1126368   382903856871   31103/2024     1126368   382903856871   31103/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   3004/2024     1126368   38290385606   31007/2024     1086504   38290385606   31007/2024     1086504   38290385606   31007/2024     1086504   38290385606   29002/2024     1086504   38290385606   29002/2024     1086504   38290385606   29002/2024     1086504   38290385606   29002/2024     1086604   38290385601   39002/2024     1086604   38290385601   39002/2024     1086604   38290385601   39002/2024     1086604   38290385601   39002/2024     1086604   38290385601   39002/2024     1086606   38290385601   39002/2024     1086606   38290385601   30004/2024     112760   38290385601   30004/2024     112760   38290385601   30004/2024     112760   38290385601   30004/2024     112760   38290385601   30004/2024     112760   38290385601   30004/2024     112760   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     1086606   38290385602   29002/2024     108660	383682	DD North TM Observed N/ O. H. J. C. J. COCC.	1082423	382903836826		
394601  BD Nexiva™ Closed IV Catheter System 20GA						
894602  BD Nexiva ™ Closed IV Catheter System 20GA		X 1.00IIV				
394601  Name						
394601  BD Connecta™ Stopcock Without Extension Tube  BD Connecta™						
394601  BD Connecta™ Stopcock Without Extension Tube  BD Connecta™	000007	x 1.25IN				
### BD Connecta™ Stopcock Without Extension Tube  ### BD Connecta™ Stopcock Without Extension T						
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