

2nd November 2022

URGENT: FIELD SAFETY NOTICE – MDS-22-4560

BD Connecta™ Stopcock

REF: See Table 1 **Lot Numbers:** See Appendix 1

Type of Action: Product Removal

Attention: Clinical & Medical staff, Risk managers, Infection Prevention & Purchasing

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™ Stopcock** and our distribution records indicate your organisation may have received the impacted product. Product was distributed between May 2022 and September 2022.

Product Name	Product Code (REF)	Manufacturing SRN
BD Connecta™ Stopcock with extension tube - 25 cm	394926	SE-MF-000014597
BD Connecta™ Stopcock with extension tube and injection valve - 25 cm ventil	394936	
BD Connecta™ Stopcock with extension tube - 50 cm	394951	
BD Connecta™ Stopcock with extension tube - 100 cm	394961	
BD Connecta™ Stopcock with extension tube and injection valve - 100 cm ventil	394971	

Table 1: Impacted product

This product removal is limited to the product codes / lot numbers listed in Appendix 1. No other product codes or lot numbers are affected.

Description of the problem

BD has identified internally that the specific product Lots (listed in Appendix 1) may present a hole or rupture in the unit blister packaging as shown in Figure 1 and 2. As a result of this potential defect the sterility of the product may be compromised.

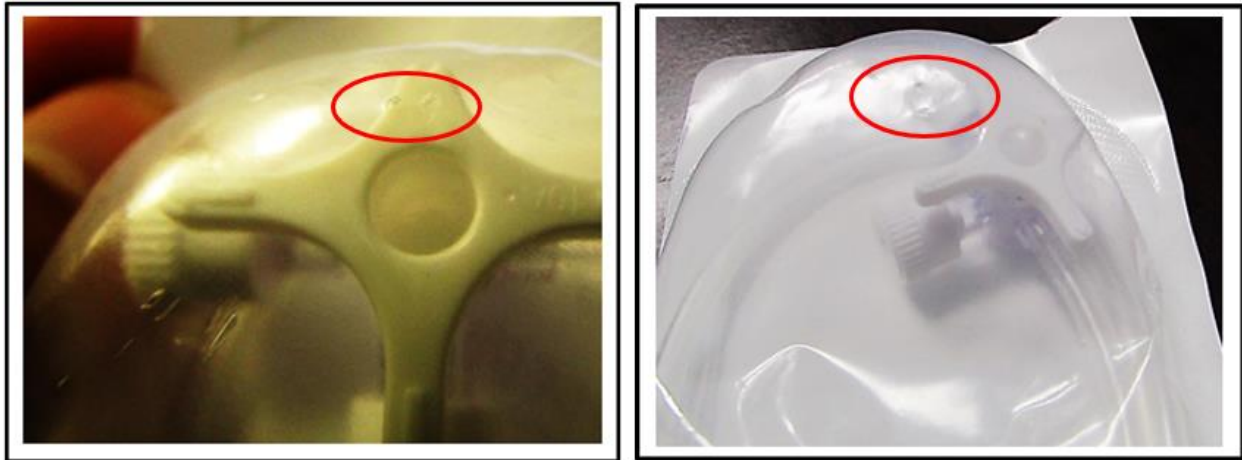


Figure 1: Hole in the blister packaging



Figure 2: Rupture in the blister packaging

Clinical risk

A potential breach in sterility of the packaging presents a health risk of exposure to microbial contaminants. This may lead to the potential introduction of infection into the bloodstream, an injury that requires medical intervention to treat.

For devices *in situ*, they should continue to be maintained and replaced in accordance with the hospital/institution's normal practices, unless there is a clinical suspicion of an infection related or unrelated to these devices.



To date there has been no adverse events worldwide related to this issue.

Actions taken by BD

BD has identified the root cause and is taking corrective actions to prevent recurrence of this issue.

Customer Actions:

- Cease use of any unused affected **BD Connecta™ Stopcocks**.
- Identify and quarantine all unused affected **BD Connecta™ Stopcocks**.
- Make a note of the lot numbers and destroy all unused affected units.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 30th November 2022**.
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- If you experience any issues with **BD Connecta™ Stopcock**, please report as a complaint as per your normal process.

Distributor Actions:

- Cease distribution.
- Identify, quarantine, making a note of the lot numbers then destroy all unused affected **BD Connecta™ Stopcocks**.
- Identify the facilities where you have distributed affected product and notify them immediately of this notice. Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by 30th November 2022.
- Complete and return the Customer Response Form following completion of your reconciliation activities.

	End User with Inventory	End User with ZERO inventory	Where to send the completed form
Purchased directly from BD	Complete the form in its entirety Upon receipt, BD will process the response, and you will receive replacements for unused devices	Complete the form and check the box indicating “no inventory”	BDUKFieldAction@bd.com
Purchased from a distributor/3rd party/NHS Supply Chain	Complete all fields on the form and contact your distributor to arrange for replacements	Complete the form and check the box indicating “no inventory”	Return the form to your distributor



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

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,

A handwritten signature in black ink, appearing to read 'L. Darrock', written in a cursive style.

Lorna Darrock
Associate Director, Post Market Quality
EMEA Quality



Customer Response Form – MDS-22-4560

BD Connecta™ Stopcock

REF: See Table 1 Lot Numbers: See Appendix 1

Return to BDUKFieldAction@bd.com as soon as possible or **no later than the 30th November 2022**

- I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Tick the appropriate box below:

We do not have any of the affected product as listed in Appendix 1 in our facility. Affected product has been used.

All product that is not available for destruction will be considered as disposed at your location and therefore physically unavailable unless otherwise specified.

OR

We had the following units of the affected product as listed in Appendix 1 in our facility and I confirm that the units have been destroyed. *(Please complete and return Appendix 1 to indicate the number of units destroyed. Replacement devices will only be sent on completion and return of this form).*

Account/Organisation/Trust Name:	
Department <i>(if applicable):</i>	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Name of your supplier for this product <i>(if not direct from BD)</i>	
Signature:	Date:

This form must be returned to BD before this action can be considered closed for your account.

**If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*



Appendix 1 – Impacted Product Codes and Lot Numbers

Return this with your Customer Response Form

Product Name	UDI-DI	Catalog (Ref) No.	Lot No / Serial No	Expiration Date (YYYYMMDD)	Product Package Size	Units Destroyed
BD Connecta™ Stopcock with extension tube - 25 cm	(01)00382903949267	394926	2091052	20250331	50	
			2091054	20250331		
			2091058	20250331		
			2125881	20250430		
			2125884	20250430		
			2125901	20250430		
			2125904	20250430		
			2125905	20250430		
BD Connecta™ Stopcock with extension tube and injection valve - 25 cm	(01)00382903949366	394936	2091050	20250331	20	
			2125908	20250430		
			2126355	20250430		
			2151833	20250430		
			2152122	20250531		
BD Connecta™ Stopcock with extension tube - 50 cm	(01)00382903949519	394951	2097331	20250331	20	
BD Connecta™ Stopcock with extension tube - 100 cm	(01)00382903949618	394961	2060613	20250228	20	
			2060614	20250228		
			2097333	20250331		
			2097334	20250331		
			2119720	20250430		
			2125865	20250430		
BD Connecta™ Stopcock with extension tube and injection valve - 100 cm	(01)00382903949717	394971	2090287	20250228	20	
			2067847	20250228		
			2067849	20250228		
			2067851	20250228		
			2067853	20250228		
			2067854	20250228		
			2067856	20250228		
			2067859	20250228		
			2091043	20250331		
			2091046	20250331		
			2125911	20250430		