



18th July 2022

URGENT: FIELD SAFETY NOTICE – MDS-21-4195

BD Phaseal™ Y-Site Connector C80

REF: 515304 Lot Numbers: See Table 1

Type of Action: Product Removal

Attention: Clinical Personnel including Clinical Pharmacists, Oncology Teams, Infusion Teams, 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 two lots of **BD BD Phaseal™ Y-Site Connector C80** identified in Table 1 below. According to our distribution records, your organisation may have received the impacted product that BD distributed between December 2020 and May 2021.

Product Code (REF)	Product Name	Lot number
515304	BD Phaseal™ Y-Site Connector C80	2007212
		2103205

Table 1: Impacted product

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

Description of the problem

BD has confirmed that these two lot numbers of BD Phaseal Y-site Connector C80 have the incorrect expiry date listed on all levels of the product labelling. The expiration date shown on the product labels is beyond the expiration date of the product. The correct expiration date for the product/impacted lot numbers is as below:

Lot Number	Incorrect Expiration Date on Product labels	Correct Expiration Date
2007212	2024-06-30	2023-04-30
2103205	2025-02-28	2023-03-31

Clinical risk

There is no immediate clinical risk to the user for the affected lots as the devices are within the true expiration date. Potential risk and/or harm can result if these products are not consumed by the user



by the correct expiration date. Products used beyond the expiration date may be compromised and may not function as intended.

BD has not received complaints or reported adverse events for this issue. No additional follow-up activities are required for patients already treated with the device.

Actions for Clinical Users

For Clinical Users:

1. If you are currently using the device, you may continue to use it for the duration of the treatment.

Actions taken by BD

BD has identified the root cause and corrective actions have been implemented to prevent reoccurrence.

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 units.
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 units.
3. If you experience any issues with the BD Phaseal Y-site Connector C80, report as a complaint as per your normal process.
4. Complete and sign the Customer Response Form on page 4 and return it to **<<insert contact details here>>** **as soon as possible or no later than 11th August 2022**, indicating the following:
 - o 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

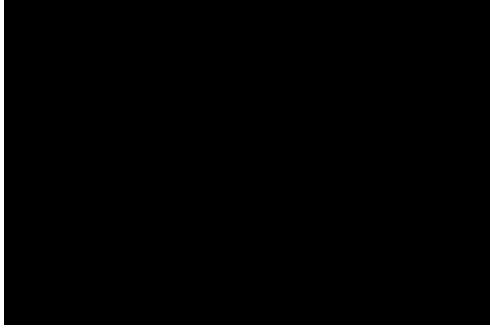
If you have any questions about this, please contact your local BD representative or the local BD office on **<<insert telephone details here>>** or e-mail **<<insert contact email address here>>**.

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,



BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com



Customer Response Form - MDS-21-4195

BD Phaseal™ Y-Site Connector C80

REF: 515304 Lot Numbers: See Table 1

Return to << insert email address>> as soon as possible or **no later than the 11th August 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 Table 1 in our possession.

OR

We have the following units of the affected product as listed in Table 1 and we confirm that the units have been destroyed. *(Please complete the table below with the lot number and the number of units destroyed. Replacement devices will be sent.)*

REF:	Lot Numbers:	Units destroyed <i>(insert unit quantity below)</i>
515304	2007212	
	2103205	

Account/Organisation 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*