

24th November 2022

URGENT: FIELD SAFETY NOTICE – PI-22-4510

Catheter Repair Kits (Various)

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 certain Catheter Repair Kits and our distribution records indicate your organisation may have received the impacted product. Product was distributed between August 2020 and November 2022.

Product Name	Product Code (REF)		Manufacturer SRN
	<i>as appears on ship carton</i>	<i>as appears on device pouch</i>	
4.2 F Broviac CV Catheters 0.7 mm Lumen (White Adapter)	0601610CE	0601610	US-MF-000017720
6.6 F Broviac CV Catheters 1.0 mm Lumen (White Adapter)	0601620CE	0601620	
White Adapter Leg for Hickman and Leonard Multiple Lumen CV Catheters	0601680CE	0601680	
Red Adapter Leg for Hickman and Leonard Multiple Lumen CV Catheters	0601690CE	0601690	
External Catheter Segment for Hickman 9 F Round Dual-Lumen CV Catheters	0601700CE	0601700	
External Catheter Segment for Leonard 10 F Round Dual-Lumen CV Catheters	0601750CE	0601750	
External Catheter Segment for Hickman 7 F Pediatric Dual-Lumen CV Catheters	0601760CE	0601760	
Groshong CV Catheter Repair Kit For use with Groshong 7 F Single-Lumen CV Catheter	7741700CE	7741700	
Groshong CV Catheter Repair Kit For use with Groshong 8 F Single-Lumen CV Catheter	7741800CE	7741800	

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.



Appendix 2 provides images on where the product code, lot number and expiry date is located.

Description of the problem

Based on customer feedback, BD has identified that there is the potential for the adhesive in the kits to become hardened or coagulated.

Clinical Risk

The catheter repair procedure requires the clinician to use adhesive to attach the repair segment to the original catheter. Hardened or coagulated adhesive has the potential to cause delays whilst an alternative repair kit or adhesive is obtained, therefore potentially prolonging surgery or necessitating catheter exchange.

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

Actions taken by BD

BD is investigating the root cause and will determine corrective actions to prevent recurrence of this issue.

Customer Actions:

- Cease use of any unused affected **Catheter Repair Kits** listed in Appendix 1.
- Identify and quarantine all unused affected **Catheter Repair Kits** listed in Appendix 1.
- 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 12th December 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 **Catheter Repair Kits**, please report as a complaint as per your normal process.

Distributor Actions:

- Cease distribution of all **Catheter Repair Kits** listed in Appendix 1.
- Identify, quarantine, making a note of the lot numbers then destroy all unused affected **Catheter Repair Kits** as listed in Appendix 1.
- 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 **12th December 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 completed form
Purchased directly from BD	Complete the form in its entirety Upon receipt, BD will process the response, and you will receive credit	Complete form and check the box indicating “no inventory”	<<insert BD email address>>
Purchased from a distributor/3rd party	Complete all fields on the form and contact your distributor to arrange credit	Complete form and check the box indicating “no inventory”	Return the form to your distributor

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,

Lorna Darrock
Associate Director, Post Market Quality
EMEA Quality



Customer Response Form – PI-22-4510

Catheter Repair Kits (Various)

REF: See Table 1 Lot Numbers: See Appendix 1

Return to <<insert fax/email address here>> as soon as possible or **no later than the 12th December 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. Credit will only be applied to your account on completion and return of this form).

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Name of your supplier for this product (if not direct from BD)	
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 completed with your Customer Response Form

Product Name	UDI-DI	Product Code (REF)	Lot numbers	Expiration Date (DDMMYYYY)	# Units Destroyed
4.2 F Broviac CV Catheters 0.7 mm Lumen (White Adapter)	(01)00801741036385	0601610CE	REGP2720	31/01/2025	
	(01)00801741036385		REFX4541	30/09/2023	
	(01)00801741036385		REFX5636	30/09/2024	
	(01)00801741036385		REFY2820	30/09/2023	
6.6 F Broviac CV Catheters 1.0 mm Lumen (White Adapter)	(01)00801741074479	0601620CE	REES0680	30/04/2023	
	(01)00801741074479		REEU0726	30/06/2023	
	(01)00801741074479		REFX4543	30/09/2023	
White Adapter Leg for Hickman and Leonard Multiple Lumen CV Catheters	(01)00801741036415	0601680CE	REER3749	31/03/2023	
Red Adapter Leg for Hickman and Leonard Multiple Lumen CV Catheters	(01)00801741036422	0601690CE	REFY0874	31/01/2023	
External Catheter Segment for Hickman 9 F Round Dual-Lumen CV Catheters	(01)00801741036439	0601700CE	REES2549	30/04/2023	
External Catheter Segment for Leonard 10 F Round Dual-Lumen CV Catheters	(01)00801741036477	0601750CE	REFY0744	31/07/2023	
External Catheter Segment for Hickman 7 F Pediatric Dual-Lumen CV Catheters	(01)00801741036484	0601760CE	REEU1534	30/06/2023	
Groshong CV Catheter Repair Kit For use with Groshong 7 F Single-Lumen CV Catheter	(01)00801741036798	7741700CE	REET0877	31/01/2024	
Groshong CV Catheter Repair Kit For use with Groshong 8 F Single-Lumen CV Catheter	(01)00801741036804	7741800CE	REFW3156	31/01/2025	

Appendix 2 – Product Code, lot number & expiry date Identification

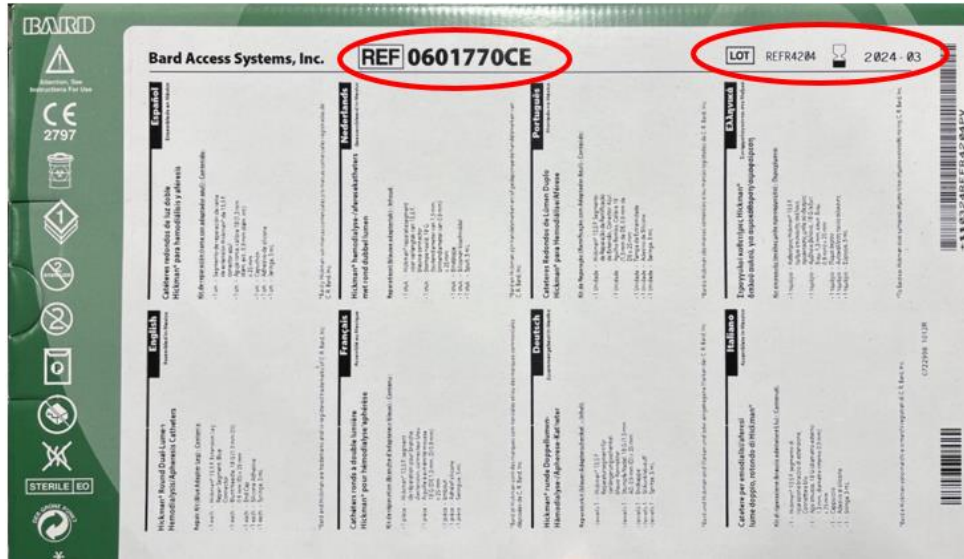


Figure 1: Ship carton product code, lot number and expiry date identification

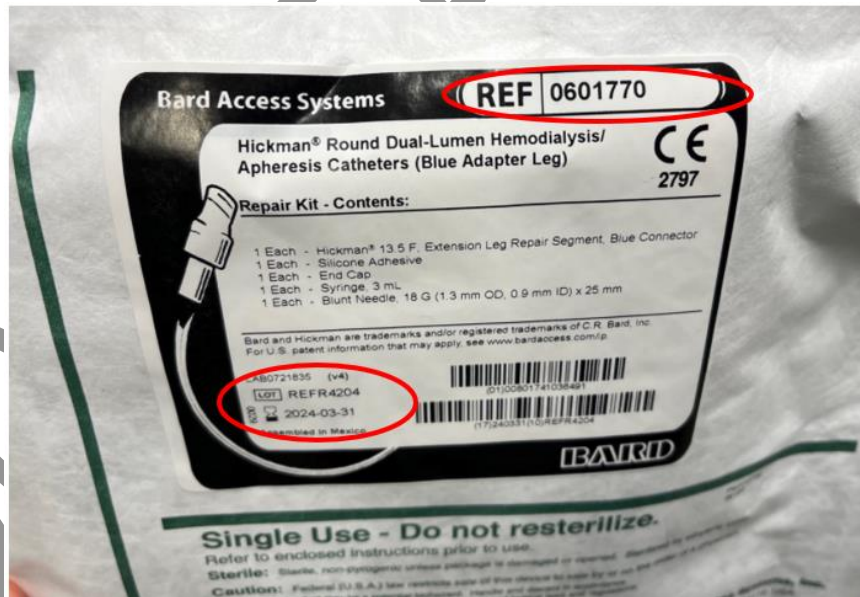


Figure 2: Pouch product code, lot number and expiry date identification