13th January 2026

**NEW**

# URGENT: FIELD SAFETY NOTICE – PI-26-06013

## Hickman™/ Broviac™ Central Venous Catheters

**REF:** Appendix 1 **Lot Numbers:** Appendix 1

**Type of Action**: Product Removal

**Attention: Interventional Radiologist Vascular surgeons, Clinical Personnel, Risk Managers, Biomedical Personnel, 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 **Hickman™/ Broviac™ Central Venous Catheters**. According to our distribution records your organisation may have received the impacted product in Appendix 1. Product was distributed between July and November 2025.

### Device Type

Hickman™ and Broviac™ Central Venous Catheters are constructed of specially formulated and processed silicone. The catheters are radiopaque with female luer locking connectors and SureCuff Tissue Ingrowth Cuffs for fixation of the catheters in a subcutaneous tunnel. Each catheter is provided in a double sterile package.

### Primary clinical purpose of devices

Hickman™ and Broviac™ Central Venous Catheters are designed for long-term vascular access and for use in patients that lack adequate peripheral venous access. They are available in single, dual and triple lumen catheters. All Hickman™ and Broviac™ Central Venous Catheters are designed for the administration of I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal.
Note: While smaller lumen Broviac™ catheters have been used successfully for blood withdrawal, their small lumen sizes increase the chance of clotting.

## Description of the product problem

BD has identified, via internal inspections, that the packaging of some Hickman™ Catheter and Broviac™ Catheter kits may have damage present on the outer tray, potentially compromising the sterile barrier. This product features a double-tray packaging structure (outer tray and inner tray). The inner tray, which contains the catheter and accessories, is sealed inside the outer tray along with the instructions for use. The sterility of the outer surface of the inner tray and the instructions for use may be compromised.

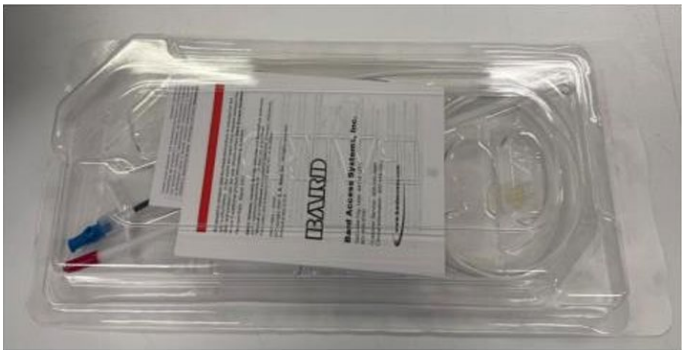

Image 1: Finished Product Outer Tray

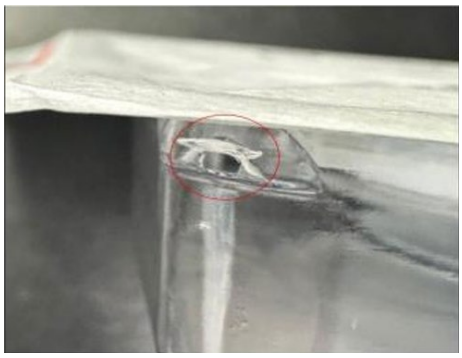

Image 2: Example of the Sterile Barrier Defect

## Clinical risk

While the inner tray typically remains intact, an outer breach can allow microbial contamination during handling, creating a potential infection risk. Contamination may cause local insertion-site infection or progress to catheter-related bloodstream infection. Treatment often requires systemic antibiotics and, if clinically indicated, catheter removal and replacement. Severe or untreated cases can lead to sepsis, hospitalization, and therapy interruption.

To date, there have been no complaints or adverse events worldwide reported for this issue.

## Clinical User Actions

- Do not place any of the affected catheters and discard.
- Do not remove catheters in situ unless infection is suspected or the device is no longer clinically necessary.
- Inspect insertion sites daily for signs of infection.

## BD Actions:

1. BD is investigating this issue and has identified that the probable root cause was related to the equipment used to seal the outer tray. BD has implemented equipment corrections and will implement further measures to prevent recurrence of this product issue.
2. BD will provide replacement upon receipt of a completed customer response form.

To date, BD does not plan to initiate any further advice or information in a follow-up FSN

**Customer Actions:**

- Cease use of any unused affected **Hickman™/ Broviac™ Central Venous Catheters**.
- Identify and quarantine all unused affected **Hickman™/ Broviac™ Central Venous Catheters.**
- 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 5th February 2026.**
- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

**Distributor Actions:**

- Cease distribution.
- Identify, quarantine, making a note of the lot numbers then destroy all undistributed affected **Hickman™/ Broviac™ Central Venous Catheters**.
- This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.
- 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 **5th February 2026.**
    - There is no requirement to return your customer response forms to BD, you should maintain these on file at your facility. Return only your final consolidated response form.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

| | **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 **replacements** for unused product | Complete form and check the box indicating “no inventory” | BDFieldActions@bd.com |
| Purchased from a **distributor/3rd party** | Complete all fields on the form and contact your distributor to arrange for **replacements** | 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 or e-mail BDFieldActions@bd.com.

The Regulatory Authority of your country has been informed about this communication to customers.

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,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

13th January 2026

# Customer Response Form – PI-26-06013

## Hickman™/ Broviac™ Central Venous Catheters

**REF:** Appendix 1 **Lot Numbers:** Appendix 1

---

Return to BDFieldActions@bd.com as soon as possible or **no later than the 5th February 2026.**

- **I confirm this Field Safety 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 **Appendix1** in our facility. Affected product has been used.

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

**OR**

☐ We have the following units of the affected product as listed in **Appendix1** in our possession and I confirm that the units have been destroyed *(Please complete the table below with the lot number and the number of units destroyed. **Replacement** product will only be sent on completion and return of this form).*

| REF: | Lot Number/s: | Units destroyed *(insert quantity below)* |
|---|---|---|
| | | |
| | | |

| | |
|---|---|
| **Account/Organisation Name:** St Thomas ' NHS Foundation Trust | |
| **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

This product removal is limited to the product codes / lot numbers listed below.

**Manufacturer's SRN: US-MF-000017720**

| Product Code (REF) | Product Name | Lot Number | Expiry Date | UDI |
|---|---|---|---|---|
| 0600310CE | Hickman 7 Fr Dual-Lumen CV Catheter, Cutdown Tray with SureCuff Tissue Ingrowth Cuff | HUKS0783 | 28-Apr-2030 | (01)00801741051739(17)300428(10)HUKS0783 |
| 0600520CE | Broviac 4.2 Fr Single-Lumen CV Catheter Peel-Apart Introducer Kit with SureCuff Tissue Ingrowth Cuff | HUKS1468 | 28-May-2027 | (01)00801741051807(17)270528(10)HUKS1468 |
| 0600540CE | Broviac 6.6 Fr Single-Lumen CV Catheter Peel-Apart Introducer Kit with SureCuff Tissue Ingrowth Cuff | HUKR0064 | 28-Apr-2029 | (01)00801741051821(17)290428(10)HUKR0064 |
| | | HUKR0065 | 28-Jun-2029 | (01)00801741051821(17)290628(10)HUKR0065 |
| | | HUKR0067 | 28-Jun-2029 | (01)00801741051821(17)290628(10)HUKR0067 |
| 0600560CE | Hickman 9.6 Fr Single-Lumen CV Catheter, Peel-Apart Introducer Kit with SureCuff Tissue Ingrowth Cuff | HUKS0776 | 28-Aug-2029 | (01)00801741051845(17)290828(10)HUKS0776 |
| | | HUKS0816 | 28-Aug-2029 | (01)00801741051845(17)290828(10)HUKS0816 |
| | | HUKS1220 | | (01)00801741051845(17)290928(10)HUKS1220 |
| | | HUKU0350 | 28-Jan-2030 | (01)00801741051845(17)300128(10)HUKU0350 |
| 0600570CE | Hickman 7 Fr Dual-Lumen CV Catheter, Peel-Apart Introducer Kit with SureCuff Tissue Ingrowth Cuff | HUKR1344 | 28-Jun-2029 | (01)00801741051869(17)290628(10)HUKR1344 |
| | | HUKR1346 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKR1346 |
| | | HUKR1347 | 28-Jun-2029 | (01)00801741051869(17)290628(10)HUKR1347 |
| | | HUKR1356 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKR1356 |
| | | HUKR1363 | 28-Jun-2029 | (01)00801741051869(17)290628(10)HUKR1363 |
| | | HUKR1367 | 28-Jun-2029 | (01)00801741051869(17)290628(10)HUKR1367 |
| | | HUKU0242 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKU0242 |
| | | HUKU0247 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKU0247 |
| | | HUKU0253 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKU0253 |
| | | HUKU0266 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKU0266 |
| | | HUKU0280 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKU0280 |
| | | HUKU0312 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKU0312 |
| | | HUKU0344 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKU0344 |
| | | HUKU0354 | 28-Jan-2030 | (01)00801741051869(17)300128(10)HUKU0354 |
| 0600620CE | Hickman 12 Fr Dual-Lumen CV Catheter, Peel-Apart Introducer kit with SureCuff Tissue Ingrowth Cuff | HUJY0302 | 28-Oct-2029 | (01)00801741051913(17)291028(10)HUJY0302 |
| | | HUJY1095 | 28-Oct-2029 | (01)00801741051913(17)291028(10)HUJY1095 |
| | | HUJZ1332 | 28-Nov-2029 | (01)00801741051913(17)291128(10)HUJZ1332 |

| Product Code (REF) | Product Name | Lot Number | Expiry Date | UDI |
|---|---|---|---|---|
| 0600620CE | Hickman 12 Fr Dual-Lumen CV Catheter, Peel-Apart Introducer kit with SureCuff Tissue Ingrowth Cuff | HUJZ1336 | 28-Nov-2029 | (01)00801741051913(17)291128(10)HUJZ1336 |
| | | HUJZ1339 | 28-Nov-2029 | (01)00801741051913(17)291128(10)HUJZ1339 |
| | | HUJZ1340 | 28-Nov-2029 | (01)00801741051913(17)291128(10)HUJZ1340 |
| | | HUKR1349 | 28-Mar-2030 | (01)00801741051913(17)300328(10)HUKR1349 |
| | | HUKS0784 | 28-Apr-2030 | (01)00801741051913(17)300428(10)HUKS0784 |
| | | HUKS1217 | 28-Apr-2030 | (01)00801741051913(17)300428(10)HUKS1217 |
| | | HUKU0351 | 28-Jun-2030 | (01)00801741051913(17)300628(10)HUKU0351 |
| 0606560CE | Hickman 10 Fr Triple-Lumen CV Catheter, Peel-Apart Introducer Kit with SureCuff Tissue Ingrowth Cuff | HUKR1370 | 28-Aug-2029 | (01)00801741052019(17)290828(10)HUKR1370 |
| | | HUKS1219 | 28-Sep-2029 | (01)00801741052019(17)290928(10)HUKS1219 |
| | | HUKU0255 | 28-Jan-2030 | (01)00801741052019(17)300128(10)HUKU0255 |