6th November 2025

NEW

URGENT: FIELD SAFETY NOTICE – UCC-25-5370

Inlay Optima™ Ureteral Stents

REF: see Table 1 **Lot Numbers:** see Table 1

Type of Action: Product Removal

Attention: 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 Inlay Optima™ Ureteral Stents. According to our distribution records your organisation may have received the impacted product indicated in Table 1. Product was distributed between November 2024 and June 2025.

Manufacturer's SRN: US-MF-000018892

Product Code (REF)	Lot Number	Expiry Date	UDI
788826	NGJU4328	28 Feb 2029	00801741015922
788630	NGJU4327	30 Jun 2028	00801741015786
788426	NGJU4181	31 May 2029	00801741015687

Table 1: Impacted product

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

Device Type

The InLay Optima™ Ureteral Stent is a coated, double pigtail ureteral stent with a monofilament suture loop attached to aid in stent removal.

Picture 1: InLay Optima™ Ureteral Stent

Primary clinical purpose of devices

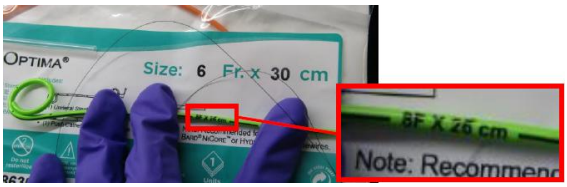
Ureteral stents are used to reestablish or maintain patency of the ureter.

Description of the product problem

Based on customer feedback, BD has identified a labeling discrepancy involving Inlay Optima™ Ureteral Stents. Our internal investigation confirmed that the product box label and the product pouch label may display different product codes. The actual product contained within the pouch matches the product code listed on the box label.

Picture 2: Box Label

Picture 3: Pouch Label



Picture 4: Product Photo

Clinical risk

As a result of the discrepancy in labeling between the product pouch (6Fr x 30cm) and actual device (8Fr x 26cm), users may retrieve a wrong sized stent for their procedure.

Potential harms can include pain, discomfort, and require the need for a replacement device and/or interventions to correct the issue.

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

Clinical User Actions

Users should follow the recommendations provided in this communication:

If the product has been previously placed and removed, no additional action is required by the user. If the product is currently indwelling, further treatment should be determined by the treating clinician. If the product has not been used, dispose of the affected product and source product not included in this recall.

BD Actions:

BD has taken appropriate action to prevent further distribution of affected products and has completed a thorough investigation to determine the root cause.

BD will implement corrective action for the root causes identified to prevent further recurrence.

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 Inlay Optima™ Ureteral Stents.
- Identify and quarantine all unused affected Inlay Optima™ Ureteral Stents.
- 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 26th November 2025**.
- 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. (As appropriate)
- Please transfer this notice to other organisations on which this action has an impact. (As appropriate)
- 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 Inlay Optima™ Ureteral Stents.
- 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. (As appropriate)
- 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 26th November 2025**.
    - 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.

6th November 2025

Customer Response Form - UCC-25-5370

Inlay Optima™ Ureteral Stents

REF: see Table 1 **Lot Numbers:** see Table 1

Return to *BDFieldActions@bd.com* as soon as possible or **no later than the 26th November 2025**

- **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 **Table 1** 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 **Table 1** 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. Replacemen product will only be sent on completion and return of this form).*

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

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.*