Medcaptain 麦科田

BD

FSN Number: FSN-202606-001

BD Ref: MDS-26-06119

Date of Reporting:<< 2026-07-15>>

URGENT: FIELD SAFETY NOTICE - FSN-202606-001

BD Ref: MDS-26-06119

BD® neXus Disposable Infusion Set

REF: 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,

MEDCAPTAIN LIFE SCIENCE CO., LTD., as the Legal Manufacturer is issuing a Field Safety Notice for **BD® neXus Disposable Infusion Sets.** According to distribution records your organization may have received the impacted product in Table 1.

Manufacturer's SRN: CN-MF-000006656
Legal Manufacturer: MEDCAPTAIN LIFE SCIENCE CO., LTD.

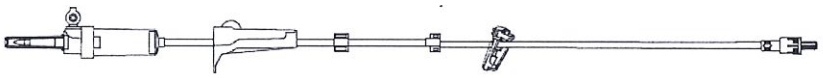
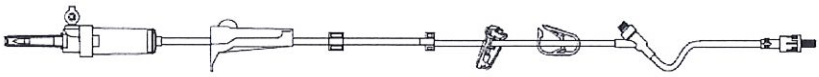
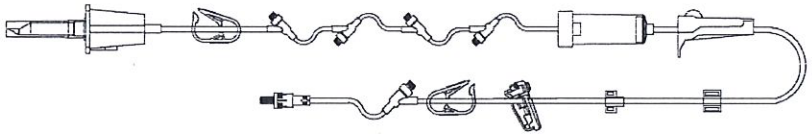
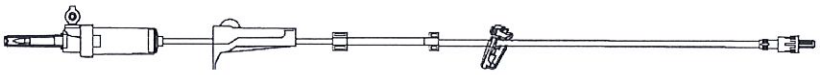
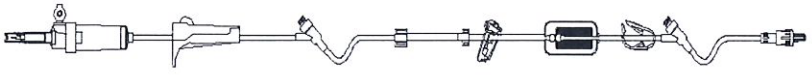
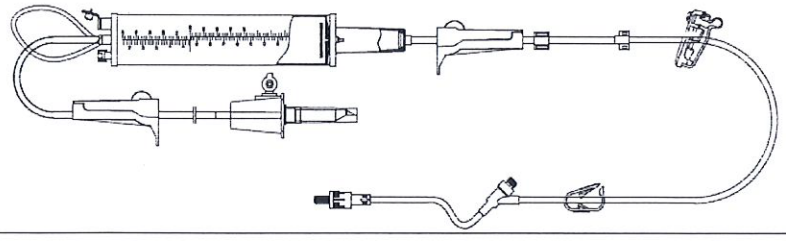
Catalog Number (REF)	Trade Name	UDI-DI	LOT
A211M	BD® neXus Disposable Infusion Set	06972991860700	157247KS, 168437KS, 171489KS, 173506KS, 174442KS, 197265KS, 198383KS, 199401KS, 206328KS, 208473KS, 211412KS, 212254KS, 216492KS, 216500KS.
A211M1F	BD® neXus Disposable Infusion Set	06972991860717	157643KS, 168440KS, 168441KS, 171488KS, 173468KS, 174441KS, 197264KS, 197429KS, 198524KS, 198605KS, 199398KS, 199468KS, 200234KS-A, 206329KS, 208586KS, 212248KS, 216423KS, 216493KS, 217252KS.
A211M5F1	BD® neXus Disposable Infusion Set	06972991860663	171423KS, 197339KS, 198526KS, 199466KS, 207365KS, 208464KS, 211465KS, 216358KS.
A311M	BD® neXus Disposable Infusion Set	06972991860649	169534KS, 171485KS, 173467KS, 174289KS, 208591KS, 209420KS, 211472KS, 216438KS, 217254KS, 217472KS.

Catalog Number (REF)	Trade Name	UDI-DI	LOT
A311M021F	BD® neXus Disposable Infusion Set	06972991860687	169533KS, 171484KS, 208592KS, 209424KS, 217255KS, 212391KS, 216491KS, 217471KS.
A212M1F	BD® neXus Disposable Infusion Set	06972991860632	171480KS, 200367KS-A, 207502KS, 209208KS, 211309KS.

Table 1: Impacted product

This Field Safety Notice is limited to the product codes listed in Table 1. No other product codes and lots are affected.

Device Type(s)

Catalog Number (REF)	Device Description	Image
A211M	Infusion Set, 15 µm filter, 265 cm.	
A211M1F	Infusion Set, 1 Needle-free Y-port, 15 µm filter, 265 cm.	
A211M5F1	Oncology Infusion Set, 5 Needle-free Y-ports, 15 µm filter, 270 cm.	
A311M	Infusion Set PVC-Free straight, 15 µm filter, 265cm.	
A311M021F	Infusion Set, 0.2 µm filter, 270cm	
A212M1F	Burette set, 150 mL, 15 µm filter, 275 cm.	

Primary clinical purpose of devices

BD® neXus Disposable Infusion Set is mainly used to administer fluids to a patient's vascular system by connecting with IV pump. It is applicable for patients with high precision control requirements.

Description of the Problem

MEDCAPTAIN LIFE SCIENCE CO., LTD., as the legal manufacturer have received reports indicating that the Male luer connection of the BD® neXus Disposable Infusion Sets may be difficult to disconnect and may crack or break.

This issue affects the products listed in Table 1: Impacted products.

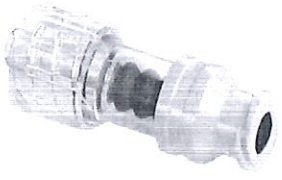
Clinical Risk

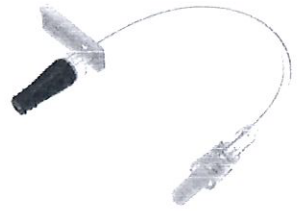
Microcracks or breakage of the Male Luer connector may occur, which could require replacement of the infusion set and potentially lead to waste of medication or the risk of under-delivery of medication. If a toxic or irritant medication is infused, leakage may cause localised skin irritation or minor exposure through inhalation for clinical staffs or patients. There have been no reports of injury in relation to this issue.

Clinical User Actions

1. Do not use the impacted sets with BD neXus Infusion System if an alternative infusion pump/set is available. If you do not have an alternative infusion system, continue to use the sets with the following mitigations in place:

- Do not use excessive force when connecting or disconnecting the infusion set, as this may damage the connector potentially leading to medication leakage.
- When handling the set use universal precautions in terms of Personal Protective Equipment (PPE)
- Connect an additional IV component, such as a needle free connector or short extension set, between the distal end of the administration set and the patient's vascular access device. When disconnecting the administration set, it is advised to manipulate the added component instead of the primary administration set. This will reduce the mechanical stress on the affected luer, therefore reducing the probability of breakage.

	Description	Example Diagram
a.	Adding a NFC (Needle-free connector) at the end of the infusion set is also intended to reduce handling of the Male Luer at the end. As shown in the figure on the right.	

b.	Adding an extension tube at the end of the infusion set is also intended to reduce handling of the Male Luer at the end. As shown in the figure on the right.	

Note: Adding an NFC or extension tube does not affect the performance of the pump. Ensure all air is removed from the added component prior to connecting the administration set to the patient. Follow the Instructions for Use provided with the NFC or extension set.

Corrective Actions

MEDCAPTAIN LIFE SCIENCE CO., LTD., as the Legal Manufacturer, will take the following corrective actions:
1. Publish this FSN to cease use of the impacted sets with the BD neXus Infusion System if an alternative method of delivery is available. Advise Clinical Users, if alternative infusion pump/set is not available on how to prevent the Male Luer from being unable to disconnect or from breaking.
2. A root cause investigation has been initiated. Based on its findings, appropriate corrective and preventive actions will be implemented to prevent recurrence. These will include design optimization of the Male Luer.
3. A follow-up Field Safety Notice will be issued to remove the impacted sets from the market once optimized male luer design is released.

Customer Actions:

- Review the information in **Table 1** to determine if **BD® neXus Disposable Infusion Sets** in your possession are impacted.
  a. If your facility is to cease use of the affected BD neXus Infusion Sets, Identify and quarantine all affected product. Make a note of the lot numbers and destroy all affected units.
  b. If your site is to continue use of the affected BD neXus Infusion Sets until the optimized design is released, ensure all users at your site receive a copy of this Field Safety Notice and follow clinical user actions.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 30 July 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. (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:

- Review the information in **Table 1** and determine if the **BD® neXus Disposable Infusion Sets** in your possession are impacted.
- 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. (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 **30 July 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 and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	BDFieldAction@bd.com
Purchased from a **distributor/3rd party**	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	Return the form to your distributor/3rd party

Contact reference person

If you have any questions or require assistance relating to this Field Safety Notice, please contact at e-mail BDFieldAction@bd.com.

We confirm that the appropriate regulatory agencies have been informed of these actions.

Sincerely,

[redacted]

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.

Customer Response Form – FSN-202606-001
BD Ref: MDS-26-06119
BD® neXus Disposable Infusion Set
REF: Table 1

Return to BDFieldAction@bd.com as soon as possible or **no later than the [date]**.

By signing below, you 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 the FSN in our facility. Affected product has been used.

OR

☐ We have the affected product as listed in the FSN in our facility and we will continue to use until the optimsed design is released

OR

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

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

Account/Organization 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*

organization for reconciliation purposes.