21st January 2026

NEW

URGENT: FIELD SAFETY NOTICE – MDS-26-06019

Alaris™ VP Infusion Sets

REF: See Table 1 **Lot Numbers:** See webpage link

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 Alaris™ VP Infusion Sets. According to our distribution records your organisation may have received the impacted product in Table 1. Product was distributed between July 2025 and December 2025.

Manufacturer's SRN: CH-MF-000026539

Product Name	Product Code (REF)	UDI-DI
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.	70693E	7613203019774
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LIGHT RESISTANT. 15 µm FILTER.	70643	7613203019705
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.	70593	7613203019750
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	70793E	7613203022231
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW PRIMING VOLUME. LIGHT RESISTANT. 15 µm FILTER.	70641	7613203028714
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 15 µm FILTER.	70953	7613203025447
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. LIGHT RESISTANT. 1.2 µm FILTER.	70123E	7613203022217
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.	70952E	7613203019835
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 0.2 µm FILTER.	70033V	7613203030830
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. UNVENTED. 1.2 µm FILTER.	70125E	7613203030816
Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSiteTM Needle-free System. BURETTE SET. NO FILTER.	70103E	7613203021470

Table 1: Impacted product

Device Type

Alaris™ VP Infusion Sets are dedicated infusion administration sets providing a flexible sterile fluid path to deliver intravenous solutions from a reservoir to the infusion site. Refer to Image 1.



Image 1: Representative photo of the product

Primary clinical purpose of devices

Alaris™ VP Infusion Sets are intended to be used with the Alaris™ VP Volumetric Pump

Description of the product problem

BD has identified, as a result of customer complaints, that the specific lots of Alaris™ VP Infusion Sets listed in the webpage https://bdx.my.site.com/CC360/s/impactedproducts?rn=MDS-26-06019 GLOBAL have the potential for fluid leakage from the silicone tube at the end of the pumping segment (see Image 2).

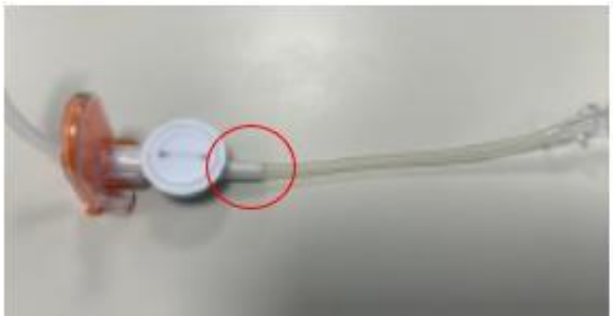


Image 2: Location of silicone tube at the end of the pumping segment

Clinical risk

Leakage at the silicone pumping segment during priming or infusion may result in under-infusion of prescribed therapy, unintended exposure to hazardous drugs, and increased risk of air embolism or bacterial contamination if urgent set replacement compromises sterility. Potential clinical consequences include therapy delay or interruption, local irritation, systemic toxicity, infection, or sepsis, particularly in critically ill patients. Due to the size of the potential leakage, it is not visible to the naked eye, so would unlikely to be detected by the clinician prior to use.

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

Clinical User Actions

- Cease use of the affected product.
  - The affected product lot numbers can be found on the webpage: https://bdx.my.site.com/CC360/s/impactedproducts?rn=MDS-26-06019 GLOBAL
- If devices have been safely used, no patient follow up activities are required
- Replace any impacted infusion set currently in use.
- If the product is currently in use and you are unable to determine if it is within scope, continue to monitor for leakage or replace product.
- When infusing hazardous substances (e.g. cytotoxics), prime the pump set with a non-hazardous fluid, wear appropriate Personal Protective Equipment (PPE) as per local hospital guidelines.

Action TAKEN by BD

BD has completed the investigation and identified the root cause to be related to sub-assemblies from a supplier. BD is conducting increased inspections to ensure products now being shipped are not impacted.

Actions TO BE taken by BD

- BD is implementing corrective actions with the supplier to avoid 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 affected Alaris™ VP Infusion Sets.
- Identify and quarantine all affected Alaris™ VP Infusion Sets.
- Make a note of the lot numbers and destroy all affected units.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 18th February 2026**.
- This notice needs to be passed onto 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 Alaris™ VP Infusion Sets.
- This notice needs to be passed onto 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 **18th 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 affected 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.

Customer Response Form – MDS-26-06019

Alaris™ VP Infusion Sets

Return to BDFieldActions@bd.com as soon as possible or **no later than the 18th 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 the webpage 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 the webpage 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:	
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.*