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30th November 2022

URGENT: FIELD SAFETY NOTICE – MMS-23-4626

BD Alaris™ GP Plus Guardrails Pump & BD Alaris™ neXus GP Pump

REF: See Table 1 **Serial Number Range:** See Table 1

Type of Action: Product Removal

Attention: Clinical & Medical staff, Risk Managers, Biomedical & Purchasing

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove specific serial numbers of **BD Alaris™ GP Plus Guardrails Pumps** and **BD Alaris™ neXus GP pumps** and our distribution records indicate your organisation may have received the affected pumps. Affected pumps were distributed between August 2022 and November 2022.

Product Name	UDI-DI	Product Code (REF)	Serial No. Range	Manufacturer SRN
BD Alaris™ GP Plus Guardrails Pump	10885403462290	9002TIG03-G	470068951 - 470068950	CH-MF-000026539
BD Alaris™ neXus GP Pump	10885403484698	GPNEXUS1	410017110 - 410017262	

Table 1: Impacted product

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

Description of the problem

During an internal review, BD has identified that the specific pumps within the serial number range listed in Table 1, contain a fuse that may blow upon connection of the pump to AC power. This will result in the pump not charging.

Clinical risk

If the pump battery depletes and the pump cannot be charged, there is a potential for a delay in infusion therapy.

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

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Actions taken by BD

BD has identified this issue and has launched an investigation to identify root cause and prevent recurrence.

Actions to be taken by BD

Upon receipt of the completed response form, BD will commence processing your replacement pumps.

Clinical User/Biomedical Actions:

- Cease use of any affected **BD Alaris™ GP Plus Guardrails Pumps** and **BD Alaris™ neXus GP pumps**.
- Identify and quarantine all affected serial numbers of **BD Alaris™ GP Plus Guardrails Pumps** and **BD Alaris™ neXus GP pumps** in your facility.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 19th December 2022**.
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected pumps have been transferred.
- If you experience any issues with **BD Alaris™ GP Plus Guardrails Pumps** and **BD Alaris™ neXus GP pumps**, report as a complaint as per your normal process.

Distributor Actions:

- Cease distribution.
- Identify, quarantine all affected serial numbers of **BD Alaris™ GP Plus Guardrails Pumps** and **BD Alaris™ neXus GP pumps** in your facility.
- Identify the facilities where you have distributed affected pumps and notify them immediately of this notice. Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **19th 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 replacements	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 for replacements	Complete form and check the box indicating "no inventory"	Return the form to your distributor

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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

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REF: See Table 1 **Serial Number Range:** See Table 1

Return to <*<insert fax/email address here>>* as soon as possible or **no later than the 19th 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 pumps as listed in Table 1 in our facility.
All pumps that are not available for return will be considered as dispositioned at your location and therefore physically unavailable for clinical use unless otherwise specified.

OR

☐ We have affected pumps as listed in Table 1 in our facility and I confirm that the units will be returned to BD for replacement pumps. *(Replacement pumps will only be sent on completion & 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:**

Please complete only if the contact to arrange return/replacement is different from above:			
Name:	Job Title:	Telephone:	E-mail:

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.*