



12 March 2021

Generic Customer letter

Customer Name

Address

Suburb, postcode, State

Quality Managers, Biomedical Engineering, Pharmacy, Clinical Product Advisors, Risk Managers

Dear Sir / Madam

**Urgent Medical Device Recall
Medsafe Ref: #27403**

**Dedicated Infusion Sets for BD Alaris™ Pumps (GP, VP, CC and SE)
and
Non-Dedicated Infusion sets and accessories**

See Appendix 1 for full lists of all impacted Catalogue Numbers.

Representative images of the affected dedicated and non-dedicated sets are provided in Appendix 2

Following consultation with Medsafe, Ministry for Health, BD is initiating an Urgent Medical Device Recall relating to the above-mentioned products.

The following information describes the potential issues and the actions to take.

Issue

BD has been notified by a 3rd party sterilization services provider that they intentionally falsified sterilization process records related to the processing of BD products.

BD immediately conducted an investigation and has determined that BD is unable to guarantee the sterility of the products listed in the attached appendices. Therefore, we are removing the products from the market.

The scope of this product removal includes unexpired lots of the distributed SKUs listed in the appendices. BD has an on-line tool to support the identification of impacted lot numbers bd.com/MDS-21-4072

Health Hazard Evaluation / Potential Risk

The use of non-sterile product in the clinical setting could lead to an increased risk of infection which may cause serious harm or life-threatening conditions.

Worldwide BD has received zero (0) reports of this issue occurring while the product was in clinical use. There have been no reports of harm in New Zealand or worldwide.

No specific patient follow-up activities are required if the product has already been used.

Required action for users

1. Cease use of all impacted lot numbers in your possession.
2. Until BD can resume shipments, BD recommends:
 - a. Contact your local BD representative to discuss possible product alternatives.
 - b. Where product alternatives are not available, consider general measures to guarantee infusion continuity such as:

For BD Alaris™ CC Plus users:

- i) Check with your local BD representative regarding the possibility to temporarily convert your pump into "Semi-dedicated" mode (this allows pump operation only in mL/h and without In-line pressure monitoring capability) using standard extension sets as an alternative.
- ii) Should filtration be a requirement, add-on filters (0.22 / 1.2 µm filters) can be used.
- iii) Due to limited supply of extension sets with pressure discs, In Line Pressure Measurements may not be possible. Hence, we recommend using a pressure disc on ONE pump that is closest to the patient so it can monitor the in-line pressure for all pumps in the system (i.e. multi infusion set up).

For BD Alaris™ GP Plus & BD Alaris™ SE users:

- i) Use any alternative pumps available.
- ii) Consider the use of syringe pumps for high-alert medications that require continuous infusions (including weight-based drugs)
- iii) Consider use of gravity infusions for large volume infusates that do not require high-accuracy or weight-based infusion.
- iv) When transitioning parenteral nutrition, chemotherapy or other infusions that require infusion sets with filters (0.2 or 1.2 µm), consider use of add-on inline filters during gravity-based infusions (with or without flow rate regulators).
- v) Consider use of tubing with integrated dial-calibrated IV flow rate regulators can be used to regulate the flow rate instead of the roller clamp.

For BD Alaris™ VP Plus users:

- i) As pump set replacement alternatives are not possible, gravity infusion may be the only option or use any alternative pumps available.
 - ii) Consider use of syringe pumps for high-alert medications that require continuous infusions (including weight-based drugs).
 - iii) Consider use of gravity infusions for large volume infusates that do not require high-accuracy or weight-based infusion.
 - iv) When transitioning parenteral nutrition or chemotherapy or other infusions that require infusion sets with filters (0.2 or 1.2 µm), consider use of add-on inline filters during gravity-based infusions (with or without flow rate regulators).
 - v) Consider use of tubing with integrated dial-calibrated IV flow rate regulators can be used to regulate the flow rate instead of the roller clamp.
- c. Consider alternative arrangements for your infusion therapy needs in line with guidance from ISMP (Institute for Safe Medication Practices, an ECRI affiliate), for alternative infusion therapy arrangements in situations of supply interruptions for IV disposables:
 - i. **IV to oral conversion.** Organizations should switch patients from IV to oral therapies as soon as possible. This should be considered for all appropriate patients who can swallow and meet other facility-defined criteria (e.g., no fever), including patients in the emergency department (ED) and long-term care facilities associated with the health system.
 - ii. **Use IV push instead of infusions.** Administering medications via IV push instead of as a secondary infusion should also be considered when appropriate. Hospital-specific IV push guidelines, along with the [ISMP Safe Practice Guidelines for Adult IV Push Medications](#), should be consulted before considering this alternative.
 - iii. **Potential role for gravity infusions.** Examples may include IV hydration, some IV antibiotics, medications that are not high-alert, and others that might be appropriate for gravity infusion upon assessment during the ordering and dispensing process. To gauge the rate of flow in mL/hour for gravity infusions, it is necessary to know how many drops per mL the administration set delivers (e.g., 10, 15, 20, 60 drops per mL). The number of drops delivered is controlled by the roller clamp (gravity flow control clamp).
 - iv. **Other alternatives.** Other alternative types of infusion devices should be considered during infusion set shortages, such as volumetric burette tubing, elastomeric devices, and other non-electronic rate controllers.

Customer Next Steps:

1. Circulate this Urgent Medical Device Recall to all those in your organisation, that need to be made aware.
If you have further distributed any products, please identify those facilities, and forward this notification to them immediately.
2. Use the BD online tool bd.com/MDS-21-4072 to identify lot numbers in your inventory which are impacted by this product recall.
NOTE: If you are unable to access the online tool, please contact your local BD representative.
3. Quarantine and destroy any units of the impacted lots and complete the customer response form on Page 4 and return to ANZ_Quality@bd.com or sandra_mckenzie@bd.com whether they have any of the impacted material so that BD may acknowledge receipt of this notification.
4. Report any adverse health consequences experienced with the use of this product to BD and the Medsafe.

Action taken by BD

BD is qualifying an alternate sterilisation facility for these devices and has commenced manufacture of replacement stock.

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 will cause. BD has increased resources to resolve this matter as quickly and effectively as possible.

Sincerely,



Sarah Murie

Quality Manager

ANZ_Quality@bd.com

14b George Bourke Drive,

Mt Wellington, Auckland, 1060, NZ

Appendix 1: Infusion Sets for Alaris™ Pumps (GP, VP, CC and SE)

Material	Description	WAND
Alaris GP Volumetric Pump Set		
60643	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LIGHT RESISTANT. 15 µm FILTER.	180703-WAND-6QMGVF
60793	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.	180703-WAND-6QMGVF
60894	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 µm FILTER.	180705-WAND-6QMWKK
60950E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.	180703-WAND-6QMGVF
60951E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.	180703-WAND-6QMGVF
60952E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.	180703-WAND-6QMGVF
60953V	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.	180703-WAND-6QMGVF
63200NY B	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. NO FILTER.	180705-WAND-6QMWKK
63401EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	180703-WAND-6QMGVF
63420EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	180703-WAND-6QMGVF
63423BE	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.	180703-WAND-6QMGVF
63477EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 µm FILTER	180703-WAND-6QMGVF
Alaris VP Volumetric Pump Set		
70593	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.	180703-WAND-6QMGVF
70093E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.	180703-WAND-6QMGVF
Alaris SE Volumetric Pump Set		
72013EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. No Filter.	180705-WAND-6QMWKK
72024EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set 15 µm Filter.	180705-WAND-6QMWKK
72953B	Alaris™ SE Pump. Infusion Set. Low Sorbing. 15 µm Filter.	180705-WAND-6QMWKK
Alaris CC Syringe Pump Set		
G30402M	Alaris™ Products. Alaris™ CC Syringe Pump, Asena™ CC Syringe Pump, IVACTM 701/711/770/P7000 Pumps. EXTENSION SET.	180703-WAND-6QMH5Y

Non Dedicated Infusion Sets and Accessories

Catalogue Number	Description	WAND
388002	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented.	180705-WAND-6QMWKK
02008382189-A	Alaris™ Products. INFUSION SET. UNVENTED. NO FILTER.	180705-WAND-6QMWKK
04100010162-A	Alaris™ Products. INFUSION SET. UNVENTED. NO FILTER.	180705-WAND-6QMWKK
04100801162-A	Alaris™ Products. INFUSION SET. UNVENTED. NO FILTER.	180705-WAND-6QMWKK
04302243317-A	Alaris™ Products. INFUSION SET. UNVENTED. NO FILTER.	180705-WAND-6QMWKK
04302260452-A	Alaris™ Products. INFUSION SET. UNVENTED. NO FILTER.	180703-WAND-6QMH5Y
500-002V	Alaris™ Products. TIVA 2 WAY SET. ANTI-SIPHON VALVE. BACK CHECK VALVE.	180703-WAND-6QMH5Y
500-003V	Alaris™ Products. TIVA 3 WAY SET. ANTI-SIPHON VALVE. BACK CHECK VALVE.	180703-WAND-6QMH5Y
500-031EV	Alaris™ Products. TIVA 3 WAY SET. ANTI-SIPHON VALVE. BACK CHECK VALVE.	180703-WAND-6QMH5Y
72951NE	Secondary Set. Oncology. Vented. Light Resistant.	180705-WAND-6QMWKK
901-020E	SmartSite™ Needle-free System. Transfusion/Blood Set. Vented. 200 µm Filter.	180705-WAND-6QMWKK
901-024E	SmartSite™ Needle-free System. Transfusion/Blood Set. Vented. 200 µm Filter.	180705-WAND-6QMWKK
901-028E	SmartSite™ Needle-free System. Transfusion/Blood Set. Vented. 200 µm Filter.	180705-WAND-6QMWKK
G59173E	Alaris™ Products. IVACTM 590 Series Volumetric Pumps. SmartSite™ needle-free system. INFUSION SET. NO FILTER.	180703-WAND-6QMGVF
MFX2254V	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. MALE TO MALE. BACK CHECK VALVE.	180705-WAND-6QMWKK
MFX2255V	Extension Set.	180705-WAND-6QMWKK
MFX2301EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. VENTED. BACK CHECK VALVE.	180705-WAND-6QMWKK
MFX2302EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. VENTED. BACK CHECK VALVE. 0.2 µm FILTER.	180705-WAND-6QMWKK
04100006162-A	Extension Set.	180705-WAND-6QMWKK
500-013V	Alaris™ Products. TIVA 3 WAY EXTENSION SET. ANTI-SIPHON VALVES. BACK CHECK VALVE.	180703-WAND-6QMH5Y
MFX2300EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. LOW SORBING (TPU/EVA) LIGHT RESISTANT. VENTED. BACK CHECK VALVE.	180705-WAND-6QMWKK



Appendix 2: Representative Images









BD Alaris™ Plus and Signature dedicated sets for the pumps above are **AFFECTED** by this notification.



BD Alaris™ System dedicated sets are **NOT AFFECTED** by this notification.

Dedicated IV Sets for BD Alaris™ Plus pumps			
Product		Purpose	Alternative
	Large Volume Infusion Pump Sets	Accurate IV infusion and transfusion delivery throughout hospital	No alternative sets – see Required Actions for Users Page 2
	CC Syringe Pump Sets with In-Line Pressure Monitoring	Accurate IV infusion and transfusion delivery in specialised areas	No alternative sets – see Required Actions for Users Page 2

Non-dedicated IV Sets and Connectors			
Product		Purpose	
	Primary and secondary administration sets	IV fluids and drugs administration	Other non-dedicated IV sets from BD or competitor portfolio. Contact local BD representative
	Transfusion Sets	Blood Transfusions	Other transfusion sets from BD or competitor portfolio. Contact local BD representative
	Vial and bag access devices	Needleless bag and vial access, including hazardous drug protection	Contact local BD representative
	Multi-way Extension Sets	To deliver multiple infusions	Other sets from BD or competitor portfolio. Contact local BD representative
	Extension Sets	Administration of IV fluid and medications	Other sets from BD or competitor portfolio. Contact local BD representative
	Valves	Back Check Valve and Anti-siphon valve for infusion delivery	Other connector technology from BD or competitor portfolio. Contact local BD representative



CUSTOMER ACKNOWLEDGEMENT FORM

Urgent Medical Device Recall Medsafe Ref: #27403

Name of Hospital:	
Name of Purchasing Group:	
Name of Recall Coordinator:	
Contact Phone for Coordinator: *Essential	
Contact email:	
Date:	
Hospital / Facility Address:	

- Please complete this acknowledgement reply form even if you do not have any stock of the listed product by ticking the appropriate boxes below

Acknowledgement: On behalf of this organisation,

<input type="checkbox"/>	I have read and understood the contents of this Urgent Medical Device Recall and confirm that our inventory has been checked and we have no inventory of the products listed in Appendix 1.
<input type="checkbox"/>	We have the units of the impacted devices as listed in Appendix 1 in our possession and I confirm that the following units have been destroyed in return for credit as indicated below. <i>(Please note there may be delays in the replacement product subject to product availability).</i>

Please credit the following product listed below

Cat #	Lot Number	Quantity Destroyed	Cat #	Lot Number	Quantity Destroyed

Please Email: ANZ_Quality@bd.com