HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Alaris™ GS, GH, CC, TIVA, PK, Enteral Syringe Pumps & Asena™ GS, GH, CC, TIVA, PK Syringe Pumps

Priority 2 – Warning

HPRA Safety Notice: SN2017(20) **Issue Date: 30 May 2017**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
BD/CareFusion, Switzerland	V30350

ISSUE
BD/Carefusion identified a potential risk of syringe siphonage with Alaris Syringe Pumps which have a broken 'plunger backplate spring' in the plunger backplate assembly. In some circumstances, this may result in a clinically significant over infusion. Neonatal and paediatric patients, or those receiving critical drugs, at low infusion rates, are considered to be the most at risk if small volumes of fluids reach the patient due to siphoning. BD/CareFusion issued a field safety notice (FSN) recommending all plunger backplate springs should be replaced on syringe pumps older than three years from date of manufacture.

ACTION OR RECOMMENDATIONS

The HPRA advises that healthcare professionals:

1. Refer to the accompanying FSN and follow the instructions provided.
2. Ensure that relevant personnel receive a copy of the FSN.
3. Acknowledge receipt of the FSN if you have not already done so.
4. Ensure all plunger backplate springs are replaced on syringe pumps older than three years from the date of manufacture.
5. Ensure all syringe pumps are regularly maintained and serviced in accordance with the manufacturer's updated preventative maintenance instructions.
6. Forward a copy of this Safety Notice and FSN, to all relevant personnel within your organisation, or to any organisation/person where these devices have been transferred.
7. Report any concerns/adverse incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs	Paediatricians
Risk Managers	Palliative Care Staff
All wards	Purchasing Managers
Clinical Directors	Supplies Managers
Nursing Managers	Hospital Pharmacists
Oncology Nurse Specialists	Nursing Homes
Nursing staff	Hospices
Paediatric wards	

BACKGROUND

BD/CareFusion has identified a risk with the Alaris Syringe Pumps that could result in a potential scenario for syringe siphonage to occur due to movement of the syringe plunger within the plunger holder mechanism depending on a number of factors including the syringe brand, syringe size used, syringe 'stiction' and height of pump/syringe in relation to the patient. The volume of siphonage is potentially greater when smaller syringes (i.e. 20ml and below) are used.

BD/CareFusion has also changed the preventative maintenance recommendations in the Technical Service Manuals. Preventative maintenance inspections should be performed at least every three years as detailed in the Technical Service Manual.

There are approximately 2665 affected units on the Irish market. Please refer to the accompanying FSN for further information.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **distributor** should be addressed to:

Aquilant Services Aquilant House	Telephone: 01-4048330 E-mail: Damien.Deehan@aquilantservices.com

21 Fonthill Business Park Clondalkin Dublin 22	

Enquiries to the **European authorised representative** should be addressed to:

CareFusion The Crescent, Jays Close Basingstoke RG22 4BS United Kingdom	Telephone: +44-1256-388-562 E-mail: colin.walters@bd.com

Enquiries to the **manufacturer** should be addressed to:

CareFusion Switzerland 317 Sárl A-One Business Centre Z.A. Vers-la-Piece No 10 Rolle, CH-1180 Switzerland	Telephone: +41-21-556-3041 E-mail: Ralph.HILBERATH@bd.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: devicesafety@hpra.ie Website: www.hpra.ie