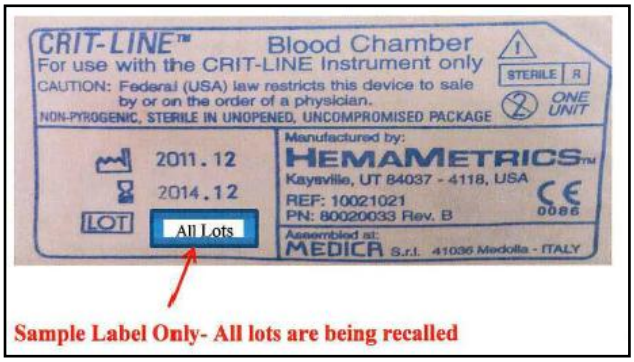
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

CRIT-LINE® Blood Chamber

Priority 2 – Warning



HPRA Safety Notice: SN2015(15) **Issue Date: 18 June 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Fresenius Medical Care Ltd	V24356

ISSUE

The Health Products Regulatory Authority (HPRA) has been notified by Fresenius USA Manufacturing Inc Renal Therapies Group of the **recall of all lots** for Product Code CL10021021 of the CRIT-LINE® Blood Chamber, due to possibility of blood chamber connection leaks associated with the use of CRIT-LINE® Blood Chamber.

ACTION OR RECOMMENDATIONS

The HPRA advise that users:

1 Immediately examine your stock for CRIT-LINE® Blood Chambers.

2 If any product with product code CL10021021 is found, discontinue use immediately. A listing of all lot numbers is included in the Field Safety Notice (FSN).

3 Follow the actions outlined by Fresenius Medical Care in the FSN.

4 Forward this Safety Notice to other departments or facilities, and to all those that need

to be aware of this recall and any centres/organisation where devices may have been transferred.

5 Contact Fresenius Medical Care if you have any additional concerns or questions.

TARGET GROUPS

Hospital Managers / CEOs	Adult intensive care units
Risk Managers	Day surgery units
Clinical Directors	Paediatric wards
Clinical Engineers	Renal centres
Nursing Managers	Oncology units
Nursing staff	Paediatric intensive care units
Purchasing Managers	Neonatal units
Palliative Care Units	Theatres
Intensive Care Units	Healthcare professionals who use these devices
Anaesthetic Officers	
Nephrology Departments	

BACKGROUND

Fresenius Medical Care Renal Therapies Group, LLC received an increased number of complaints relating to blood chamber connection leaks during user of the CRIT-LINE Blood Chamber.

The manufacturer has outlined that the health consequences from blood loss may include low blood pressure, dizziness, shortness of breath, confusion, chest pain, loss of consciousness, shock, and in extreme cases, excessive blood loss may lead to death. Separation in the connection of the blood circuit that allows blood loss could provide entry for bacteria with resultant risk of bacteria, blood stream infection, and sepsis that may lead to death.

The manufacturer has issued a FSN advising of the issue – see attached.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

Fresenius USA Manufacturing, Inc.
695 North 900 West
84037-4118, Kaysville
USA

Telephone: 801-549-9224
E-mail: doug.cox@fmc-na.com

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

Medical Device Safety Service (MDSS GmbH)
Schiffgraben 41
30175 Hannover

Telephone: +49 511 6262 8630
Fax: +49 511 6262 8633
E-mail: vigilance@mdss.com

Germany

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