HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Prismaflex and OXIRIS S sets – Risk of kinked line

Priority 2 – Warning

HPRA Safety Notice: SN2019(19) **Issue Date: 31st May 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Gambro Industries / Baxter	V39968

ISSUE

The HPRA has been informed that some access lines in specific lots of Prismaflex and OXIRIS S sets may be kinked. The affected set types may be used in haemodialysis, continuous renal replacement therapy (CRRT) and therapeutic plasma exchange (TPE). If a line is kinked it may prevent blood flow which could result in a delay in therapy, clotting in the blood circuit or haemolysis. If blood flow is prevented, the Prismaflex or Primax Control Unit will alarm.

The affected sets and lots which have been placed on the Irish market are detailed below and in the accompanying field safety notice (FSN).

ACTION OR RECOMMENDATIONS

The HPRA advises that healthcare professionals:

1. Refer to the accompanying FSN and follow the instructions provided.
2. Acknowledge receipt of the FSN if you have not already done so.
3. Forward a copy of this safety notice and the FSN to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

All wards	Nursing Managers
Hospital Managers / CEOs	Nursing Staff
Cardiologists	Pharmacists
Clinical Directors	Purchasing Managers
Clinical Engineers	Renal Consultants
Dialysis Centres	Respiratory Consultants
General Practitioners	Risk Managers
Nephrology Departments	Transplant co-ordinators

BACKGROUND

Following customer reports of kinked access lines, Baxter is issuing an FSN advising users to inspect affected Prismaflex and OXIRIS S sets prior to treatment.

Baxter has indicated that customers can continue to safely use sets from the affected lots listed below if no kink is observed. If a kink is observed before treatment, users are advised to replace the set as per the instructions for use. If a kink is observed during treatment, users are advised to interrupt therapy, return extracorporeal blood in the circuit to the patient and replace the set prior to continuing therapy.

Affected sets

- **Prismaflex M100 sets,** with expiry between 2020-03-01 – 2021-03-01
- **Prismaflex HF1000 sets** with expiry between 2020-03-01 – 2021-02-01
- **Prismaflex ST150 sets** with expiry between 2020-03-01 – 2021-02-01
- **Prismaflex TPE2000 sets** with expiry between 2021-01-01 – 2022-02-01
- **OXIRIS S** with expiry between 2020-03-01 – 2021-03-01

Please refer to the accompanying FSN for further information.
The HPRA is issuing this Safety Notice to raise awareness of this issue.

MANUFACTURER CONTACT INFORMATION

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

Baxter (on behalf of Gambro Industries)
Unit 7 Deansgrange Business Park
Blackrock
Co. Dublin

Telephone: +353-1-2065500
E-mail: qa_dublin@baxter.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