Obex Medical Limited 303 Manukau Rd, Epsom, PO Box 26511, Auckland 1344 New Zealand
Telephone +64 9 630 3456, Toll Free 0800 656 239, Facsimile +64 9 630 9009
www.obex.co.nz

Product Safety Alert
Vyaire enFlow Fluid Warming System

Date: 13th March 2019
Medsafe reference#: 24289

Attention: Recall Administrators, Clinical Product Coordinators, Risk Management, End-users of the enFlow® fluid warming system

Dear Valued Customer,

This Product Safety Alert is being issued due to concerns raised regarding the potential risk of aluminium exposure to patients associated with the enFlow® fluid warming system. Obex Medical Ltd is the New Zealand distributor of the enFlow® fluid warming system. This action is being taken in consultation with Medsafe, New Zealand Ministry of Health and CARSL Consulting (New Zealand WAND sponsor).

As part of this Product Safety Alert, we recommend that all customers discontinue use of the enFlow Disposable Cartridge associated with the enFlow® fluid warming system ("enFlow®") as follows:

Obex Part Number	Description
VSI-980202EU	enFlow Disposable Sterile Cartridge with IV Extension Set

Guidance for end-users of this product:

We recommend that customers discontinue the use of the enFlow Disposable Cartridges. To ensure patients receive this much needed therapy, we recommend utilising an alternate fluid warming device until the investigation into the potential patient safety risk can be thoroughly investigated.

If no alternative is available, we recommend that end-users carry out and document a local risk assessment based on a clinical risk-benefit analysis before using this device.

Customers who are unable to transition to an alternative fluid warming system are recommended to follow the instructions below:

- Only use with normal saline.
- Do not use the Disposable Cartridge for more than 24 hours.
- Limit enFlow® Disposable Cartridge use to not more than 3 Disposable Cartridges per single-patient use, with a duration of use up to 24 hours for a maximum duration of device usage up to 72 hours.
- Observe the enFlow® Instructions for Use (IFU), which note that the Disposable

Obex Medical Limited 303 Manukau Rd, Epsom, PO Box 26511, Auckland 1344 New Zealand
Telephone +64 9 630 3456, Toll Free 0800 656 239, Facsimile +64 9 630 9009
www.obex.co.nz

Cartridge contains aluminium, and that end-users should review the preparation or solution manufacturer's instructions for use about chemical sensitivity.

Actions to be taken by the end-users:

- If transition to an alternative fluid warming system is available, immediately quarantine all units of part number VSI-980202EU until further investigation has been completed by the manufacturer.
- All end-users are required to read and take into consideration the guidance listed in the content of this Product Safety Alert.
- Please report any adverse events related to this Product Safety Alert to your local Obex Medical Sales Consultant or email Natasha.chand@obex.co.nz immediately.

The manufacturer, Vyaire Medical, is working diligently to complete a comprehensive investigation into the concerns raised regarding the potential risk of aluminium exposure associated with the enFlow® fluid warming system.

This notice must be shared with appropriate personnel, including down to the end-user level, within your organisation or to any organisation where the potentially affected devices may have been transferred.

Should you need further information or support on this matter please contact:

Peter Burnand
Business Unit Leader - Anaesthesia / Critical Care

Mob: 021 490 489

Email: peter.burnand@obex.co.nz

We recognise this situation is a disruption to your normal operations and we sincerely apologise. Thank you again for your immediate assistance in this matter.

Yours sincerely,

Natasha Chand
Regulatory, Quality and Customer Experience Manager
Obex Medical Ltd

Cc: Brian Day (CARSL)