URGENT RECALL NOTIFICATION
enFlow® Fluid Warming System - Disposable Cartridges

Attention: Distributors and End-Users of the enFlow® fluid warming system.

Dear Valued Customer,

The purpose of this communication is to inform you of a Global Recall initiated by Vyaire Medical (a company comprised of the Respiratory Solutions businesses previously a part of CareFusion/BD) involving the enFlow® Disposable Cartridges used with the enFlow® fluid warming system ("enFlow®") from the global market.

Vyaire's decision to initiate this URGENT RECALL NOTIFICATION was based on recently conducted internal testing which has indicated that there is the potential to elude aluminum from the enFlow® Disposable Cartridge during intravenous warming therapy with fluid and blood solutions. This Global Recall is being conducted based on the potential patient safety risk associated with aluminium toxicity.

Vyaire is notifying all customers to suspend use of the following enFlow® Disposable Cartridge Part Numbers:

Vyaire Part Number	Description
980200EU	enFlow® Disposable Cartridge
980202EU	enFlow® Disposable Cartridge with IV Extension Set

Actions to be taken by the End-Users / Distributors

- Inspect current inventory on-hand. A 100% physical inventory should immediately be performed to identify and remove all enFlow® cartridges devices from commercial distribution due to the identified potential patient safety risk.
- Destroy all affected product(s) in-stock in accordance with your facility's destruction protocol. If you are not able to destroy the product on site or require further assistance, please contact us at VyaireSupport@stericycle.com or call [insert country specific phone number] for assistance.
- Complete the enclosed Customer Response Form and return it to VyaireSupport@stericycle.com. You will receive credit within 45 days of returning your Customer Response Form.
- Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to Vyaire's International Technical Support Department by e-mail GMB-DE-EnFlow®-Service@Vyaire.Com or telephone at : +49 931 4972 393 (Office).

Distributors Only:

- If you are an end-user or distributor that has further distributed affected product to other persons or facilities, promptly forward a copy of this URGENT RECALL NOTIFICATION

and Response Form to those recipients and include contact information of those parties to Vyaire for tracking purposes. If you need assistance with this, please contact us at VyaireSupport@stericycle.com or call [insert country specific phone number] for assistance.

Actions being taken by the manufacturer:

- A global recall notification will be issued to all customers globally.

  Customers are encouraged to retain their separate enFlow® Warmer, Controller, and accessories.

Vyaire puts patient safety above all else. We recognize the inconvenience this issue may cause your facility and thank you for your support in this important matter. Vyaire is committed to ensuring the highest standards of safety and effectiveness for its products – and is in the best interests of both our customers and their patients. For any additional questions concerning this notice, please contact VyaireSupport@stericycle.com.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.