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.

Richard Brown,
VP Regulatory Management

enFlow® URGENT RECALL NOTIFICATION | Frequently Asked Questions (FAQs)

1. What is enFlow®?

- enFlow® is a device used to prevent the condition hypothermia in patients who are receiving fluids intravenously. The device warms these fluids within seconds before they are introduced to the patient, allowing for time-critical surgical and other procedures to occur without pause.

- enFlow® has been in the market since 2006. The device underwent a rigorous technical review for safety and effectiveness before receiving clearance for use by the U.S. Food and Drug Administration and CE Mark approval in the EU.

2. Why has Vyaire initiated this Recall Notification regarding enFlow®?

- 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 notification is being conducted based on the identified potential patient safety risk associated with exposure to aluminum.

- At Vyaire, we put patient safety above all else, and therefore take any data point regarding the safety of our products seriously.

3. Have any patient injuries been recorded?

- Vyaire has received zero (0) customer complaints *to-date* related to the signs, symptoms or complications associated with aluminum toxicity subsequent to patient use.

- Vyaire is continuing to monitor and initiate customer reports, as applicable, that relating to concerns associated with enFlow® Warming System.

4. Can I continue to use the product?

- No, this URGENT RECALL NOTIFICATION has been initiated due to concerns raised regarding the potential risk of aluminum exposure to patients. It is important that our distributors and healthcare facilities take prompt action and follow their facility's procedures for destruction of the enFlow® Disposable Cartridges. Attention to this matter is mandated by Regulatory Agencies around the globe. In cases where no alternate fluid warming device is available a Medical Necessity Form may be obtained by contacting **VyaireSupport@stericycle.com**.

5. Are all enFlow® units affected by this URGENT RECALL NOTIFICATION?

- This notification applies to all units of the following part numbers: 980200EU and 980202EU within the 3-year expiry commercially distributed.

6. **What should I do with my inventory of the enFlow® Fluid Warming System?**

<u>enFlow® Disposable Cartridge (part numbers: 980200EU, and 980202EU)</u>

- Customers should sequester and quarantine all units of the following part numbers: 980200EU, and 980202EU in accordance with your facility's destruction protocol.
- Should your facility not allow for destruction of affected product, contact **VyaireSupport@stericycle.com.**

<u>enFlow® Warmer, Controller, and accessories</u>

- Customers are encouraged to retain inventory of the enFlow®Warmer, Controller, and accessories.
- Should your facility choose to return inventory of the enFlow®Warmer, Controller, and accessories please contact **VyaireSupport@stericycle.com.**

7. **How will I receive credit for the enFlow® Fluid Warming System Parts that our facility destroys/ returns?**
   - Your request for credit will be managed through the return of the customer response form with PO# provided.

8. **Are there alternative cartridges I can buy to use with my current enFlow® warmer?**
   - There are no alternative cartridges available at this time.

9. **What should I do if an adverse event occurs following the use of enFlow®?**
   - Any adverse reactions experienced with the use of this product, and/or quality problems should be reported to Vyaire's International Tech Support Dept by e-mail GMB-DE-EnFlow®-Service@Vyaire.Com or by telephone at: +49 931 4972 393 (Office).

10. **I'd like more information on the** URGENT RECALL NOTIFICATION**. Who should I contact?**
    - Please contact: **VyaireSupport@stericycle.com**

26125 N. Riverwoods Blvd.
Mettawa, IL 60045

Vyaire.com

CUSTOMER RESPONSE FORM

enFlow® fluid warming system - Disposable Cartridges

Indicate quantity of boxes/eaches that you will be destroying for the Model / Part Numbers (as applicable). Purchase order (PO) # must be provided in order to process credit request:

Model / Part Number	Description	Quantity (Boxes of 10)	Quantity (Individual Cartridges)	Purchase Order #
980200EU	enFlow Disposable Cartridge			
980202EU	enFlow Disposable Cartridge with IV Extension Set			

Name of Healthcare Facility/Distributor	
Address of Healthcare Facility/Distributor	
Email address	
Telephone number	
Name of person completing form (Please Print)	

By signature completion of this form, I certify the following:

- ✓ I have read and understand the contents of this voluntary Recall Notice and confirm that I understand all instructions noted within the notification.
- ✓ I have performed a **100% physical inventory inspection** and I have accurately reported the quantity in stock above.
- ✓ I certify that I have destroyed all affected product indicated.
- ✓ Applicable to **distributors Only**: I certify that I have further notified my end user customers (indicate method below).

☐ Mail ☐ E-mail ☐ Phone ☐ Other _____

Signature of person completing form	

Please return this form via email to: VyaireSupport@stericycle.com