Urgent Safety Communication

Urgent FSN's of enFlow IV Fluid and Blood Warmers Manufactured by Vyaire Medical

<table>
<tr><td>Device/ Product Name:</td><td>enFlow IV Fluid and Blood Warmers</td></tr>
<tr><td>Lot numbers/Serials:</td><td>
<table>
<tr><th>Part Number</th><th>Description</th></tr>
<tr><td>980200EU</td><td>enFlow® Disposable Cartridge</td></tr>
<tr><td>980202EU</td><td>enFlow® Disposable Cartridge with IV Extension Set</td></tr>
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</td></tr>
<tr><td>Manufacturer:</td><td>Vyaire Medical</td></tr>
<tr><td>Problem:</td><td>SFDA would like to bring to your attention the URGENT FSN issued by Vyaire Medical regarding enFlow IV Fluid and Blood Warmers which indicated that there is a potential to elude aluminum from the enFlow® Disposable Cartridge during intravenous warming therapy with fluid and blood solutions.</td></tr>
<tr><td>Recommendation/Actions:</td><td>

Inspect current inventory on-hand. A 100% physical inventory should immediately be performed to identify and remove all enFlow® cartridges devices due to the identified potential patient safety risk.
Destroy all affected product(s) in-stock in accordance with your facility's destruction protocol.
Report to SFDA any adverse events suspected to be associated with enFlow IV Fluid and Blood Warmers through National Center for Medical Devices Reporting (NCMDR) Or Saudi Vigilance Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices.

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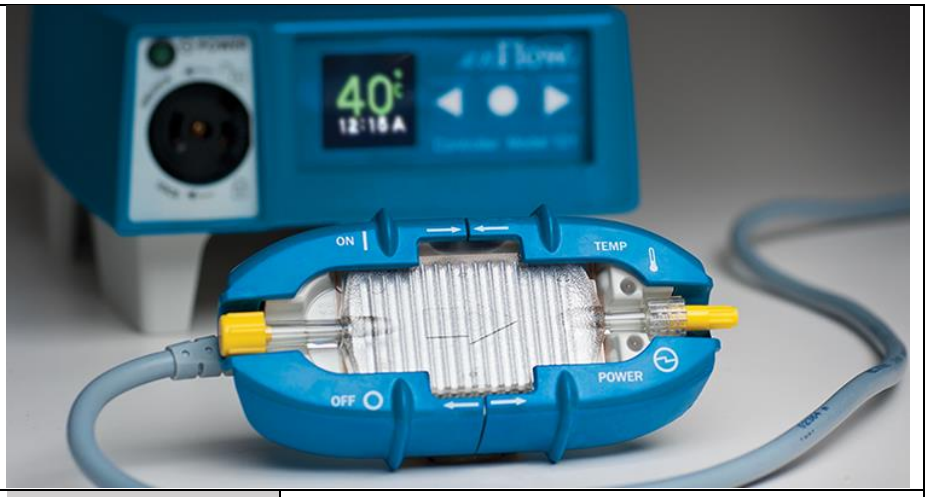
Devices/Products photo:		
Authorized Representative Details	**Company name:**	**Vyaire Medical**
	Contact Person:	**Mohammed Alsheikh**
	Phone:	**+966 504419883**
	Email:	**mohammed.alsheikh@spectromedgroup.com**

For further information, please **see the letter** issued by the manufacturer. (**Click Here**)

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2479
Fax: +966 (11) 2757245
Or
Saudi Vigilance

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team

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

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

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