Urgent Field Safety Notice – FSCA 19-001

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 Field Safety Corrective Action initiated by Vyaire Medical (a company comprised of the Respiratory Solutions businesses previously a part of CareFusion/BD) involving enFlow® fluid warming system.

This Field Safety Corrective Action has been initiated due to concerns raised regarding the potential risk of aluminium exposure to patients. As part of this Field Safety Corrective Action, Vyaire is recommending that all customers discontinue use of the enFlow Disposable Cartridges associated with the enFlow® fluid warming system ("enFlow®") as follows:

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

Guidance for end users of these products:

Vyaire is recommending that customers discontinue the use of the enFlow Cartridges. To ensure patients receive this much needed therapy, Vyaire recommends utilizing an alternate fluid warming device until the investigation into the potential patient safety risk can be thoroughly investigated.

If no alternative is available, Vyaire recommends that users carry out and document a local risk assessment based on a clinical risk-benefit analysis before using these devices.

Vyaire is providing the following guidance to customers who are unable to transition to an alternative fluid warming system, to follow the instructions below:

- Only use with Normal Saline.
- Do not use the Disposable Cartridge for more than 24 hours.
- Limit enFlow® cartridge use to not more than 3 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 cartridge contains aluminium, and that users should review the preparation or solution manufacturer's instructions for use about chemical sensitivity.

Identified issues, potential harm:

Vyaire is not aware of a single incident related to enFlow® in a clinical setting where aluminum was observed to have been transmitted to a patient in amounts above scientifically-recognized

safe limits, nor have there been any reported adverse events related to aluminum exposure. Vyaire's investigations are still ongoing to review the extent of the issue. We may communicate further following completion of the investigation.

Actions to be taken by the end-users:

- If transition to an alternative fluid warming system is available immediately sequester and quarantine all units of the following part numbers: 980200EU and 980202EU.
- All users are required to read and take into consideration the guidance listed in the content of this FSN.
- Return the completed and signed Response Forms to Vyaire as per the provided instructions.

Actions to be taken by the distributors:

- Immediately notify all affected end-user customers.
- Initiate an immediate ship-hold for the following part numbers: 980200EU and 980202EU.
- Return of the completed and signed Response Forms to Vyaire Medical as per the provided instructions.

Actions being taken by the manufacturer:

- A field safety notice (FSN) will be issued to all customers globally.
- Vyaire 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.

For all events that reasonably suggest being related to the subject of this FSN please report to Vyaire without delay including all available information that is relevant and could be important for further investigation of those cases.

Should you need further information or support on this matter please contact Vyaire's International Tech Support Dept by e-mail GMB-DE-Enflow-Service@Vyaire.Com or by telephone at: +49 931 4972 393 (Office) and your cause will be paid further attention by the appropriate parties.

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

Richard Brown,
VP Regulatory Management