

Potential Risk of Aluminum Leaching with Use of Certain Fluid Warmer Devices - Letter to Health Care Providers

September 15, 2021

The U.S. Food and Drug Administration (FDA) is reminding health care providers about the use of certain fluid warmers and the potential for aluminum leaching and exposing the patient to high levels of aluminum. Based on information reviewed by the FDA, aluminum leaching may occur when the fluid warmer is designed with an aluminum heating element where the heated aluminum is in direct contact with the fluids or blood products being administered to a patient.

The FDA has identified the devices listed in the table below as having this type of design. Three original equipment manufacturers (Eight Medical International BV, Smisson Cartledge Biomedical and Smith Medical) provided revised instructions for use for these devices, a type of voluntarily recall action, which were initiated on the dates shown. Users who did not purchase devices from these original equipment manufacturers may not be aware of the revised instructions. A fourth original equipment manufacturer (Vyair Medical) voluntarily removed its product from the market.

Manufacturer Name	Device Information	Recall Notice
Eight Medical International BV	Recirculator 8.0 Disposable Lavage kit (Product Code: 8100) Lot Numbers: 20021361, 20202106, 20018480, 19854186, 20019438, 19854185, 20019438, 19854184, 18687686	Recall Notice (/medical-devices/medical-device-recalls/eight-medical-international-recalls-recirculator-80-disposable-lavage-kits-due-potential-exposure) Initiated June 4, 2021

Manufacturer Name	Device Information	Recall Notice
Smisson-Cartledge Biomedical	ThermaCor 1200 Disposable Sets Disposable Set Models: PTC-1200, DNC-1200, PNC-1200	Recall Notice (/medical-devices/medical-device-recalls/smisson-cartledge-biomedical-llc-recalls-thermacor-1200-disposable-sets-risk-patient-contact) Initiated February 18, 2021
Smiths Medical	Level 1 Fluid Warmer Models: H-1000, H-500 Level 1 Fluid Warming System Models: H-1028, H-1200 Level 1 Normothermic I.V. Fluid Administration Set Models: D-100, D-300, D-50, D-60HL, DI-100, DI-300, DI-50, DI-60HL NORMOFLO Irrigation Warming Set Models: IR-40, IR-500, IR-600, IR-700, IRI-600, IRI-600B, IR-700	Recall Notice (/medical-devices/medical-device-recalls/smiths-medical-recalls-normoflo-irrigation-fluid-warmers-and-warming-sets-due-possibility-harmful) Initiated August 6, 2021

Manufacturer Name	Device Information	Recall Notice
Vyaire Medical	enFlow Fluid Warmer System Disposable Cartridges Models: 980200EU enFlow - Disposable Cartridge, 980202EU enFlow - Disposable Cartridge with IV Extension Set	Recall Notice (https://wayback.archive-it.org/7993/20201222124155/https://www.fda.gov/medical-devices/medical-device-recalls/vyaire-medical-recalls-enflow-fluid-warming-system-disposable-cartridges-due-potential-risk-exposure) ⏏ (http://www.fda.gov/about-fda/website-policies/website-disclaimer) Initiated March 13, 2019

Recommendations

The FDA recommends health care providers:

- Be aware that aluminum leaching from some fluid warmers may occur when **both** of the following conditions are present:
 - The fluid warmer is designed with an aluminum heating element.
 - The aluminum heating element is in direct contact with the fluids or blood products being administered.
- Be aware that higher levels of aluminum leaching may generally occur under the following conditions:
 - Lower flow rates
 - Higher warming temperatures
 - Certain fluids, including balanced electrolyte solutions, may leach more aluminum than other solutions (such as Lactated Ringers solutions)
 - Longer duration of use.
- Be aware that exposure to high levels of aluminum may result in adverse clinical effects and symptoms such as:
 - Bone, muscle pain and muscle weakness
 - Blood and metabolic derangements (such as increased levels of calcium or interference with iron absorption leading to anemia)
 - Neurological effects (such as altered consciousness, seizures, and coma).

- Conduct a clinical benefit-risk analysis before using a fluid warmer which has an aluminum heating element and is in direct contact with the fluids or blood products. To mitigate potential harm from aluminum leaching:
 - When possible, avoid using these fluid warmers in high-risk patient populations including those with poor renal function, neonates, infants, pregnant mothers, and the elderly because exposure to small amounts of aluminum may lead to toxicity.
 - If available, use alternative therapies to maintain patient temperature, such as an alternative fluid warmer which uses a different design, or a warming blanket.
- For specific information on steps to take to mitigate aluminum leaching, review the applicable recall notices from each company (see table above) or contact the manufacturer directly for more information.

Background

Fluid warmers are generally used to warm intravenous (IV) fluids and blood products to maintain normal temperature or prevent hypothermia and can also be used during surgical procedures for surgical site irrigation or lavage in different areas of the body. These devices have different clinical uses which impact their device design and specifications, including flow rate and heating capabilities, duration of use, and intended patient populations.

Data from *in vitro* testing with uncoated fluid warmers indicates that in certain cases (for example, lower flow rates, higher temperatures, certain infusates such as balanced electrolyte solutions, and longer duration of use), the quantity of aluminum released from these devices may significantly exceed the FDA-derived threshold value of 25 mcg/L, which was established for small and large volume parenteral administration. The dissolving (elution) of aluminum into the body may lead to systemic aluminum exposure and subsequent toxicity under some clinical situations and with high-risk patient populations including neonates, infants, pregnant mothers, and the elderly as well as patients with poor renal function or on dialysis. Literature reports describe neurotoxicity concomitant with increased aluminum serum levels. For example, manifestations of encephalopathy after irrigation with solutions containing aluminum have been reported at serum concentrations as low as 17, 22, or 40 mcg AL/L blood. See [Additional Resources](#) below for details on the literature reports and data.

The FDA is not aware of any reported cases of aluminum toxicity or high levels of aluminum exposure associated with the clinical use of these fluid warmers. Symptoms of harmful levels of aluminum exposure may not be easily recognized and may include bone or muscle pain and weakness, anemia, seizures, or coma. However, it is possible that symptoms associated with high levels of aluminum exposure may be attributed to other comorbidities, disease processes, or side effects from other medications due to lack of awareness of this potential source of aluminum.

FDA Actions

In addition to reminding users who were already provided revised instructions for use by the original equipment manufacturers, we have issued this letter to health care providers to assure that users who may have purchased these models from other sources are aware of these recommendations for reducing or eliminating the risk of aluminum exposure.

The FDA is working with the applicable manufacturers to further mitigate aluminum exposure with this type of device design.

The FDA will continue to keep health care providers and the public informed if significant new information becomes available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with the fluid warmers.

- Voluntary reports can be submitted through [MedWatch, the FDA Safety Information and Adverse Event Reporting program \(/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda\)](https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable [Medical Device Reporting \(MDR\) regulations \(/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities\)](https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements \(/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities\)](https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Additional Resources

- Cabrera JA, Borton LK, Barrett G. Quantified aluminium levels released into blood and fluids using the Level 1 Fast Flow Fluid Warmer (<https://pubmed.ncbi.nlm.nih.gov/31916604/>). *Anaesthesia* 2020; 75: 271–2.
- Kanwar, V. S., Jenkins, J. J., 3rd, Mandrell, B. N., & Furman, W. L. (1996). Aluminum toxicity following intravesical alum irrigation for hemorrhagic cystitis (<https://pubmed.ncbi.nlm.nih.gov/8614395/>). *Medical and Pediatric Oncology*, 27(1), 64–67.
- Perl, T., Kunze-Szikszay, N., Bräuer, A., Quintel, M., Röhrig, A. L., Kerpen, K., & Telgheder, U. (2019). Aluminium release by coated and uncoated fluid-warming devices (<https://pubmed.ncbi.nlm.nih.gov/30793280/>). *Anaesthesia*, 74(6), 708–713.
- Perl, T. (2021). Aluminium release and fluid warming: provocational setting and devices at risk (<https://pubmed.ncbi.nlm.nih.gov/34044771/>). *BMC Anesthesiology*, 21(1).
- Phelps, K. R., Naylor, K., Brien, T. P., Wilbur, H., & Haqqie, S. S. (1999). Encephalopathy after bladder irrigation with alum: case report and literature review (<https://pubmed.ncbi.nlm.nih.gov/10487408/>). *The American Journal of the Medical Sciences*, 318(3), 181–185.
- U.S. Food and Drug Administration. Labelling aluminium in large and small volume parenterals used in total parenteral nutrition, 21CFR201.323, 1 April 2020, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?fr=201.323> (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?fr=201.323>)

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) (DICE).