

# NOT ALL RAPID INFUSERS ARE CREATED EQUAL

## Level 1® Fast Flow Fluid Warmer

### Aluminum Heat Exchanger

Studies have shown many blood and fluid warmers leach unsafe levels of aluminum into infusates, which has led to the US FDA and global regulatory bodies issuing safety notices and recalls of affected warmers.<sup>1,2,3,4</sup>

### Class I Recalls:

- Level 1® Fast Flow Fluid Warmer and NORMOFLO® Irrigation Warming System (August 2021)

### Product Availability:<sup>5</sup>

- As of June 1, 2023, Level 1® Fast Flow Fluid Warmer is not available for sale in the European Union

### FDA Notice Excerpts:<sup>6</sup>

- "Avoid using the identified fluid warmers when treating at-risk populations: patients with poor renal function, neonates, infants, pregnant mothers, and elderly patients."
- "If available, use alternative therapies to maintain patient temperature, such as an alternative fluid warmer which uses a different design..."

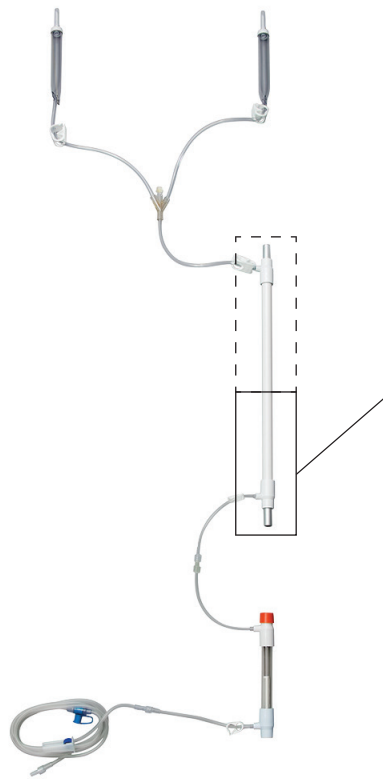


Figure A. Level 1® D-100 Fluid Set

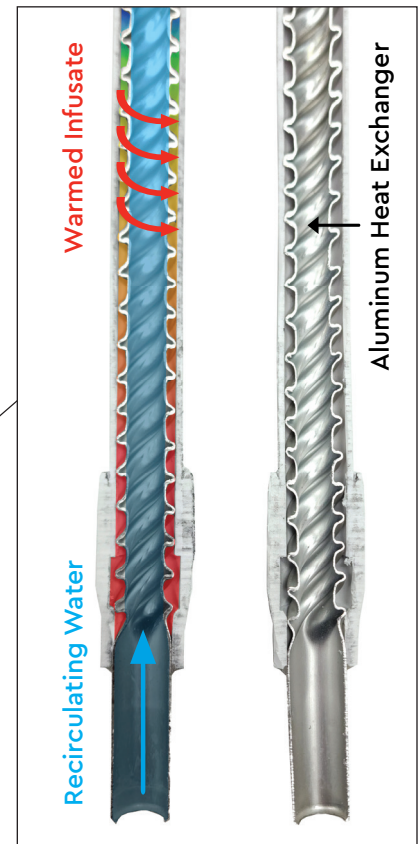


Figure B. Level 1® D-100 Fluid Set Cross Section

## The Belmont® Rapid Infuser RI-2

### Stainless Steel Heat Exchanger

The Belmont Rapid Infuser RI-2 is the **ONLY** rapid infuser to offer a **100% aluminum-free** fluid path along with high-flow performance\* and comprehensive safety featured designed to reduce transfusion related complications.

### Why worry when you don't have to?

- Sixteen medical grade stainless steel rings within the fluid path combine with dry, electromagnetic induction to precisely deliver warmed fluids with zero aluminum exposure.

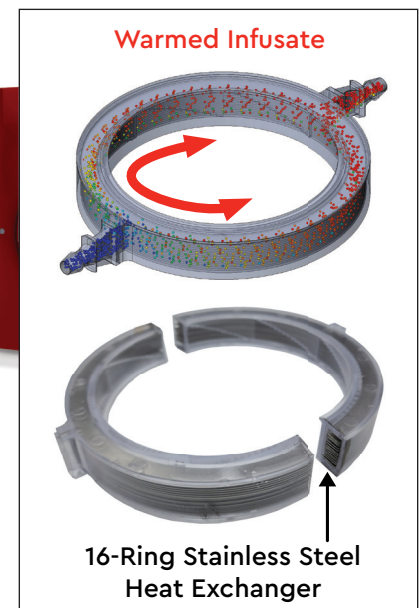


Figure C. 3-Spike Heat Exchanger

\*Precise control of fluid delivery from 2.5 to 1000 mL/min

1 Cabrera, J.A., Borton, L.K. and Barrett, G. (2020), Quantified aluminium levels released into blood and fluids using the Level 1 Fast Flow Fluid Warmer. *Anaesthesia*, 75: 271-272. <https://doi.org/10.1111/anae.14881>

2 Perl, T., Kunze-Szikszay, N., Bräuer, A. et al. Aluminium release and fluid warming: provocation setting and devices at risk. *BMC Anesthesiol* 21, 163 (2021). <https://doi.org/10.1186/s12871-021-01378-7> - <https://bmcanesthesiol.biomedcentral.com/articles/10.1186/s12871-021-01378-7>

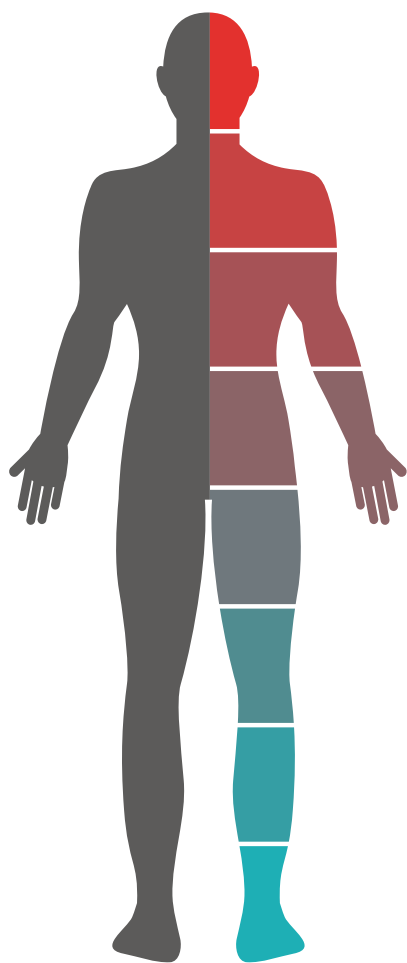
3 Perl, T., Kunze-Szikszay, N., Bräuer, A., Quintel, M., Röhrig, A.L., Kerpen, K. and Telgheder, U. (2019), Aluminium release by coated and uncoated fluid-warming devices. *Anaesthesia*, 74: 708-713. <https://doi.org/10.1111/anae.14601> <https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/10.1111/anae.14601>

4 Pike H. enFlow fluid warming device: warning over risk of aluminum toxicity *BMJ* 2019; 364 :l1126 doi:10.1136/bmj.l1126 - <https://www.bmj.com/content/364/bmj.l1126>

5 Level 1 fast flow fluid warmer. (2023, June 1). ICU Medical - Human Connections. <https://www.icumed.com/about-us/news-events/news/2023/level-1-fast-flow-fluid-warmer>

6 Center for Devices and Radiological Health. "Potential Risk of Aluminum Leaching with Use of Certain Fluid Warmer Devices - Letter to Health Care Providers." U.S. Food and Drug Administration, FDA

# POTENTIAL HEALTH EFFECTS OF TOXIC ALUMINUM EXPOSURE<sup>7</sup>



Alzheimer's disease and dementia



Congenital heart defects, inflammation and dysfunction of the myocardium and cardiovascular thrombosis



Pulmonary lesions and pulmonary edema



Crohn's disease and inflammatory bowel diseases



Male/female infertility, pregnancy failures, and poor fetal growth and fetal death



Slow growth and development in children



Osteoporosis, osteomalacia, rickets, exostosis, osteodystrophy and osteitis fibrosa

<sup>7</sup> Igbokwe IO, Igwenagu E, Igbokwe NA. Aluminium toxicosis: a review of toxic actions and effects. *Interdiscip Toxicol.* 2019;12(2):45-70. doi:10.2478/intox-2019-0007 - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7071840/>

## Literature References:

- **Quantified aluminium levels released into blood and fluids using the Level 1 Fast Flow Fluid Warmer**  
*J. A. Cabrera, L. K. Borton, G. Barrett, Anaesthesia, February 2020*
- **Aluminium release and fluid warming: provocation setting and devices at risk**  
*T. Perl, N. Kunze-Szikszay, A. Bräuer, BMC Anesthesiol, May 2021*
- **Aluminium release by coated and uncoated fluid-warming devices**  
*T. Perl, N. Kunze-Szikszay, A. Bräuer, M. Quintel, A. L. Röhrig, K. Kerpen, U. Telgheder, Anaesthesia, June 2019*
- **enFlow fluid warming device: warning over risk of aluminum toxicity**  
*H. Pike, BMJ, March 2019*

## Ready to make a switch to Belmont?

Our devices are designed to be safely operated by a single operator, and this is not the only way we can help you save costs. We are confident that with our medical technologies, you have the right devices in hand to achieve the best clinical outcomes while also reducing known complications, such as air embolism.

**SAVING LIVES. TOGETHER.**

Email [sales@belmontmedtech.com](mailto:sales@belmontmedtech.com) for more information or to set up a product demonstration, or give us a call at **+1 978-663-0212**



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