

## Statement from Fresenius Medical Care

**Date:** October 25, 2023

**Topic:** FDA class I recall of Fresenius Medical Care 2008T dialysis machines

Fresenius Medical Care's top priority is to always provide safe, high-quality, and life-sustaining acute and chronic dialysis therapy.

The voluntary 2008T recall classified and published by the Food and Drug Administration (FDA) does not involve the removal of any Fresenius Medical Care products from the marketplace. In early 2022, Fresenius Medical Care voluntarily reported to the FDA a finding of non-dioxin-like (NDL) polychlorinated biphenyl acids, or PCBAs (not polychlorinated biphenyls, or PCBs) in the peroxide cross-linked silicone tubing in its 2008 Series hemodialysis machines. The company did not find any reports of known health risks or impact of PCBAs in medical literature. We worked closely with the FDA and have since resolved the issue. After conducting extensive investigations and testing to determine the potential impact on patient health, it was found that PCBAs in new dialysis machines rinse out after 36 days, or 486 hours, of use. Fresenius Medical Care informed the small subset of customers with impacted machines. We worked diligently to change to and gain FDA clearance for new platinum catalyst silicone tubing. In October 2022, the FDA cleared the 2008 Series hemodialysis machine with new platinum catalyst silicone tubing for use. All new machines, shipped since October 27, 2022, use platinum catalyst silicone tubing that does not contain PCBAs.

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