



August 25th, 2022

2008 Series Hemodialysis Machine Spare Parts Release

This is a follow up to the May 6, 2022 Fresenius Medical Care notification entitled: "Silicone Tubing in Hemodialysis Machines" regarding the voluntary distribution hold on machine spare parts containing peroxide catalyst tubing.

www.freseniusmedicalcare.com/fileadmin/data/com/pdf/HCP/services/Fresenius_Field_Notification_FINAL.pdf

We are pleased to announce that we anticipate shipping spare parts containing silicone tubing for 2008 Series hemodialysis machines beginning August 26, 2022. New shipments of spare parts will use platinum catalyst silicone tubing instead of peroxide catalyst silicone tubing. Orders for these spare parts will be prioritized based on availability and the date the order was placed. The FDA is aware the spare parts will contain platinum catalyst tubing.

At this current time, new 2008 Series hemodialysis machines remain on a voluntary distribution hold.

Please contact the Fresenius Medical Care Medical Information Office at medical.information@fmc-na.com or 1-855-616-2309 with any questions or inquiries regarding this communication.