



October 28, 2022

2008 Series Hemodialysis Machine 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 new machines and 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 new machines containing our new tubing for 2008 Series hemodialysis machines beginning October 28, 2022. New shipments of machines will use platinum catalyst silicone tubing instead of peroxide catalyst silicone tubing previously employed. Orders for these machines will be prioritized based on availability and the date the order was placed. Machines containing platinum catalyst silicone tubing have received 510(k) clearance from FDA.

We sincerely appreciate the trust and confidence you have in our products and look forward to continuing to meet your business and patient needs.

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.