

IMPORTANT MEDICAL DEVICE CORRECTION**2008® Series Hemodialysis Machine/Blood Pump Rotor Spare Part
New Blood Pump Rotor Design
Field Action Number: FA-2022-33-W_REV A**

Dear Valued Customer,

The purpose of this notification is to inform you that an updated Blood Pump Rotor design (Part Number, F40015481, Rev C) is now available. Fresenius Medical Care updated the Blood Pump Rotor design due to previously reported failures in the field. It was reported the Blood Pump Rotor guide post (pin) sleeves were coming loose. The snap fit retention feature of the guide post sleeve can wear causing the sleeve to come loose exposing the metal guide post and, in some cases, causing blood line damage.

There have been reports of blood line damage that resulted in minor blood loss and in one case, a suspected air infusion, which resulted in a machine alarm.

The blood Pump Rotor design was changed to improve the retention of the guide post sleeves by using a captured roller retention design, see Figure 1 below.

Customer actions:

- As per the 2008T Operators Manual P/N 490122 Rev AA: Blood Pump Rotors should be inspected for proper operation, as stated in Chapter 2: Daily preparation for treatment:



Warning! Inspect the blood pump rotor for proper operation (tubing guide posts not bent, rollers move freely, crank lever moves freely). Bent or loose tubing guide posts can damage bloodlines. Replace rotor if necessary. See page 184 for rotor diagram.

- If you experience a dislodged guide post sleeve, bent or loose tubing guide posts, or roller cannot move freely on your current parts: F40014866 (Blood Pump Rotor) or F40015481 (packaged version of Blood Pump Rotor as a spare part), please contact Fresenius Medical Care Customer Service at 800-227-2572, OPTION 3, for a replacement Blood Pump Rotor.
 - Please have Blood Pump Rotor Part Number and Lot Number available when requesting a replacement.



Part Number

Lot Number (11th week of year 2024)

- Please provide this letter to your Biomedical Technician.

Fresenius Medical Care Renal Therapies Group, LLC

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