



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.

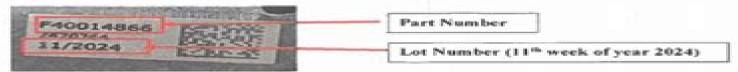
Customer actions:

 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.



Please provide this letter to your Biomedical Technician.

Fresenius Medical Care Renal Theraples Group, LLC

Fresenius Service Bulletin

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Table of Contents Fresenius Service Bulletin

- 1. Understanding the eBook Fresenius Service Bulletin
 - The Rise of Digital Reading Fresenius Service Bulletin
 - Advantages of eBooks Over Traditional Books
- 2. Identifying Fresenius Service Bulletin
 - Exploring Different Genres
 - o Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
- 3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Fresenius Service Bulletin
 - User-Friendly Interface
- 4. Exploring eBook Recommendations from Fresenius Service Bulletin
 - Personalized Recommendations
 - Fresenius Service Bulletin User Reviews and Ratings
 - Fresenius Service Bulletin and Bestseller Lists
- 5. Accessing Fresenius Service Bulletin Free and Paid eBooks
 - Fresenius Service Bulletin Public Domain eBooks
 - Fresenius Service Bulletin eBook Subscription Services
 - Fresenius Service Bulletin Budget-Friendly Options
- 6. Navigating Fresenius Service Bulletin eBook Formats

- o ePub, PDF, MOBI, and More
- Fresenius Service Bulletin Compatibility with Devices
- Fresenius Service Bulletin Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Fresenius Service Bulletin
 - Highlighting and Note-Taking Fresenius Service Bulletin
 - Interactive Elements Fresenius Service Bulletin
- 8. Staying Engaged with Fresenius Service Bulletin
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Fresenius Service Bulletin
- 9. Balancing eBooks and Physical Books Fresenius Service Bulletin
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Fresenius Service Bulletin
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Fresenius Service Bulletin
 - Setting Reading Goals Fresenius Service Bulletin
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Fresenius Service Bulletin
 - Fact-Checking eBook Content of Fresenius Service Bulletin
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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