

FIELD SAFETY NOTICE

Inspection and Cleaning of pump exterior components in Aurora Plasmapheresis System

Date: November xxx

Subject: Field Safety Notice regarding inspection and cleaning of pump exterior components in Aurora Plasmapheresis System

Affected Product Code

Product	Product Code	Serial number
Aurora Plasmapheresis System (Fresenius Kabi branding)	6R4601	All fielded products
Aurora Plasmapheresis System (Fenwal branding)	4R4601	All fielded products
Aurora Plasmapheresis System (Fenwal, remanufactured)	4R4601R	All fielded products

Table 1: Affected products

Dear Customer / Health Care Professional,

Fresenius Kabi is issuing this letter to inform about a potential issue concerning the inspection and cleaning of pump exterior components in the Aurora Plasmapheresis System, product codes listed above. This product notification details the issue and provides the necessary steps required by customersto take.

Our records indicate that your facility has received one or more of these devices.

Issue and Potential Risk

As part of our post market surveillance, cases of donor discolored urine or donor hemolysis from Aurora plasmapheresis donations as well as blood pump tubing kinks and/or blood leaks and/or blood pump tubing elongation were reported to Fresenius Kabi.

During root cause investigation, it was determined that application of lubricant had contributed to kinks, which can hemolyze red blood cells during their return to the donor.

No lubricant should be applied to the Aurora exterior pump components at any time. However, because lubricant has been observed on returned pump components, we

are asking for an **one-time enhanced pump inspection** to be completed on all Aurora pumps at their next regularly scheduled monthly maintenance.

Fresenius Kabi has been notified of rare cases in which donors experienced discolored urine. Some donors sought medical attention/medical clarification for their symptoms. No treatment was provided apart from the administration of fluids. Fresenius Kabi has not been informed about any serious deterioration in the donors' state of health or medicinal treatment.

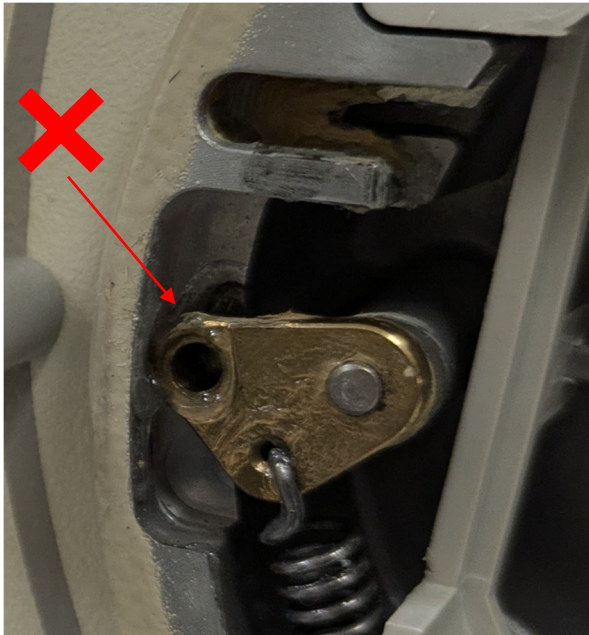
Required Actions for Users

As noted in the Aurora 2.1 Operator's Manual (471913378 [D], February 2022), monthly maintenance of the pump is required as follows:

- Instrument Maintenance, Monthly (Section 6.3)
- Clean the pump roller and verify pump rollers turn freely. Replace any worn or loose components.

Therefore, we are asking for an **one-time enhanced pump inspection and cleaning** to be completed on all Aurora pumps at their next regularly scheduled monthly maintenance.

1. Remove the pump cover, roller cage, and mandrel
2. Inspect for lubricant on the front face of the bronze link
 - a. Lubricant is expected in the bronze roller channel; it may appear white, yellow, or black in color, but should not be built-up from the surface of the channel
 - b. **Note:** if you are unsure if excess lubricant is present, please contact your Fresenius Kabi service representative

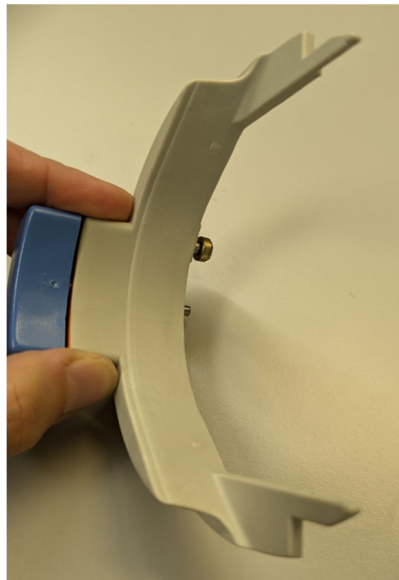


Figur 1: Unacceptable lubrication on/near the bronze link

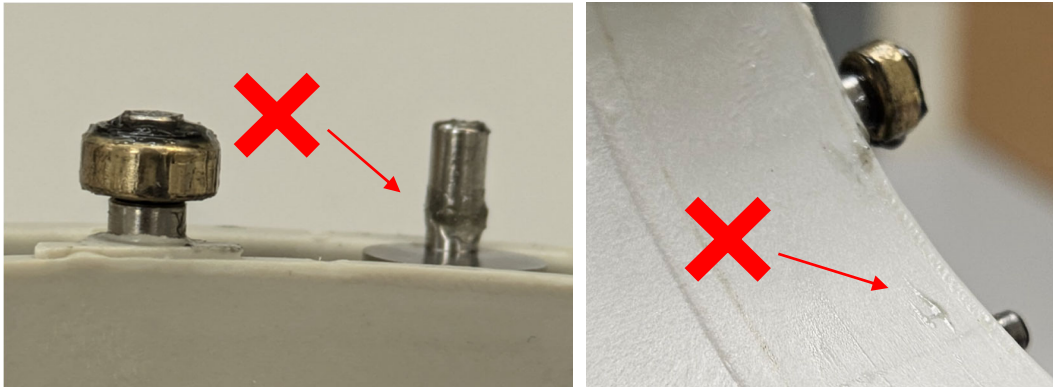


Figur 2: Acceptable lubrication on/near the bronze link

3. Inspect for lubricant on the mandrel, including build-up on the raceway, bronze roller, and crankpin

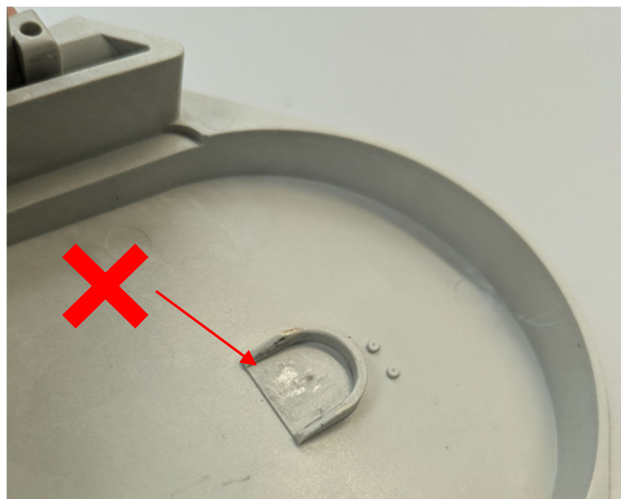


Figur 3: Pump mandrel



Figur 4: Unacceptable lubrication on pump mandrel

4. Inspect for lubricant on the pump cover. Lubricant can be identified as a reflective surface.



Figur 5: Unacceptable lubrication on the pump cover

5. Verify that the pump rollers spin freely.

Note: Pump rollers “turn freely” indicates that they coast after releasing, like other pump rollers.

6. If lubricant is present on any unintended pump component or if any pump roller does not spin freely, clean all of the following components per the cleaning instructions below:
 - a. Bronze link (front face)
 - b. Mandrel (raceway)
 - c. Roller cage (front face, rear face, raceway, shoulders, and rollers)

Note: When cleaning the rollers, ensure to spin the rollers 360° with the wipe held firmly against the surface.

- d. Pump cover (inner surface)
- e. Pump shaft
7. Replace any worn or loose components, or any components that are unable to be fully cleaned.

Cleaning Instructions

For each of the component surfaces described above, perform the following steps:

1. Using a dry paper towel, wipe all visible lubricant from the surfaces described.
2. Wipe the component with a 70% isopropyl alcohol wipe. (The alcohol wipe may be pre-moistened or solution applied to a paper towel.)
3. Let the surface dry for at least 30 seconds.
4. Wipe the surface again with a dry paper towel.
5. Wipe the surface again with a fresh alcohol wipe.

If the pump rollers do not spin freely, perform the following steps:

1. Soak the pump roller cage in 70% isopropyl alcohol.
2. Swirl the roller cage around in the solution to ensure coverage on all surfaces.
3. Remove the roller cage from the alcohol solution and place into a mild soap solution.
4. Swirl the roller cage around in the soap solution to remove the alcohol.
5. Remove the roller cage from the mild soap solution and rinse thoroughly under warm running water.
6. Dry all roller cage components thoroughly, and may use a hair dryer.
7. Do not reassemble the pump until all components are completely dry.
8. When the roller cage is dry, verify that the pump rollers spin freely.

Note: Pump rollers “turn freely” indicates that they coast after releasing, like other pump rollers.

Replace any worn or loose components, or any components that are unable to be fully cleaned.

**PLEASE COMPLETE THE ENCLOSED "CUSTOMER REPLY FORM" AND
SEND IT BACK TO US IMMEDIATELY.**

Please ensure within your organization that every user of the concerned products and all other relevant persons or entities where the concerned products have been transferred are informed about this letter and the actions as described herein.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Thank you for your support and cooperation on this important matter. Fresenius Kabi is committed to providing you with the highest level of service, product quality, safety, and reliability. We apologize for any inconvenience.

If you have any further questions concerning this FSN, please contact your local Fresenius Kabi representative.

Sincerely,

Name
Position
Organization

Enclosure:
Customer Reply Form