



URGENT MEDICAL DEVICE CORRECTION

CentriMag™ Blood Pump (102953, 201-20003, 201-90010, 201-90016)
CentriMag™ RVAD HDE KIT (104318)
CentriMag™ Pre-connected Pack (CMAEK00)
CentriMag™ VAD KIT (201-51006, 201-51007, 201-90001 201-90001T)
Blood Pump with CentriMag™ Acute Circulatory Support System for ECMO (CMAEK01)
(UDI: 07640135140627, 07640135140603, 05415067036414)

Heart Failure Division
Abbott Medical
6035 Stoneridge Dr.
Pleasanton, CA 94588

October 2025

Dear CentriMag Customer,

This letter is to inform you that Abbott is initiating a voluntary customer notification to remind you that when using the CentriMag™ Acute Circulatory Support System you must always ensure the CentriMag Blood Pump is securely locked into the CentriMag Motor as described in the Instructions for Use (IFU). Failure to properly lock the Blood Pump into the Motor could lead to particulate or increased heat while using the system. At this time, Abbott is not requesting that this product be returned or removed from the field. If the pump is able to be locked into the motor, the product is safe for use and functions as intended when the IFU is followed to securely seat the pump.

IMPACT AND ASSOCIATED RISK

Abbott has received 26 pump complaints out of more than 103,000 pumps distributed globally. In these cases, Abbott identified that the bottom housing rim of the pump did not meet specifications for flatness and thickness. This flatness and thickness issue may prevent proper insertion of the pump housing into the CentriMag Motor, potentially leading to misalignment.

Out of the 26 pump complaints, 18 involved user anxiety or inconvenience during system setup, prior to patient involvement. The remaining complaints included reports of anxiety and inconvenience, delay in hemodynamic/ECMO support, which may have resulted from increased friction caused by a pump housing being misaligned to the motor. While no high severity outcomes have been reported in connection with this issue, there remains a potential risk of adverse health outcomes such as stroke, embolism, or death if the pump does not fit correctly into the motor.

WHAT YOU NEED TO KNOW

The CentriMag Blood Pump IFU outlines the procedure for aligning and inserting the pump into the motor receptacle prior to engaging the locking mechanism. To ensure secure pump seating, the IFU instructs users to rotate the pump counterclockwise for the screw-in locking feature illustrated in Appendix A, or clockwise for the snap-in locking feature before locking it into place.

This issue applies to CentriMag Blood Pumps, in standalone configuration (102953) and in Pre-connected Pack configuration (CMAEK00), when used with CentriMag Motors that use a screw-in locking screw. However, it is not applicable to PediMag Blood Pumps, or CentriMag Blood Pumps used with CentriMag Motors containing the new Snap-in Locking Feature.

WHAT YOU NEED TO DO

Read this notification thoroughly, complete and sign the form included with this letter acknowledging that you received and understand this information, and that you will communicate this information with those in your facility to whom it is relevant. Once complete, return the form to Abbott.

Ensure the CentriMag Blood Pump is securely locked into the motor, following the IFU. If you are unable to fully rotate and lock a blood pump into a motor, exchange the pump for a new one, and return the original pump to Abbott for a full refund or credit, please contact your Abbott Representative or Abbott Customer Service at 1-800-456-1477.

Continue to follow Abbott IFU for the CentriMag Motor for setting up the system as described in the Section "Pump Setup" in Appendix A. Instructions for Use are available for the CentriMag™ Blood Pump and Motor on the Abbott website (<https://manuals.eifu.abbott/en/index.html>).



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WHAT IS ABBOTT DOING

Abbott has implemented an in-process manufacturing step to confirm the pumps can be fitted into the CentriMag motor while continuing with the implementation of corrective actions to help ensure that new CentriMag Blood Pumps will lock into the motor.

Abbott has notified the United States Food & Drug Administration (FDA) about these issues. Should you have any questions about this notice, please contact your Abbott representative or Abbott Technical Support at 1-800-456-1477.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete the voluntary Form FDA 3500 online at <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>.
- Download the form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return it to the address on the pre-addressed form or submit it by fax to 1-800-FDA-0178.

We sincerely apologize for any difficulties or inconvenience this may cause you and your patients. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for your partnership in assisting us with this process.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Carolyn Tabion'.

Carolyn Tabion
Divisional Vice President, Quality
Abbott Heart Failure

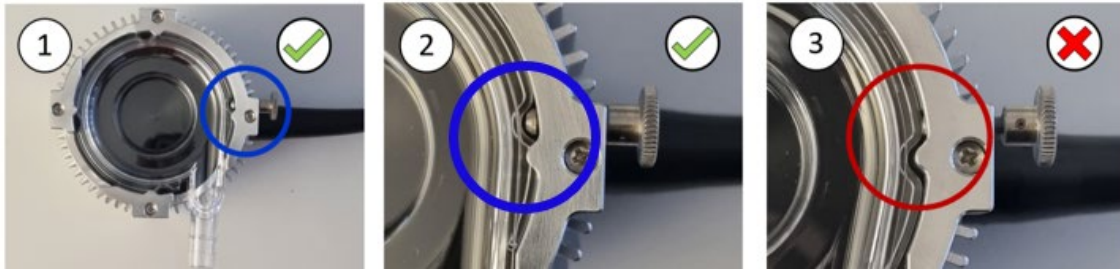
Enclosed:

- Appendix A –Secure Pump Seating Instructions
- Acknowledgment Form

Appendix A

The following pictures on Figure 1 clarify the IFU. After matching the grooves on the periphery of the Pump with the fittings on the motor receptacle, proceed with the following:

Figure 1- Illustration of Pump Correct and Incorrect Fit



1. Ensuring that the pump remains flat/level with the motor/ to the pump, Rotate the pump counterclockwise until the matching groove on the pump is located in front of the locking screw.
2. Turn the locking screw until it is completely seated into the groove and the blood pump is secured in place.
3. Do not lock screw if groove is not located in front of the locking screw.
4. **Always rely on visual confirmation that the pump is correctly locked in the motor, even if the “pump not inserted” alarm is not present.**