CentriMag™ Acute Circulatory Support System Corrective Action FAQ

- As you have learned, Abbott is conducting a corrective action for the CentriMag™ Acute Circulatory Support System.
- No product is being exchanged or removed – Abbott recommends continued use of the CentriMag™ System in indicated patients.
- The following information is intended to provide a quick reference for clinicians and administrators subject to the action.

WHAT IS THE SUBJECT OF THE CORRECTIVE ACTION?

Abbott is reinforcing the requirement to maintain a backup system in the immediate vicinity of any patient on support, and the importance of following the proper method for exchanging the CentriMag System in the event of an interruption of support. Abbott is also providing clarity on appropriate handling and inspection of the cable that connects the CentriMag™ Motor to the CentriMag™ Console.

CAN I CONTINUE TO USE THE CENTRIMAG™ SYSTEM?

Yes, it is still safe to continue use of the CentriMag system. **The device is not being removed from the marketplace.**

DO I NEED TO RETURN ANY PRODUCTS TO ABBOTT? / IS ABBOTT EXECUTING A MANDATORY PRODUCT EXCHANGE?

No products are being exchanged at this time. This communication is intended to reinforce intended use as specified in the IFU, and release updates to the labeling/IFU.

IS THIS A FIELD ACTION OR A RECALL?

The FDA terminology for a Medical Device Advisory is “Recall,” which can include either the correction or the removal of a marketed product. A correction can include updated or additional use instructions, or new labels or IFUs, as is the case in this instance.

A Recall can be classified as Class I, II, or III. FDA has not yet classified this Advisory as of September 5, 2018.

WHAT ARE THE NEXT STEPS?

Abbott asks that all recipients of the Customer Letter respond with acknowledgement of receipt, per the instructions included with the letter. In the near future, a representative of Abbott will visit your hospital to deliver copies of revised IFUs and warning labels to be placed on all Consoles (see Customer letter for details).

WHAT DO I NEED TO DO?

Review the clinician communication, including the appendices with the updated information and warnings, and take the following actions:

1. Ensure all patients on support with a CentriMag System have a complete backup system (Console, Flow Probe, Power Cable, and Motor) in the immediate vicinity.
2. Ensure all staff are properly trained that if a change to the backup system is necessary, move the CentriMag or PediMag™ Pump from the primary to the backup system and do not continue use of any of the components (Console, Flow Probe, Power Cable, or Motor) from the primary system. This process is described in the Operating Manual.
3. Ensure proper handling and inspection of the CentriMag Motor and the attached cable per the revised Motor IFU and Operating Manual.

WILL ADDITIONAL ACTION BE REQUIRED IN THE FUTURE?

Abbott has identified complaints affecting 8 out of over 50,000 uses of the CentriMag Motor that were attributed to broken wires inside the cable that connects the Motor to the Console. Of these, there were 2 instances of patient death and 6 instances of serious injury.

Abbott plans to release an updated CentriMag Motor in the future, designed to reduce the likelihood of such failures. You will be notified when this updated design is available.

DOES THIS IMPACT 1st GENERATION AND 2nd GENERATION CENTRIMAG SYSTEMS?

Yes. The motor is identical between systems and therefore both consoles will receive updated labeling and either an updated Operating Manual (2nd generation) or supplemental materials (1st generation).

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warning, precautions, potential adverse events and directions for use.