



HeartMate PHP™ (Percutaneous Heart Pump)
Catalogue Numbers 10002111, 109875

Urgent Field Safety Corrective Action Notice - Recall

Date: February 6, 2017

Re: HeartMate PHP Catheter

Dear Physician,

This notice is to advise you that we are conducting a Field Safety Corrective Action (FSCA) in Europe for the Thoratec (now an Abbott Company) HeartMate PHP (Percutaneous Heart Pump) Catheter. For reference, the HeartMate PHP System consists of a console and a catheter. Only the catheter is subject to this FSCA.

The HeartMate PHP is commercially available in Europe for patients undergoing high risk percutaneous coronary intervention (PCI) who need left ventricular support. Any pump stop event may contribute to hemodynamic instability resulting in emergency intervention and/or death.

This step is being taken as a precaution due to reports of a small number of clinical events associated with pump stoppage during support of high-risk percutaneous coronary intervention (PCI) patients in both clinical and commercial uses. To date, Abbott has received reports of eight (8) motor stoppage events worldwide, representing 1.9% of devices shipped. Of the eight (8) devices, one (1) stoppage caused hemodynamic instability requiring emergency intervention and one (1) resulted in death associated with sepsis several days after the intervention. The remaining pump stoppage reports were not associated with an adverse event.

Abbott is temporarily pausing the use of HeartMate PHP devices to allow the Company time to evaluate and implement corrective actions. In the interim, do not use units within your possession. Use of the PHP Catheter will resume once any necessary actions are complete. Global regulatory authorities have been informed.

Affected Devices

All serial numbers of the HeartMate PHP Catheter with model #:

109875	HeartMate PHP Catheter (for investigational use only)
10002111	HeartMate PHP Catheter (for commercial use)

Actions Required

- Physicians should immediately discontinue use of HeartMate PHP.
- Hospitals will be required to return all HeartMate PHP catheter inventory to Abbott.
- Your Abbott representative will contact you to facilitate the return of the product.

We are taking this action because Abbott is committed to the health and safety of patients who use our products. We hope to update you as soon as we resolve any necessary corrective actions.

Contact for Additional Information

Should you have questions regarding this notice, please contact Abbott Technical Services at +46-8474-4147 which is available 24 hours a day, 7 days a week. Alternatively, your Abbott Sales Representative is available to answer any questions you may have.

We apologize for any difficulties this may cause you and your patients. Abbott is committed to providing the highest quality products and support.

Thank you for your continued support.

Sincerely,