Abbott

ABBOTT HEARTMATE 3 LVAD UPDATE

May 23, 2018

Dear HeartMate 3 Patient,

Abbott recently shared communications with your hospital center regarding the FDA's issue of a Class I recall for the HeartMate 3 left ventricular assist device (LVAD). As the manufacturer of the HeartMate 3 LVAD, we are sending this letter to notify you that we are **not recommending** physicians remove your device as it is still considered a safe option for heart failure management.

The Class 1 recall was issued due to possible twisting of the tubing connecting the pump to your heart, potentially causing low blood flow, and the need for a correction procedure (0.72%). We are working closely with your physician to keep them updated on any changes.

If you have any questions about this communication, please contact your LVAD coordinator. We apologize for this situation and want to assure you that Abbott is committed to providing the highest quality products and support.

Best regards,

Ann Graves
Divisional Vice President, Regulatory

Lance Mattoon
Divisional Vice President, Quality