Abbott Implements Corrective Action For HeartMate 3 Heart Pump

- Abbott previously communicated safety alert related to potential outflow graft twisting to physicians on April 5, 2018

ABBOTT PARK, Ill., May 4, 2018 -- Abbott is communicating to physicians about a field corrective action related to the HeartMate 3™ Left Ventricular Assist Device (LVAD). Abbott notified physicians and global regulatory bodies on April 5, 2018, that outflow graft twisting could occur post-implant in the HeartMate 3 LVAD, resulting in a persistent low flow alarm that may signal a potential safety risk to patients, such as low blood flow or clotting.

No devices are being recalled from patients or hospitals as a result of the corrective action, and the recommendations made by Abbott remain in place for physicians managing patients implanted with HeartMate 3.

Abbott is currently aware of 32 reports of outflow graft twisting in 4,467 HeartMate 3 devices worldwide (incidence rate of 0.72%), including reports of low blood flow, clotting (known as thrombus), and three reported deaths that could be associated with outflow graft twisting. As a result, Abbott has contacted physicians managing patients implanted with a HeartMate 3 LVAD in the event their patients report persistent low flow alarms that could indicate outflow graft twisting. Twisting of the outflow graft can occur at any point after implant.

In patients living with an LVAD, low flow alarms can often indicate unrelated conditions such as hypertension. For patients who experience a persistent low flow alarm after such causes have been ruled out, a computed tomography (CT) scan can help detect any possible outflow graft twisting. In addition, physicians managing patients that exhibit a persistent low flow alarm should determine patient care recommendations based on each unique clinical case.

Abbott has also alerted implanting physicians that as stated in the device's instructions for use (IFU), properly hand tightening the screw ring at the time of implant may reduce the chance of outflow graft twisting. Abbott has proactively contacted all physicians who treat patients impacted by this safety alert and will continue to assess current reports of outflow graft twisting to further provide physicians with patient care recommendations.

About Abbott
At Abbott, we're committed to helping you live your best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world – in nutrition, diagnostics, medical devices and branded generic pharmaceuticals – that create more possibilities for more people at all stages of life. Today, 99,000 of us are working to help people live not just longer, but better, in the more than 150 countries we serve.

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