HeartMate 3 Outflow Graft Twist FAQ

- We believe HeartMate 3 is the best pump for indicated patients and we are 100% confident in the performance of the pump in even the most challenging clinical cases.
- The data behind the HeartMate 3 is the strongest data the industry has seen to date, and we're proud of the performance of HeartMate 3 in trial settings as well as in the real world.

CAN I CONTINUE TO IMPLANT HEARTMATE 3?

Yes. A labeling/IFU correction is being implemented, but the device is not being removed from the marketplace.

IS THIS A FIELD ACTION OR RECALL?

The FDA terminology for a Medical Device Advisory is "Recall," which can include removal of the product **or the correction of a marketed product.** The FDA classified this field action on May 21 as a Class 1 recall.

DOES RECALL MEAN CUSTOMER NEED TO PULL PRODUCT OFF THE SHELF?

No. FDA does not recommend return of products or not using the product with new patients. In this case, Abbott is making a correction to the Labeling / Instructions for Use for managing new patients getting the device or patients who have the device already implanted.

HOW MANY DEVICES ARE IMPACTED?

Currently, we are aware of 35 total reports associated with outflow graft twisting in the HM3 device, an occurrence of 0.62 percent based on 5,607 devices sold worldwide. Our original communications to physicians cited 32 total reports out of 4,467 implants and an incidence rate of 0.72 percent, which is the number outlined in our original Health Hazard Evaluation. Since that time, we have communicated with the FDA and global regulatory partners as the number of global implants has increased.

SHOULD CUSTOMERS STOP ENROLLING IN THE CAP?

Customers should continue enrolling in the CAP as usual. Long-term data from the MOMENTUM 3 study found Abbott's HeartMate 3™ LVAD demonstrated improved survival, lower rates of stroke and lower rates of pump thrombosis over HeartMate II, which is the most widely used LVAD in the world.

IS THE HEARTMATE 3 STILL SAFE TO USE IN NEW PATIENTS?

Yes. Long-term data from the MOMENTUM 3 study demonstrated HeartMate 3 had improved survival free of disabling stroke and reoperation for a malfunctioning device compared with the HeartMate II.

WHY IS ABBOTT ISSUING THIS SECOND LETTER ON THE HEARTMATE 3 OUTFLOW GRAFT TWIST?

This current communication provides further clarification on the origin of the outflow graft twist, the persistent low flow alarm, additional recommendations for patient management, and future mitigations that we will implement. This is not a new issue, but rather an update to the initial communication.

WHEN WILL THE UPDATED IFU BE INCLUDED IN THE PACKAGING?

The IFU updates were included with the physician letter; the IFU in HeartMate 3 kits will be updated in the near future.

HOW MANY PATIENTS HAVE DIED OR HAD SERIOUS INJURY?

Our evaluation includes three reported deaths that could be associated with outflow graft twisting.

COULD THIS IMPACT ANY HEARTMATE 3 DEVICE?

While the rate of reports related to this issue is low, any physician managing patients implanted with HeartMate 3 should be aware of this issue in the event their patients report consistent low flow alarms that could be a result of outflow graft twisting.

WHAT TYPE OF ADVERSE EVENTS HAVE OCCURRED?

Some reports of Outflow Graft twists have been associated with low blood flow, re-operation, and thrombus. Of the 35 adverse events, three are associated with patient death.

HOW DOES THIS TWISTING OCCUR?

Our analysis suggests that over time, normal motion such as the heart beating, respiration and patient activity can cause small rotations between the outflow graft bend relief component and the outflow graft metallic connector underneath. These forces are known as “in vivo loads” and we believe these forces could contribute to outflow graft twisting.

In addition, our analysis suggests that twisting may occur more easily if the screw ring is not firmly hand tightened during implant.

IS THE SCREW RING HAND TIGHTENED DURING IMPLANT?

Yes. During implant, when physicians attach the outflow graft to the pump cover, they turn a screw ring. We are reminding physicians to turn the screw ring until it comes to a complete stop and stops clicking for a firm hand tightened connection, per the instructions for use.

SHOULD A TOOL BE USED TO TIGHTEN THE SCREW RING?

We do not recommend a tool to tighten the screw ring. As noted in the instructions for use, physicians should turn the screw ring until it comes to a complete stop and stops clicking for a firm hand tightened connection.

HOW LONG AFTER IMPLANT CAN TWISTING OCCUR?

We are aware of outflow graft twists occurring shortly after implant up to nearly two years post-implant. Most reports of outflow graft twisting have been reported after the first year post-implant, however twisting can occur at any point after implant.

WHAT SHOULD A PHYSICIAN DO IF THEIR PATIENT EXPERIENCES A PERSISTENT LOW FLOW ALARM?

At any time following implant, in the presence of a persistent low flow alarm, not resolved after all relevant patient medical conditions having been ruled out as the cause, a Computed Tomography (CT) angiography should be taken to identify the possibility of an outflow graft twist occlusion.

Physicians should follow patient management recommendations outlined in their letter.

HOW IS A PERSISTENT LOW FLOW ALARM DIFFERENT THAN A NORMAL LOW FLOW ALARM?

Sometimes, patients will experience a low flow alarm because of other medical conditions (such as a cardiac arrhythmia). A persistent low flow alarm is one that is not resolved by addressing any other medical condition such as hypertension, right heart function, volume status and arrhythmias.

DOES THIS ACTION IMPACT DEVICES OUTSIDE THE UNITED STATES?

Yes, this is a global advisory.

HAS ABBOTT COORDINATED WITH GLOBAL REGULATORY AGENCIES ON THIS ISSUE?

Yes.