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LOUISVILLE SURGEONS GIVE UPDATE ON PATIENTS' CONDITION

(LOUISVILLE, Ky) – The University of Louisville surgeons who implanted the world's first totally implantable replacement heart at Jewish Hospital on July 2 reported today that the patient, Bob Tools, has suffered a stroke.

Mr. Tools, who has been living with the AbioCor replacement heart for 135 days, "had been making good progress overall," Dr. Laman Gray explained. "He has enjoyed a relatively high quality of life – making frequent trips outside the hospital and beginning to improve his ability to eat."

On Sunday afternoon, November 11, Mr. Tools experienced weakness on his right side. Gray explained that clots that lead to stroke are a risk any time a foreign body interacts with circulating blood. In fact, the risk is explicitly explained to the patient and patient family during the trial's informed consent process.

"When we put in one artificial valve during standard open-heart surgery, we must keep that patient on anticoagulation," Dr. Rob Dowling said. "This patient has four artificial valves, and was totally off anticoagulation for several weeks due to his GI bleeding."

"The AbioCor is specifically designed to minimize the risk of stroke – assuming that the patient is adequately anticoagulated. However, we cannot eliminate stroke as a risk for these patients."

Following the stroke, Mr. Tools was returned to ventilator support in response to some respiratory distress Tuesday evening. According to his neurologist, Dr. Lynn Simon, "Strokes frequently cause problems with swallowing, which causes a build-up of secretions and leads to problems with airway management. Mr. Tools was intubated to alleviate this problem."

Mr. Tools has had limited speech since his stroke, and his current speech is difficult to evaluate due to his intubation. "Because Mr. Tools is left-handed, there may be some language ability in his right brain – which could be good news for potential speech recovery," Simon said. "However, it's too soon to guess at this point."

Gray, Simon, and Dr. Rob Dowling continue to work with other colleagues and the Tools family to determine the best course of treatment.

This is the first neurological event that the doctors have considered to be significant in the AbioCor experience. "During the time he (Tools) was off anticoagulation therapy, he experienced a brief episode where speech became difficult for him," Gray continued. "However, the problem cleared readily and was

not accompanied by any muscle weakness. The episode did not significantly impact his function or the progress of his long-term recovery.”

When asked about the progress of the team’s second patient, Tom Christerson, Dr. Gray was pleased to describe some progress following the fevers that were reported last week. “Mr. Christerson is neurologically normal, and has been adequately anticoagulated for the vast majority of the time.”

Dowling added, “His CT scans are completely normal, and his strength is improving. He’s spending more time sitting up each day and lifting his arms and legs off the bed.”

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