

THE OHIO STATE UNIVERSITY

WEXNER MEDICAL CENTER



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## OHIO STATE FIRST IN U.S. TO USE NEW ATRIAL FIBRILLATION DEVICE

COLUMBUS, Ohio – Promising results are emerging from an ongoing clinical trial testing a new type of ablation technology for patients suffering from atrial fibrillation, a common type of irregular heartbeat. In February, cardiologists at <u>The Ohio State University Wexner Medical Center</u> were the first in the United States to perform the procedure, and since then it has been performed successfully on 13 additional patients worldwide.

The global clinical trial is assessing pulsed field ablation (PFA) technology to treat patients with atrial fibrillation. Developed by <u>Medtronic</u>, the PulseSelect PFA System uses pulsed electric fields to interrupt pathways and atrial fibrillation triggers in the heart. Doing so can help the heart restore its regular rhythm. Unlike traditional methods, this technology is non-thermal (meaning there is no heat or extreme cold) and can efficiently isolate the pulmonary veins, which are a major source of triggers of the arrhythmia.

"This new technology is potentially everything we've hoped for in catheter ablation. It's easier to use, more efficient and will be better for patients because there's less risk of damage to surrounding tissue and a shorter recovery time. It also may eliminate the need for overnight hospital stays," said <u>Dr. John Hummel</u>, an electrophysiologist at Ohio State's <u>Richard M. Ross Heart Hospital</u>, who performed the first procedure on a patient in the United States.

Initial trial results show PFA achieves 100 percent pulmonary vein isolation without any nerve injuries or serious side effects. Doctors will continue to follow up with patients for a year to monitor the ongoing effectiveness of the new device.

"When you do a traditional ablation, there's the risk that it can cause damage to structures around the heart as heat or cooling spreads beyond the heart border," he said. "But this type of energy delivery is nonthermal, and heart muscle cells are uniquely sensitive to it, thus helping to avoid affecting other types of tissue around the heart. It's also very rapid and will likely significantly cut down on surgery time."

With continued success, experts hope PFA will become the standard tool to resolve <u>atrial fibrillation</u> for the more than 2.7 million Americans living with this dangerous heart condition. It can lead to blood clots, stroke, heart failure and other complications, according to the American Heart Association. It's common among people with coronary heart disease, valve disease, an inflamed heart muscle or lining or those who've had a heart attack, congestive heart failure or heart surgery. Other risk factors include high blood pressure, clogged arteries, diabetes, overactive thyroid, emphysema or other lung diseases, viral infections, sleep apnea, stress, fatigue and age.

In January, the U.S. Food and Drug Administration approved the <u>clinical trial</u>, which is funded by Medtronic and for whom Hummel collaborates with as a consultant and researcher. The current phase of the non-randomized study – which also is taking place in Australia, Canada and Europe – is projected to last six months. It's looking at how effective the PFA system is for patients with recurrent and symptomatic atrial fibrillation and patients who don't respond to drug therapy.

"There's only one site in the country for the pilot phase of this clinical trial, and we're excited that it's Ohio State, because we have one of the nation's largest ablation centers," Hummel said.