

## ► New Tech Aiding AFib, Other EP Patients

More patients than ever today receive the diagnosis of atrial fibrillation (AFib) or are determined to need pacemakers. Amidst an aging populace and better evaluation, cardiac electrophysiology care strives to keep pace. And indeed, EP technology and capabilities are rising to the challenge with innovation that is preventing disability and saving lives.

### AFib Ablation + Left Atrial Appendage Occlusion

Even patients whose AFib appears adequately controlled by medication are at added risk for stroke due to pooling and embolization as a result of ineffective contraction and sluggish blood flow in the atrium. Likewise, while ablation is effective in permanently eliminating atrial fibrillation for most other patients who need this step, many of these individuals require blood thinners as well to reduce their risk of clots that originate in the heart. For patients who cannot take blood thinners to guard against this danger, left atrial appendage occlusion is a procedure in which a basket-like screening device is placed in the heart to block this most common area where blood clots form in people with AFib.

The recently published OPTION trial examined the value of left atrial appendage occlusion in patients who are also undergoing AFib ablation. The trial showed no significant difference in the risk of stroke or TIA in patients continuing on long-term blood thinners versus patients who instead had a Watchman occlusion device with blood thinners stopped. However, the trial also showed a 60% reduction in clinical bleeding in the Watchman group.

“Traditionally, we’ve performed these two interventions—the ablation and occlusion—at separate times, resulting in an increased number of procedures for patients,” said Darius Sholevar, MD, FACC, FHRS, a heart rhythm specialist who directs the electrophysiology laboratory at Virtua Our Lady of Lourdes Hospital. “For suitable patients, providing both of these steps in the same EP-cath lab session means a more-convenient solution and an opportunity for these individuals to be free of ongoing anticoagulant therapy.”

The Virtua EP team completed its first combined atrial fibrillation ablation and left atrial appendage occlusion in October 2024. The service is now performing these procedures at the same time for select patients who would have clinical indications for each procedure separately.

### Pulsed Field Ablation

Tissue ablation in the heart wall has always come with a finite amount of risk of injury to noncardiac tissue such as the esophagus and pulmonary veins. As a new tool, pulsed field ablation applies high-voltage, ultra-short-duration bursts of energy to achieve nonthermal electroporation (creation of cell pores and thus cell death), resulting in low risk to adjacent structures. Virtua is among the first health systems in the region to perform pulsed field ablation.

### Dual-Chamber Leadless Pacemakers

To date, pacemaker design has relied on wires running to the heart from the implanted control/battery unit. These leads can become infected or dislodged and can be difficult to remove and replace. Virtua now provides a next-generation pacemaker that is leadless. Used in a dual-chamber configuration (*see figure*) and easily placed endovascularly, the two AAA battery-sized devices are self-contained for battery and sensing, computing, and stimulating electronics.

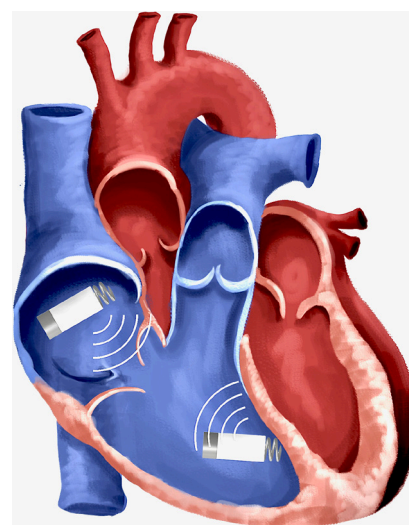


Image courtesy Abbott

The new leadless dual-chamber pacemaker system regulates the contractions of the right atrium and right ventricle. The two devices (about 1.5 inches in length) have no wires and communicate with each other to coordinate the heart's contractions.

To contact cardiac electrophysiology services at Virtua, call 856-424-3600.

## Cardiology Research Update: **Virtua Enrolling HTN Pts in Renal Denervation Trial**

Renal denervation (RDN) is seen as the most significant development in hypertension (HTN) treatment in many years, and Virtua is now offering access to the procedure, including through ongoing post-approval studies. Interventional cardiologists ablate nerves around the renal arteries to reduce sympathetic nerve activity, in a procedure approved by the FDA in October 2023 (see *Virtua's Interventional Cardiology TODAY July/August 2024*).

Virtua performed New Jersey's first RDN in January 2024 using Medtronic's Spyral® catheter and now serves as a site for the Symplicity RDN procedure, including through the SPYRAL AFFIRM post-approval surveillance study. The innovative treatment is appropriate for patients for whom conventional hypertension care, through lifestyle changes and medication, is inadequate or poorly tolerated.

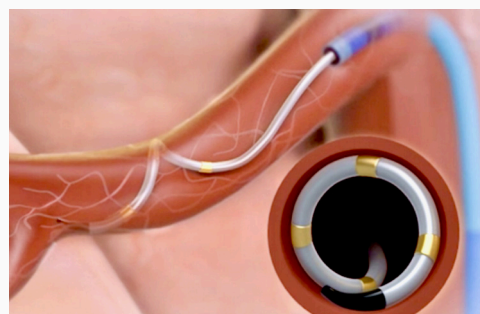
Last month, CMS approved transitional pass-through payment for the procedure. The field currently awaits a national CMS coverage decision and assigned CPT codes. However, the average age for best candidacy for RDN is well under 65, and private insurance reimbursement for the procedure remains a longer-term process. The current trial offers sponsor coverage of the cost of the treatment portion (interventional procedure) of RDN evaluation and care.

The Spyral catheter delivers radiofrequency energy through the wall of the renal artery and its branches without harming the arteries. Multiple clinical trials have shown a mean reduction in office systolic blood pressure of 9 mmHg at three-to-six months post RDN in patients on and off

medications, with a mean 17 mmHg reduction at three years post-procedure. Most trials to date have enrolled patients with both systolic and diastolic hypertension and excluded those with severe impairment in kidney function.

"We are pleased to provide the Symplicity RDN procedure to qualified patients and, starting now, through the clinical study as well," said Virtua interventional cardiologist Kintur Sanghvi, MD, FACC, FSCCAI, who has one of the largest experiences in the country in the provision of RDN. "Ideally in the future we would apply such intervention to appropriately selected patients before they suffer complications of hypertension, such as heart attack, heart failure, kidney failure, or stroke."

Interventional cardiologists also can perform RDN using ultrasound energy, and the Virtua hypertension team is participating in Recor Medical's Global Paradise® System U.S. post-approval study, and a pre-approval study of SoniVie's Therapeutic Intra-Vascular Ultrasound System (TIVUS™).



Renal denervation brings the function of renal sympathetic nerves to a more restive level\*, resulting in significant and sustained blood pressure reductions. *Image* shows how the spiral SPYRAL catheter applies energy to locations in renal artery walls to permanently quiet surrounding nerves.