Virtua Health

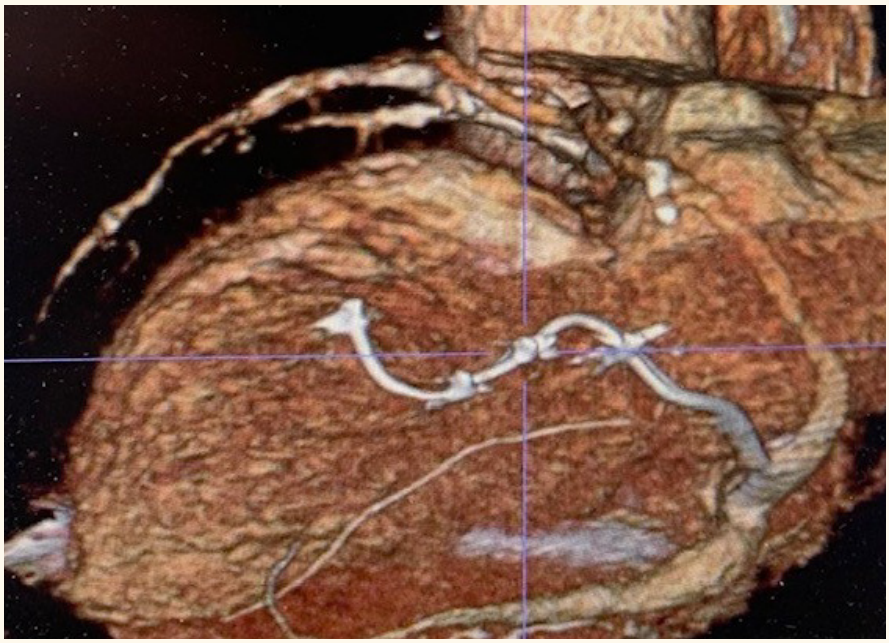
Heart Rhythm Review

Updates and advances in electrophysiology at Virtua Health and beyond

In this Issue:

IMAGE OF THE DAY

Non-invasive coronary sinus venous branch map



Non-invasive coronary sinus venous branch map in a patient with high threshold being considered for repeat surgery, showing left ventricular lead course and lack of suitable alternative branches for BiV pacing. *Image Courtesy of Dr. Mark Finch.*

Rechargeable defibrillators with CCM therapy now being implanted as part of Integra D trial

Dr. Heath Saltzman and the electrophysiology team at Virtua Our Lady of Lourdes Hospital performed the first Optimizer Integra CCM-D system implant in the tri-state area. The Integra D system is the first implantable defibrillator with a rechargeable battery featuring a life span of at least 20 years. This device also combines leading-edge cardiac contractility modulation (CCM) therapy with an implantable cardioverter defibrillator, paving the way for enhanced heart failure treatment. CCM therapy is designed to improve heart failure symptoms in patients who are not candidates for a BiV device.

In the past, the Impulse Dynamics CCM system required a separate implant from a defibrillator, but the new Integra device is the first to combine both therapies. Other areas of active research at Virtua Cardiology include long-term follow-up of patients with stand-alone CCM devices with current clinical indications.

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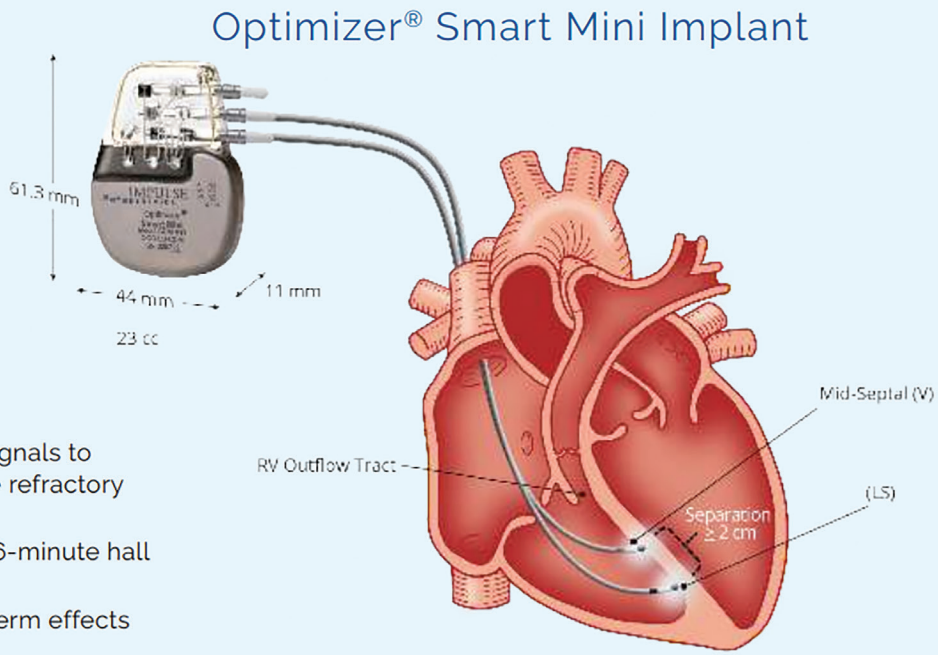
Rechargeable defibrillators with CCM therapy now being implanted as part of Integra D Trial

WHO
For patients with:

- LVEF 25–45%
- NYHA Class III
- Symptomatic despite guideline directed medical therapy
- Not indicated for Cardiac Resynchronization Therapy

WHAT
The Optimizer® Smart Mini delivers *CCM®* therapy, which:

- Applies non-excitatory electrical signals to the RV septum during the absolute refractory period using standard leads
- Improves NYHA functional status, 6-minute hall walk distance and QoL status
- Has rapid, intermediate and long-term effects



CCM® is also known as Cardiac Contractility Modulation

Update on left atrial appendage closure procedures: Watchman Pro FLX

Virtua's structural heart and electrophysiology teams are first in the region to test performance of new device

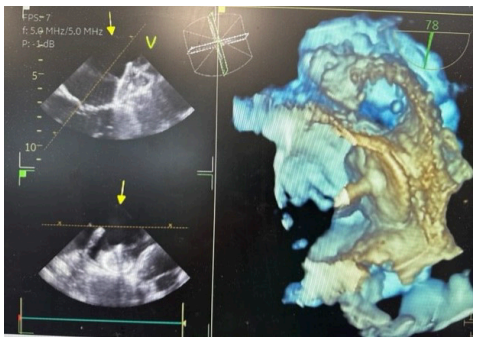
Virtua performed the first implants of a next-generation left atrial appendage (LAA) occlusion device in the Mid-Atlantic region in December 2023. Patients were implanted as part of the Boston Scientific Heal LAA study that will test a new Watchman left atrial appendage occlusion device. The device has a Hemocoat coating designed to enhance early healing. Virtua is the first center in the Philadelphia area to enroll in this trial and with access to the device.

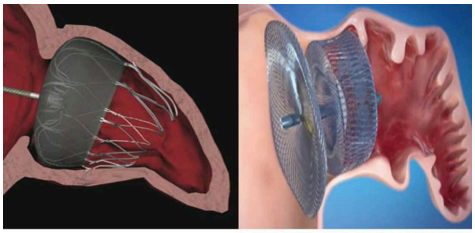
All current devices require months of anticoagulation or dual anti-platelet therapy (DAPT) while patients are healing in place to prevent blood clots from forming on the device. This can risk bleeding in the recovery period from the procedure.

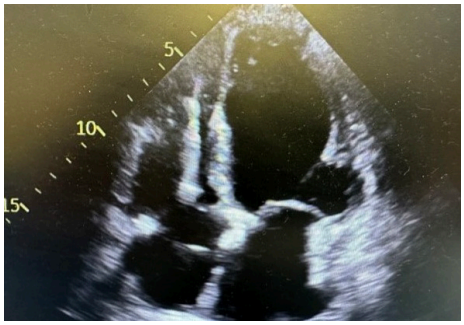
This is the first clinical testing of a new device that is designed to promote faster endothelialization of the surface of the device. The Heal LAA study is an early study of the use of coated LAA occlusion devices using traditional anticoagulation or DAPT. A follow-up study is expected looking at immediate transition to aspirin monotherapy after device placement.

Amulet

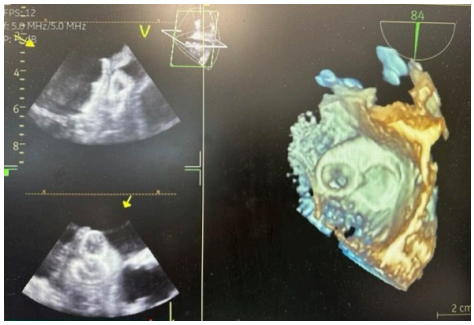
The EP and Structural Heart teams are now implanting a new type of left atrial appendage occlusion device called an Amulet. The device has the same indications and complications as Watchman (below left) left atrial appendage occlusion devices and is a more recent entry into the U.S. market. The Amulet device (below right) is a two-piece device adapted from the Amplatzer Septal Occluder and consists of a distal anchor /plug and a more proximal disk. The first two implants were performed successfully and without complication at Virtua on November 20, 2023.







Amulet devices are often visible on transthoracic Echocardiograms at the anterior-lateral wall of the left atrium on four-chamber views.



Amulet has a distinct TEE echocardiographic appearance and may show a figure-eight pattern in the disc with on-face views.
Images courtesy of Dr. Zarrella

Atrial high-rate (AHR) episodes detected on pacemaker and CRM device checks

NOAH AF Net-6 versus ARTESIA and current guidelines

Atrial fibrillation detected only on cardiac rhythm management (CRM) devices has been a quandary for clinicians for years. This is often termed sub-clinical atrial fibrillation. Early work from the ASSERT trial, of which Virtua Cardiology was one of the top enrolling groups, suggested an elevated risk of stroke with AHR episodes longer than 6 minutes. While most clinicians agree that episodes longer than 24 hours should be anticoagulated based on CHADS-Vasc score standards, the risk-benefit analysis for shorter episodes has been unclear. Two large, randomized trials published in fall 2023 showed similar findings.

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ARTESIA

65-year-old plus with AHR > 6 minutes < 24 hours

Randomized 1:1 apixaban versus placebo or aspirin

Median 1.5 hours of AHR with median CHADS-Vasc score of 3.9

Stroke or systemic embolism 0.78%/year versus 1.24 (HR 0.63)

Major bleed 1.7 versus 0.94

NOAH AF NET-6

65-year-old plus with AHR > 6 minutes < 24 hours

Randomized 1:1 edoxaban versus placebo

Median 2.8 hours of AHR with median CHADS-Vasc score of 4

No change in stroke rate through trend towards lower risk with AC—very low stroke risk

Terminated early due to higher risk of death or major bleeding with edoxaban

In both trials, the rate of stroke was very low, and the risk of major bleeding was higher with anticoagulation. Both trials showed a reduction in stroke rate that was small and did not reach statistical significance in NOAH trial, likely due to early termination of the trial due to an increased risk of major bleeding or death with anticoagulation.

Recommendations for Oral Anticoagulation for Device-Detected Atrial High-Rate Episodes Among Patients Without a Previous Diagnosis of AF Referenced studies that support the recommendations are summarized in the Online Data Supplement.

COR	LOE	Recommendations
2a	B-NR	1. For patients with a device-detected atrial high-rate episode (AHRE) lasting ≥24 hours[1] and with a CHA_2DS_2-VASc score ≥2 or equivalent stroke risk,[2] it is reasonable to initiate oral anticoagulation[3] within a SDM framework that considers episode duration and individual patient risk.
2b	B-NR	2. For patients with a device-detected AHRE lasting between 5 minutes and 24 hours and with a CHA_2DS_2-VASc score ≥3 or equivalent stroke risk,[2] it may be reasonable to initiate anticoagulation within a SDM framework that considers episode duration and individual patient risk.
3: No Benefit	B-NR	3. Patients with a device-detected AHRE lasting <5 minutes and without another indication for oral anticoagulation should not receive oral anticoagulation.[4,5]

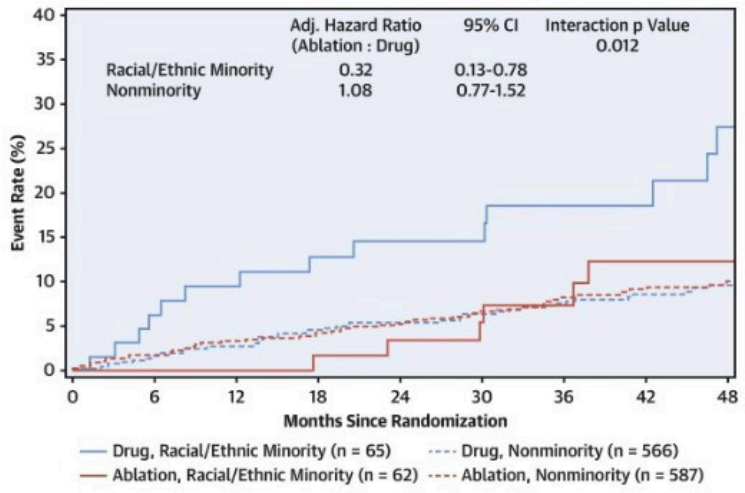
Where does this leave clinicians? Most experts currently agree that episodes less than 6 minutes should not be treated, and episodes longer than 24 hours should be treated by standard guidelines. Most also agree that patients with a prior history of stroke, TIA or systemic embolism should be treated for episodes longer than 6 minutes. For other patients, we are left with a quandary. An individual discussion should be carried out with these patients examining both their CHADS-Vasc and HAS-BLED scores, as well as the duration of their episodes of atrial fibrillation. Based on the median duration of episodes in the trials, some physicians are recommending a cutoff of 2 hours for anticoagulation, though this remains controversial. If anticoagulation is carried out, the current evidence would favor the use of Eliquis.

LITERATURE REVIEW

ACC new guidelines on atrial fibrillation management—highlights

- For Medicare beneficiaries with atrial fibrillation, the 5-year outcomes included a 48% risk of death, 13.7% risk of heart failure, and 7% risk of stroke.
- Guidelines emphasize risk factor modification for patients at risk for atrial fibrillation and define Pre-AF in patients with left atrial enlargement or evidence of atrial electrical instability.
- Sub-clinical atrial fibrillation occurs when atrial fibrillation is only detected on cardiac rhythm management (CRM) devices or wearable heart monitors where there is no 12-lead EKG evidence of an arrhythmia.

CENTRAL ILLUSTRATION: Kaplan-Meier Estimates of the Primary Composite Endpoint Among Racial and Ethnic Minorities and Nonminorities by Randomized Treatment in CABANA



Thomas, K.L. et al. J Am Coll Cardiol. 2021;78(2):126-38.

- Women and Communities of Color are less likely to be anticoagulated, less likely to be referred early for a rhythm control strategy, and have worse outcomes than white men.
- Atrial fibrillation ablation has a Class 1 or 2a indication for first-line therapy in all patient populations with paroxysmal atrial fibrillation or symptomatic atrial fibrillation.

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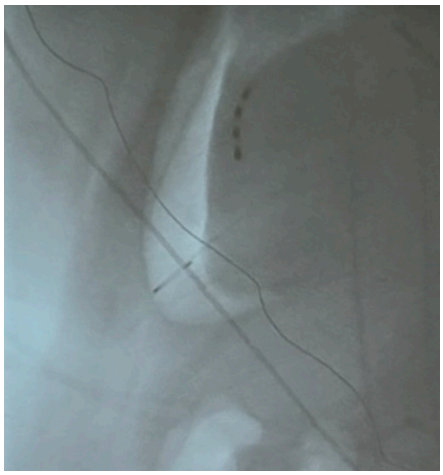
- Rhythm control has been shown to provide a survival benefit if performed in the first year after diagnosis in patients over the age of 75 or in patients over 65 with serious cardiovascular problems.
- Atrial fibrillation ablation has been shown to have a survival advantage in patients with HFrEF and to reduce the need for LVAD and heart transplant.
- Atrial fibrillation ablation has shown a survival benefit in Communities of Color.
- Patients with a Left Atrial Appendage Occlusion (LAAO) device should be considered for imaging to exclude left atrial clot or anticoagulation prior to cardioversion.
- Cardioversion's initial energy for atrial fibrillation should be at least 200J.
- Intravenous magnesium has been added to acute rate control as a class 2a indication. The mechanism is a blockade of slow inward calcium current in the SA and AV nodes. A 2-to 5-gram dose is commonly used. (*J Cardiol. 2021;78:375–381.*)
- Diltiazem is a contra-indicated with EF less than 40%.
- There is no class 1 indication for anti-arrhythmic use. Most agents have a class 2a indication. Sotalol has a lower class (2b) indication. After failure of one prior anti-arrhythmic medication, the chance of a second medication being effective is less than 20%.
- Atrial flutter has a class 1 indication for ablation, but close follow-up and consideration of continuing anti-coagulation in high stroke-risk patients should be considered strongly—33% at 5 years.
- For patients with lone atrial fibrillation before the age 45 years, consider genetic testing and close follow-up for long-term risk of cardiomyopathy.
- For patients with prior bariatric surgery, DOAC drug levels are lower than expected likely due to decreased drug absorption, and there is a class 2b indication to use warfarin instead of DOAC. Consider this in patients with embolic events or LAA thrombus on DOAC.
- Patients with hypertrophic cardiomyopathy should be anticoagulated regardless of CHADS-Vasc status.
- For pregnant patients, sotalol and flecainide have the best track record if pharmacologic rhythm control is needed. Propranolol, metoprolol, and digoxin are preferred for rate control.
- In patients with "triggered" atrial fibrillation in the setting of critical illness or post-surgical state, 39% will develop clinical atrial fibrillation in the next five years and these patients should receive close follow-up. (*Wang EY, Hulme OL, Khurshid S, et al. Initial precipitants and recurrence of atrial fibrillation. Circ Arrhythm Electrophysiol. 2020;13:e007716.*)

Epicardial VT ablation program starting at Virtua Our Lady of Lourdes

Virtua's cardiothoracic surgery and electrophysiology teams are launching an epicardial VT ablation program

Cardiac ablation is one of the fastest-growing areas in cardio-vascular care in the United States. Traditional ablation involves ablation from inside the heart (endocardial ablation). Certain areas of the heart are amenable to ablation from the coronary sinus venous system either with the use of heat or alcohol injection. The vast majority of the outside of the heart cannot be approached except through direct puncture into the epicedial space using a needle or a surgically created window. Epicardial ablation techniques are often critical in the ablation of patients with non-ischemic cardiomyopathies, refractory arrhythmias,



CO2 insufflation of the pericardium facilitating epicardial puncture

and patients in whom the right phrenic nerve course limits ablation. Newer techniques may allow safer access to the pericardial space using insufflation with carbon dioxide administered via a deliberate micro-perforation of the coronary sinus system. Virtua is in the last phases of the implementation process for these procedures and the cardiac team expects to perform the first cases in early 2024.

Please contact Dr. Aatish Garg, Dr. Evan Blank, or any member of the Virtua Heart Rhythm team with questions or patients who you feel may benefit from VT ablation.

PROVIDER SPOTLIGHT

Welcome Dr. Evan Blank

Evan Blank, MD, is a Freehold, New Jersey native who attended medical school at Mount Sinai School of Medicine and obtained fellowships in cardiovascular medicine and cardiac electrophysiology from Emory University.

As an electrophysiologist, Dr. Blank performs all aspects of cardiac rhythm device management therapy and ablations. He has additional training in left atrial appendage occlusion procedures, lead extraction, and epicardial ablation.

Dr. Blank is now accepting new patients at Brace Road in Cherry Hill and the Virtua Health and Wellness Center at the Rohrer Center in Voorhees.

Meet the Virtua Heart Rhythm Team

Our team provides outstanding care for heart rhythm disorders with a focus on advancing care with excellent patient satisfaction in an inclusive and efficient manner.

For New Patient Scheduling/EP Hotline
856-363-0696
In EPIC: choose ambulatory referral to electrophysiology.

Darius P. Sholevar, MD
M: 856-889-0705
Complex ablations, left atrial appendage occlusion, physiologic pacing, and lead extractions

Evan A. Blank, MD
M: 908-309-9070
Complex ablations, epicardial VT ablation, left atrial appendage occlusion, and lead extractions

Aatish Garg, MD
M: 216-571-5954
Complex ablations, epicardial VT ablation, physiologic pacing, and left atrial appendage occlusion

Heath E. Saltzman, MD
M: 609-636-3527
Complex ablations, left atrial appendage occlusion, physiologic pacing, and lead extractions

Sivaraman Yegya-Raman, MD
M: 609-923-5176
Ablation, physiologic pacing, and cardiac rhythm devices

Virtua Cardiology - Cherry Hill
1 Brace Road, Suite C-3
Cherry Hill, NJ 08034
856-428-4100

Virtua Cardiology - Galloway
310 Chris Gaupp Drive, Suite 103
Galloway, NJ 08205
609-641-0012

Virtua Cardiology - Hammonton
2 Sindoni Lane
Hammonton, NJ 08037
609-561-8500

Virtua Cardiology - Moorestown
728 Marne Highway, Suite 200D
Moorestown, NJ 08057
856-924-2324

Virtua Cardiology - Sewell
239 Hurffville-Crosskeys Road,
Suite 350B
Sewell, NJ 08080
856-589-0300

Virtua Cardiology - Voorhees
2309 Evesham Road, Suite 101B
(William G. Rohrer Center
for Health Fitness)
Voorhees, NJ 08043
856-424-3600

Virtua Cardiology - Willingboro
1113 Hospital Drive, Suite 202
Willingboro, NJ 08046
609-835-3550

Virtua Cardiology - Woodbury
730 N. Broad Street, Suite 200
Woodbury, NJ 08096
856-251-2340