HENRY FORD HEALTH®
Heart & Vascular

Cardiovascular Connection

Fall 2025

Atrial Fibrillation (AFib) Center of Excellence Announced

Atrial Fibrillation (AFib) is a progressive condition. Arfaat Khan, M.D., section chief Cardiac Electrophysiology (EP), Henry Ford Medical Group, explained, "clinical studies indicate better outcomes are noted if AFib is aggressively treated early in the course of the disease state." To achieve better outcomes for their AFib patients, Henry Ford Health has established its AFib Center of Excellence and meets the established requirements. They include:

1. **Dedicated EP laboratories with leading-edge equipment:** Highly-trained electrophysiologists throughout Henry Ford Health perform catheter-based ablations. All sites across Henry Ford Health have pulse field ablation which is a new non-thermal based ablation technology designed to provide a safer and more efficient procedure. Henry Ford Health also offers treatment options for patients with resistant AFib including the MAZE and minimally invasive convergent hybrid epicardial AFib ablation procedure, performed by experienced cardiothoracic surgeons. This program was developed under the supervision of Hassan Nemeh, M.D., division head of Cardiothoracic Surgery. Left atrial appendage closure procedures are performed by our highly trained structural heart disease cardiovascular medicine specialists along with cardiac electrophysiologists. All procedures are supported by a unique cardiac trained team of nurses, technicians and cardiac anesthesiologists or certified nurse anesthetists.

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HENRY FORD HEALTH®

A message from

Heart & Vascular Service Line Executive Leadership

Dr. Herbert Aronow | Dr. Shukri David | Nancy Zehnpfennig | Eric Barnaby

Henry Ford Health's Heart & Vascular Service Line continues to set a high bar for access, innovation, and quality outcomes across Michigan and beyond.

We know that an ounce of prevention is worth a pound of cure, and we remain steadfast in our commitment to community outreach. To that end, nearly 1,000 people were screened for cardiovascular risk this year through our multi-hospital "Healthy Heart" community outreach event.

We are proud to announce our Atrial Fibrillation (AFib) Center of Excellence, offering state-of-the-art pulse field ablation at all sites, hybrid surgical solutions for resistant AFib, rapid-access APP-driven AFib clinics (appointments within 48–72 hours), and comprehensive multidisciplinary protocols—matched by few programs nationwide.

Our Women's Heart Program now includes more dedicated clinics than any health system in the country, staffed by women cardiologists and offering tailored diagnostics and cardio-obstetrics care, including the Heart Healthy Moms program for pregnant and postpartum patients.

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Inside

Atrial Fibrillation (AFib) Center of Excellence Announced

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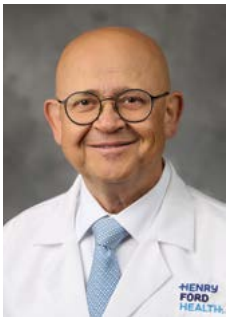
2. **Comprehensive approach for pre-ablation management:** Henry Ford Health has established Advanced Practice Provider driven AFib clinics. The AFib clinics provide early and timely access for patients diagnosed with AFib with a goal of evaluating a patient within 48-72 hours of a referral being placed. The AFib clinics provide patients with education on their condition as well as resources to aid in management of modifiable risk factors such as obesity, obstructive sleep apnea, and alcohol use. These clinics also serve to initiate early rhythm control strategy with either antiarrhythmic drugs or consideration of ablation therapy and/or left atrial appendage closure.

3. **Availability of multidisciplinary professionals:** The Henry Ford AFib team is comprised of well-trained, nationally recognized cardiac electrophysiologists, cardiovascular medicine specialists, cardiothoracic surgeons and emergency room physicians. Together protocols for managing AFib have been established including best practice alerts in our electronic medical record alerting us on patients that have AFib and are not on anti-coagulation along with AFib pathways/protocols for patients that present to the emergency room focusing on reduction of hospital admissions for AFib and timely appointments in our specialized AFib clinics.

4. **Periodic training and education for the doctors and staff:** The entire Henry Ford Health cardiovascular team of physicians and staff are consistently involved in clinical studies, evaluating new technologies and teaching physicians around the world in the latest technologies and best practices for the treatment of AFib.

5. **Rigorous peer review:** The Henry Ford Health team participates in regular peer review meetings where complications and specific cases are discussed. Feedback is provided to constantly improve the quality of the care provided. Henry Ford Health also participates in national registries allowing benchmarking with peers.

Arfaat Khan, M.D.



Nemeh Hassan, M.D.

6. **Follow-up monitoring:** Henry Ford Health has established a set of protocols for post ablation follow up which include a nurse phone call and periodic follow up with our electrophysiology APPs and electrophysiology physicians. Short- and long-term follow up data is collected and utilized both internally for continued quality improvement initiatives as well as provide externally via multiple AFib registries for cross-institutional research, contributing to the growing understanding of AFib and how best to care for our patients. Henry Ford Health participates in the NCDR AF registry, REAL AF registry along with the LAAO registry.

"At each of our centers, the same protocols and expertise is delivered to AFib patients from around the entire state of Michigan, Canada and other states. We are proud of the excellence in AFib care that Henry Ford Health has accomplished, and together we will continue to strive for quality, comprehensive care for our patient's, worthy of designation of an atrial fibrillation center of excellence," said Dr. Khan.

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Our Lead Extraction Program for implantable cardiac electronic devices is the largest in Michigan, addressing the rising need for complex device removal with a multi-specialty team and advanced techniques, drawing patients from across the Midwest and Canada. We are also among the first centers to implant the Aurora EV-ICD™, an extravascular defibrillator combining anti-tachycardia pacing and defibrillation in a smaller, more durable device.

Internationally recognized for leadership in cardiogenic shock, we are expanding the National Cardiogenic Shock Initiative into a global registry effort, while participating in pioneering new trials, like MAGENTA, which is evaluating a new lower profile, more powerful percutaneous temporary left ventricular assist device (LVAD) than the current industry standard. We are also leveraging our advanced heart failure expertise to embark upon early LVAD intervention through the TEAM Heart Failure trial, and are 1 of only 8 US centers approved to implant the novel BrioVAD™ LVAD system for end-stage heart failure and recalcitrant cardiogenic shock.

We continue to make significant system-wide capital investments to modernize our Cath labs, EP labs, and hybrid ORs, integrating cutting-edge physiology and imaging platforms to support complex structural, coronary, vascular, and electrophysiology procedures.

Henry Ford Health continues to deliver cutting-edge, patient-centered cardiovascular care—establishing us as the clear referral destination for complex patients in need of advanced diagnostic and therapeutic intervention.

Largest lead extraction program in Michigan addresses growing need

Karl Ilg, M.D.

American College of Cardiology's National Cardiovascular Data Registry data indicates approximately 200,000-225,000 pacemaker implantations are performed annually in the United States. The annual rate of ICD implantations (including CRT-D) ranges between 100,000-150,000 procedures. These numbers are slowly increasing over time, but more importantly patients are living longer with existing devices. This requires more generator changes and devices are becoming more complex. Both issues result in the increased likelihood of device-related complication.

As a result, the need for device extraction is growing as well. Over the past decade, the volume of extraction procedures has increased by 15-20%. Most of this increased need is due to device infection, which is a life-threatening emergency. For patients who require an extraction due to device infection around 25% of them actually do not need a device re-implanted. For those who do need a device re-implanted, electrophysiologists who perform transvenous lead extraction (TLE), tend to be the most adamant about using 'leadless' technology whenever possible.

Despite the acute need for lead extraction, few hospitals and health systems offer this complex service. To meet this need, the Henry Ford Health Heart & Vascular Lead Extraction Program was created.

Karl Ilg, M.D., Henry Ford Health electrophysiologist, explains, "there is a huge unmet need for lead extraction, with patients from Michigan and surrounding states and even Canada developing life-threatening infections that can only be treated successfully with complete removal of the device, or devices that have seen degraded function or are causing other heart issues due to length of time the device has been there."

Further Dr. Ilg said, "the need was obvious considering the aging population of Michigan, and the use of implanted devices to address arrhythmias. We see leads that have been in place for longer periods of time that develop fibrous tissue coating the leads that require extraction." In these cases, a multi-disciplinary approach involving cardiology, cardiac surgery, and electrophysiology is needed to ensure safe removal of these devices, which have scarred into the heart and blood vessels."

Dr. Ilg shared, in general, these procedures are done in the operating room under general anesthesia, with the procedure taking between 2 and 5 hours. Patients usually are up and walking about by evening, and postoperative discomfort is usually quite minimal. Patients are most often discharged the following day, unless the issue of infection has resulted in the need for more extensive medical care.

Main reasons for lead extraction are:
Blood infection: In most cases, antibiotics are not enough to treat an infection. Serious complications that require emergency treatment include fungal vegetation in the leads or MRSA infections. Device infection remains the most frequent indication for device extraction, accounting for 50% of those extractions done within the HFH system. Though we all pay a great deal of attention to those patients with very aggressive bacterial infections that also have a predilection for the heart (MRSA), pocket infection evidenced by pain, redness, swelling, or perhaps drainage from the chest wall site is also an indication for extraction. The patient's 6-month mortality is very high in these cases, and cannot be treated effectively with antibiotics alone.

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Meet the lead extraction team

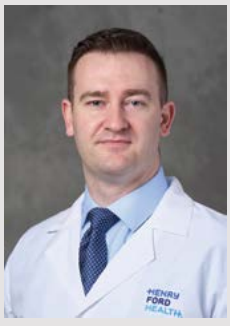
Electrophysiologists:

Madar Abed, M.D.
Henry Ford Hospital
Macomb
Henry Ford Rochester

Karl Ilg, M.D.
Henry Ford Hospital
Henry Ford Hospital
Macomb

Mohamad Raad, M.D.
Henry Ford Hospital
Henry Ford Hospital
Macomb

Cardiothoracic Surgeons



Adam Daly, M.D.
Henry Ford Hospital
Henry Ford Hospital
Macomb

Raed Alnajjar, M.D.
Henry Ford Hospital
Henry Ford Hospital
Macomb

Women's cardiovascular health is focus of exclusive clinics

A known fact to most, only 20-25% of clinical trial participants historically have been women, with most female representation limited to women's health studies. In research on other medical conditions, particularly heart disease, women remain severely underrepresented. This disparity has serious consequences: women often present with cardiovascular symptoms that differ significantly from men's heart conditions, yet these differences are poorly understood. Women also face unique cardiovascular conditions, such as microvascular disease, which frequently goes undiagnosed while their concerns are dismissed by health care providers. Following pregnancy, for example, women have a higher frequency of spontaneous coronary dissections in their coronary arteries which are often misdiagnosed or missed and can lead to death. Each year more women die of heart disease than breast cancer and five other diseases combined—heart disease is the number one cause of death in women.

The team celebrating the January 2025 opening of the Henry Ford Women's Heart Clinic-Rochester.

Henry Ford Health has expanded its focus on cardiovascular health for women. Nishtha Sareen, M.D., medical director of Women's Heart Services for legacy Ascension Michigan, said, "We decided the best way to meet this challenge is through the creation of women's heart clinics. We wanted to do in it in a smart way that raised the level of awareness about women's heart conditions within the community yet not spend millions to build centers that just said, 'Women's Heart Health Clinic.'"

As a result, existing hospital facilities were utilized, and five clinics were developed within the hospital walls. "We have created more women's heart clinic than any other health system in the country," Dr. Sareen stated. These clinics are run by women cardiovascular medicine specialists who

Leaders celebrating the Women's Heart Clinic – Henry Ford Providence Hospital Southfield on March 19, 2025

understand the uniqueness of women's cardiology needs in different stages of life. "Each clinic can provide access to certain tests women require not readily available at all hospitals and necessary diagnostic testing to deliver heart health care in a cost effective, efficient, and clinically relevant way." Shukri David, M.D., Chair of Cardiovascular Services for legacy Ascension Michigan says, "While access is important, so is awareness among physicians, emergency medicine doctors and women, especially post-menopausal women with vague symptoms."

A sixth location in downtown Detroit is also home to a program for pregnant women led by Ryhm Radjef, M.D. The *Heart Healthy Moms* program, part of Cardio-Obstetrics, provides care for both pre- and post-pregnancy. The program offers a full range of heart care for women who want to become pregnant and women who are pregnant. The program is especially important if a woman has had a heart condition since birth or experienced any type of heart disease as an adult; needs to manage high or low blood pressure in pregnancy; and or develops conditions related to high blood pressure in pregnancy or shortly after delivery.

The Women's Heart Program locations and lead physicians include:

Henry Ford Genesys Hospital
3399 Pollack Road
Grand Blanc, MI 48439
(810) 606-7550
Tamara Ivers, M.D.

Henry Ford Providence Southfield Hospital
16001 W Nine Mile Road
Southfield, MI 48075
(248) 849-2280
Carina Fadel, M.D.

Henry Ford Medical Center – 2nd Avenue
6525 Second Avenue
Detroit, MI 48202
(313) 876-4540
Ryhm Radjef, M.D.

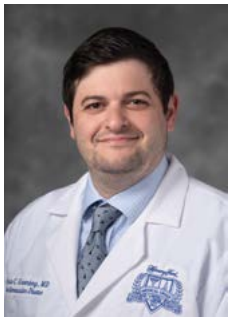
Henry Ford Rochester Hospital
1101 W University Drive
Rochester, MI 48307
(248) 652-5223
Jelena Arnautovic, D.O.

Henry Ford Providence Novi Hospital
47601 Grand River Avenue
Suite B233
Novi, MI 48374
(248) 849-2280
Nishtha Sareen, M.D.

Henry Ford St. John Hospital – Medical Pavilion Two
22201 Moross Road
Valade Outpatient Center
Detroit, MI 48236
(313) 343-7770
Nancy Mesiha, M.D.

Aurora EV-ICD™: Innovative extravascular defibrillator now available at Henry Ford Health

Electrophysiologists at Henry Ford Health have begun implanting the Aurora EV-ICD™ system, an extravascular defibrillator designed to treat sudden cardiac arrest and abnormal heart rhythms. This system combines defibrillation and antitachycardia pacing (ATP) in a single device. In March 2024, Joshua Greenberg, M.D., Henry Ford Health electrophysiologist, performed the first insertion as part of the device's limited commercial release and has since completed four procedures.



Joshua Greenberg, M.D.

"We selected this device for several different clinical scenarios including patients with infection, venous access challenges, and those unsuitable for conventional devices," explained Dr. Greenberg. "I also implanted the system in a young patient who preferred to avoid a transvenous device or the bulkiness of a subcutaneous ICD." The Aurora EV-ICD™ features a contoured, tapered design that reduces skin pressure and provides a more natural fit against the chest, enhancing patient comfort.

Madar Abed, M.D.

Madar Abed, M.D., director of Electrophysiology at Henry Ford Rochester Hospital, recently implanted the device in a 37-year-old patient who had experienced ventricular tachycardia (VT), cardiac arrest, and complex ventricular arrhythmias, defined as three or more consecutive beats at a rate exceeding 100 beats per minute. "The design of the Aurora EV-ICD™ eliminates several risks associated with traditional transvenous ICDs, such as vascular damage and infection," noted Dr. Abed. At 33 cm^3, the device is half the size of comparable ICDs and can be placed outside the vascular space, tucked under the sternum. This placement preserves the vasculature and reduces potential injury. The system is projected to have 60% greater battery longevity than subcutaneous implantable cardioverter defibrillators.

"We have already documented multiple successful interventions with this device in a single patient," Dr. Greenberg reported. The system delivers temporary post-shock pacing following defibrillation or cardioversion therapy, addressing potential temporary bradycardia or asystole after high-voltage therapy. Additionally, its pause prevention pacing feature monitors for significant cardiac pauses and provides temporary bradycardia pacing support when needed. Alerts can be delivered via device tone and the patient's home monitor.

Clinical studies have shown a 96.9% implant success rate with only a 3.9% rate of system- or procedure-related major complications through hospital discharge.

To refer a patient to one of our Henry Ford Health Electrophysiologists, call 877-434-7470.

Largest lead extraction program in Michigan addresses growing need

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Lead fracture: When the inside of a device lead becomes damaged, this fractured lead does not function correctly. This typically requires treatment within a few days.

Vein occlusion: When a fractured lead occludes the vein where it is located, this often requires implementation of a new, upgraded device. As a pacemaker or defibrillator lead lingers in the blood vessel leading back to the heart, it progressively causes scarring, which can narrow the blood vessel. This is not usually of importance to the patient unless that patient then needs additional leads added to their device in order to treat a heart condition like congestive heart failure. In this case, an older lead is extracted in order to make room for one or two new leads.

Severe Tricuspid Regurgitation: In the last year, the FDA has approved catheter-based valve replacements that are being done by structural heart interventional cardiovascular medicine specialists. The procedure has shown significant benefit in quality of life improvement and shortness of breath. Roughly 40% of these patients have conventional pacemakers or defibrillators that would be 'jailed' by this valve (risk of dislodgement and concern about long-term infection), which occupies the same space. Removal of the leads is often requested and implant alternative devices to make room for the percutaneous tricuspid valve.

Each electrophysiologist is a board-certified cardiovascular medicine specialist within the Henry Ford Heart & Vascular service line. They specialize in electrophysiology conditions, including complex arrhythmias and devices such as pacemakers and implantable cardioverter defibrillators.

To refer a patient to the Henry Ford Electrophysiology Lead Extraction Program, call 877-434-7470.

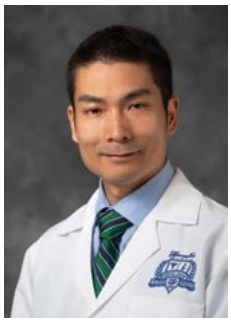
Research

Cardiogenic shock registry study expands globally

Nearly a decade ago, the Detroit Cardiogenic Shock Initiative (CSI) began. Led by William O'Neill, M.D., medical director emeritus of the Center for Structural Heart Disease at Henry Ford Health and Babar Basir, D.O., medical director of the acute mechanical circulatory support program at Henry Ford Hospital. Detroit area hospitals tested a new protocol for treatment using the Impella heart pump before performing revascularization. This protocol was associated with a dramatic improvement in survival rates at discharge to 76%.

"The Detroit collaborative was extremely successful," said Dr. O'Neill, so much that "in 2017 the National Cardiogenic Shock Initiative (NCSI) was launched and also proved to be very successful." Physicians in more the 80 hospitals across the nation were trained and enrolled 406 patients in the study. Once again, the cardiogenic shock protocol proved successful at increasing survival rates among a larger patient population. For patients classified with Society for Cardiovascular Angiography and Interventions (SCAI) shock stages C or D, the survival rate was 79% at its completion in 2020.

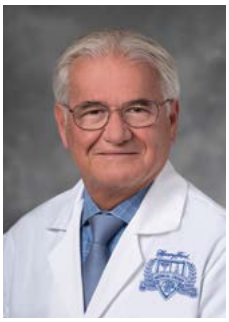
Babar Basir, D.O.



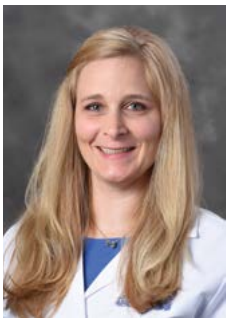
Daizo Tanaka, M.D.

Eric Simpson, NP

Theodore Schreiber, M.D.



William O'Neill, M.D.



Gillian Grafton, D.O.

Not pictured:
Amir Kaki, M.D.

Dr. Basir explained, "the next step in our mission to improving outcomes in shock was the soon to be completed Can Escalation Reduce Acute Myocardial Infarction Mortality In Cardiogenic Shock (CERAMICS) study. Herein, we used all the knowledge gained in the past decade in treating patients with rapid mechanical circulatory support (MCS) but in sites who had all of the tools for treating shock patients including having escalation capabilities." Of the 120 patients needed, 100 were recruited and "the study confirmed the implementation of shock protocols alongside a team-based approach was associated with improved patient outcomes," he explained.

In April 2024, a large trial from Europe called the DANGER shock trial "showed the shock initiative was the best way of treating patients with large heart attacks," explained Dr. Basir. "What we learned from other data sets is that our clinical experience is the best global method to treat cardiogenic shock."

In 2025, the Global Cardiogenic Shock Initiative (GCSI) registry began, the funding has been secured, and site selection has begun. "We hope to have around 30 to 40 sites throughout the world join the registry and collect data for about five years," said Dr. Basir. Participating sites are first to come in places like Hong Kong, where Dr. O'Neill has already begun work. Registries will be established in Australia and other Asia Pacific countries as well.

"As we have done in the past, we will keep clinicians up to date on the outcomes within the study. Findings will be periodically released so that patient outcomes will be enhanced, and complications can be further reduced. Dr. Basir explained, "we hope these centers will learn from our experience over the last decade and will have great outcomes with low complication rates—the data will show us if that becomes a reality." said Dr. Basir.

MAGENTA trial

While the Impella heart pump has been the only one available on the market and used in patients experiencing cardiogenic shock, the evolution to smaller and more powerful heart pumps has begun. During the summer 2025, Henry Ford will begin enrolling patients in a new trial called MAGENTA, as its manufacturer seeks FDA approval. This new heart pump, which is smaller at 10 french, provides up to 5 liters of flow and is thus more powerful than the Impella CP device. As the primary investigator at HFH, Babar Basir, D.O., medical director of Acute Mechanical Circulatory Support at Henry Ford Health, explained, "We will initially use the device in patients with complex coronary artery disease and physicians who wish can refer their patients for this trial." Dr. Basir (MBASIR1@hfhs.org) and Research Coordinator Margaret Fox (MFOX2@hfhs.org) are available to discuss or enroll patients in the Magenta trial.

Code cardiogenic shock expedites care throughout the region

Due to the innovative and extensive work in cardiogenic shock, Henry Ford has been recognized as the leader in cardiogenic shock. "Patients can initially be treated at local hospitals, but many hospitals do not have the bandwidth to care for these very sick patients for many days, especially when the patient does not come out of cardiogenic shock. That is when a tertiary care center like Henry Ford Hospital (HFH) can provide the expertise, staff and mechanicals for patients to recover," explained Babar Basir, D.O., medical director of Acute Mechanical Circulatory Support at Henry Ford Health.

Amir Kaki, M.D., medical director of acute mechanical circulatory support at Henry Ford St. John (HFSJ) and Theodore Schriber, M.D., chief of cardiology at Henry Ford Warren (HFW) also have extensive expertise in treating patients in cardiogenic shock. Both were intimately involved in the initial Detroit CGS initiative over a decade ago. At HFSJ, Dr. Kaki and his team have the option to utilize ECMO. However, if the patient requires LVAD or a heart transplant, only HFH has that capability. "Any community hospital can refer a cardiogenic shock patient to HFH or HFSJ," explained Eric Simpson, ACNP, director of Acute Mechanical Circulatory Support at Henry Ford Health. Both hospitals function as a hub, depending on the needs of the patient and capacity of the hospital.

Responsible for acute mechanical circulatory support operations, Simpson explains, "patients in cardiogenic shock already face a 50% mortality rate if untreated, and for every hour lost in treatment that rate increases by 10%. Once the patient has been identified anywhere in the system, or at a community hospital in the region they can call one of our tertiary care centers for rapid transfer. In select cases doctors can call for a Code Cardiogenic Shock and there is ongoing work on creating pathways to get patients rapidly into the system and into an ICU—ideally within 4 hours."

A "code cardiogenic shock" alert brings together a transferring center and either the HFH or HFSJ multidisciplinary shock team of cardiovascular medicine specialists, cardiac surgeons, and intensivists to evaluate the patient's needs and plan for the next best step. Daizo Tanaka, M.D., serves as the surgical director of Acute Mechanical Circulatory Support and evaluates patients needing surgical MCS. Gillian Grafton, D.O., serves as the director of the Cardiac Intensive Care Unit (CICU) at HFH and has been instrumental in allowing for the ability of transferring centers to quickly and efficiently transfer patients into the CICU. This limits time delays as the team discusses the acuity, individualized treatment, and engages the appropriate multidisciplinary members of the team to optimize treatment when the patient arrives, thus optimizing the hub and spoke model.

Simpson explains that both the cardiogenic shock pathways and the shock team or call activation team is a work in progress and continues to become more efficient. Through the efforts of all, the goal is to continue to reduce death from cardiogenic shock among members of our community.

Research studies

ALIGN-AR Continued Access

Principal Investigator: Tiberio Frisoli, M.D.

Official Title: A Study to Assess Safety and Effectiveness of the JenaValve Trilogy™ Heart Valve System in the Treatment of High Surgical Risk Patients with Symptomatic, Severe Aortic Regurgitation (AR)

Description: This study focuses on treating symptomatic severe aortic regurgitation (AR) using the JenaValve Trilogy™ Heart Valve System. AR occurs when the aortic valve leaks, causing symptoms like fatigue and shortness of breath. The study is interventional, using a single-group model to test the JenaValve system through Transcatheter Aortic Valve Replacement (TAVR). The primary outcomes include mortality, stroke, and complications within 30 days to 1 year. The aim is to assess safety and effectiveness in high-risk surgical patients. Patients will follow-up at 30 days, 6 months, and annually 1-5 years post-procedure.

Expected Enrollment Completion: Unknown

Status: Recruiting

ALLIANCE AVIV

Principal Investigator: Pedro Villablanca, M.D.

Official Title: Safety and Effectiveness of Balloon-Expandable Bioprosthetic SAPIEN X4 Transcatheter Heart Valve in Failing Aortic Bioprosthetic Valves

Description: This study aims to assess the safety and effectiveness of the Edwards SAPIEN X4 Transcatheter Heart Valve in patients with failing aortic bioprosthetic valves who are at high risk for traditional surgery. It is a prospective, single-arm, multicenter study focusing on treatment outcomes. Participants will receive the SAPIEN X4 valve through a non-randomized, single-group assignment. The primary focus is on treatment, with key outcomes measured over 1 year including death, stroke, and functional status improvements. The study will evaluate the valve's performance through primary and secondary outcomes, such as mortality, stroke incidence, and quality of life improvements using the KCCQ and NYHA classifications.

Expected Enrollment Completion: December 2025

Status: Recruiting

Research studies


Tiberio Frisoli, M.D.


Brian O'Neill, M.D.


Pedro Villablanca, M.D.


Pedro Engel Gonzalez, M.D.

ENVISION

Principal Investigator: Tiberio Frisoli, M.D.

Official Title: Evaluation of the Navitor Transcatheter Heart Valve in Low and Intermediate Risk Patients who have Severe, Symptomatic, Aortic Stenosis Requiring Aortic Valve Replacement

Description: The ENVISION Trial aims to assess the safety and effectiveness of the Navitor TAVI System in patients with symptomatic, severe aortic stenosis who are at intermediate or low surgical risk. This prospective, randomized controlled trial will enroll about 1500 subjects globally, comparing the Navitor TAVI System to other commercially available transcatheter aortic valve systems. The primary outcome is a composite of all-cause mortality or stroke at 12 months post-procedure, highlighting the intervention's potential benefits and risks.

Expected Enrollment Completion: April 2027

Status: Recruiting

REACH (SHD)

Principal Investigator:
Pedro Engel Gonzalez, M.D.

Official Title: Recognition & Evaluation of Aortic Stenosis to Create Health Data Collection Study

Description: This is a prospective, non-randomized, data collection study to be conducted on adults recently referred for transthoracic echocardiogram (TTE). Eligible subjects who have consented to take part in the study will receive noninvasive hemodynamic monitoring using a Acumen IQ finger cuff. The objective of this study is to collect data using the Acumen IQ finger cuff on adults (18 years and older) with and without severe aortic stenosis who have recently undergone TTE imaging. This noninvasive finger cuff measures blood pressure and provides information about heart function. The device technology, and the cables and monitors that connect to it, have been cleared by the Food and Drug Administration (FDA) for use on people 18 years of age and older. However, in this study, they are considered investigational because they will be used outside of the critical care hospital areas. A newer version of the cuff may also be used in this study and is also investigational. Participation in this study will take approximately 15–30 minutes. Approximately 150 adult subjects will be enrolled at this site into one of two cohorts, based on diagnosis confirmed by TTE imaging.

Expected Enrollment Completion: July 2025

Status: Recruiting

Disparities in Severe AVD

Principal Investigator: Pedro Villablanca, M.D.

Official Title: Racial and economic disparities and unmet needs in patients with severe aortic valvular disease

Description: This is a multi-center, prospective data collection study of patients scheduled for commercial TAVR with the Edwards Lifesciences SAPIEN valve. Eligible patients identified from retrospective chart review will be approached for enrollment. 150 patients meeting inclusion and exclusion criteria will complete questionnaires for the study and will have information collected from their medical chart related to 30 day and 1 year post-TAVR outcomes.

Expected Enrollment Completion: Unknown

Status: Recruiting

RESTORE

Principal Investigator:
Pedro Engel Gonzalez, M.D.

Official Title: RESTORE Study (Redo Transcatheter Aortic Valve Replacement for Transcatheter Aortic Valve Failure)

Description: This is a prospective, non-randomized, multi-center, post-market study to generate clinical evidence on valve safety and performance in subjects treated by redo TAVR with commercially available Medtronic and Edwards Transcatheter Aortic Valves (TAV) with TAV-in-TAV indication.

Expected Enrollment Completion: Unknown

Status: Recruiting

JOURNEY

Principal Investigator: Pedro Villablanca, M.D.

Official Title: J-Valve to Treat Aortic Regurgitation via Transcatheter Therapy

Description: This is a prospective, single arm, multi-center, pivotal, interventional study to assess the safety and efficacy of the J-Valve Transfemoral System in patients with symptomatic, severe, native aortic valve regurgitation (AR) and AR-dominant mixed aortic valve disease, who are judged by a multi-disciplinary heart team to be at high risk for open surgical aortic valve replacement (SAVR).

Expected Enrollment Completion:
December 2027

Status: Recruitment Starting Soon

JENA-VAD Registry

Principal Investigator: Tiberio Frisoli, M.D.

Official Title: Transcatheter Aortic Valve Replacement using the JenaValve Trilogy Heart Valve System for Clinically Significant Aortic Regurgitation in Patients with Left Ventricular Assist Devices (LVAD)

Description: This is a prospective, multi-center, single arm clinical registry nested within the ALIGN-AR study. The objective of this registry is to evaluate the safety and effectiveness of the JenaValve Trilogy Heart Valve System for transcatheter aortic valve replacement (TAVR) in subjects with continuous flow left ventricular assist device (cfLVAD) and clinically significant aortic re-gurgitation (AR) who are indicated for TAVR.

Expected Enrollment Completion:
December 2025

Status: Recruitment Starting Soon

ARTIST

Principal Investigator: Tiberio Frisoli, M.D.

Official Title: A Study to Assess Safety and Effectiveness of the JenaValve Trilogy Transcatheter Heart Valve System Versus Surgical Valve Replacement in patients with Aortic Regurgitation

Description: This is a prospective, randomized, controlled, multicenter, international, interventional study. Subjects will be randomized 1:1 to receive either transcatheter aortic valve replacement (TAVR) using the Trilogy THV System or SAVR using commercially available surgical prosthetic valves.

Expected Enrollment Completion:
February 2026

Status: Recruitment Starting Soon

SHIELD

Principal Investigator: Brian O'Neill, M.D.

Official Title: A Prospective, Randomized, Multicenter, Single-Blind Trial to Assess the Safety and Effectiveness of the EnCompass F2 Cerebral Protection System vs. Standard of Care (unprotected or Sentinel Cerebral Protection System) during Transfemoral Transcatheter Aortic Valve Replacement (TF TAVR)

Description: This study aims to assess the safety and effectiveness of the Encompass F2 Cerebral Protection System compared to standard care during Transfemoral Transcatheter Aortic Valve Replacement (TF TAVR). It is a prospective, randomized, single-blind trial involving patients with aortic stenosis. Participants are randomized to receive either the F2 CPS or standard care. The primary outcomes focus on major adverse cardiac and cerebrovascular events and total new lesion volume assessed by MRI. Secondary outcomes include stroke incidence and neurological assessments.

Expected Enrollment Completion: July 2026

Status: Recruitment Starting Soon

CLASP - IID/IIF

Principal Investigator: Brian O'Neill, M.D.

Official Title: Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial

Description: This study investigates the Edwards PASCAL Transcatheter Valve Repair System's safety and effectiveness in patients with degenerative or functional mitral regurgitation. These patients are either at prohibitive risk for surgery or on guideline-directed medical therapy. The trial compares PASCAL to the Abbott MitraClip in a randomized, controlled design. Participants are followed for major adverse events, MR severity reduction, and heart failure outcomes over 5 years, with primary outcomes assessed at 30 days and 6 months.

Expected Enrollment Completion: June 2026

Status: IIF arm is recruiting

ENCIRCLE

Principal Investigator: Brian O'Neill, M.D.

Official Title: SAPIEN M3 System Transcatheter Mitral Valve Replacement via Transseptal Access

Description: This study evaluates the safety and effectiveness of the SAPIEN M3 System for patients with severe mitral regurgitation who are not suitable for existing surgical or transcatheter treatments. It is a single-arm, multicenter trial focusing on treatment outcomes. Participants will be monitored for improvements in heart failure symptoms and quality of life over a year, using metrics like NYHA class and KCCQ score. The primary outcome measures include survival and heart failure hospitalization rates.

Expected Enrollment Completion: February 2027

Status: Recruiting

REPAIR MR

Principal Investigator: Brian O'Neill, M.D.

Official Title: Percutaneous MitraClip Device or Surgical Mitral Valve Repair in Patients with Primary Mitral Regurgitation who are Candidates for Surgery

Description: This study aims to compare the effectiveness of the MitraClip™ device with surgical repair for patients with severe primary mitral regurgitation (MR) who are at moderate surgical risk. The study is a randomized controlled trial involving patients whose mitral valves are deemed suitable for repair by the MitraClip™ device or surgery. Participants will be followed for two years to assess outcomes such as mortality, stroke, and MR severity. The primary outcomes include survival without stroke or hospitalization and maintaining moderate or less MR without further intervention. Subject will complete follow-up at 30 days and annually for 1-10 years post-procedure.

Expected Enrollment Completion: April 2026

Status: Recruiting

SUMMIT

Principal Investigator: Brian O'Neill, M.D.

Official Title: Clinical Trial to Evaluate the Safety and Effectiveness of Using the Tendyne Transcatheter Mitral Valve System for the Treatment of Symptomatic Mitral Regurgitation

Description: This study investigates the Tendyne Transcatheter Mitral Valve System for treating symptomatic mitral regurgitation or severe mitral annular calcification. It includes randomized and specific cohorts to compare Tendyne with MitraClip and assess its safety and effectiveness in high-risk patients. Participants are followed for up to 5 years with primary outcomes focusing on survival free of heart failure hospitalization. Secondary outcomes include improvements in walking distance, quality of life, and health status measurements.

Expected Enrollment Completion: Unknown

Status: MAC-CAP cohort is recruiting

AltaValve Pivotal

Principal Investigator: Brian O'Neill, M.D.

Official Title: AltaValve Pivotal Trial

Description: This study aims to assess the safety and effectiveness of the AltaValve System in treating patients with mitral regurgitation, a condition where the heart's mitral valve does not close tightly, allowing blood to flow backward in the heart. The trial is prospective, single-arm, and conducted across multiple centers. It focuses on patients who cannot undergo surgery or Transcatheter Edge-to-Edge Repair (TEER). The primary outcome measures include all-cause mortality and heart failure hospitalization over 12 months, with secondary outcomes assessing technical success and quality of life improvements over up to 5 years.

Expected Enrollment Completion: September 2029

Status: Recruiting

CLASP II TR Continued Access Study

Principal Investigator: Brian O'Neill, M.D.

Official Title: Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial

Description: The objective of the CLASP II TR continued access study (CAS) is to provide continued access to the PASCAL system for patients at selected sites in the United States with at least severe TR following the closure of enrollment of the CLASP II TR pivotal trial's randomized cohort. The CAS RCT-eligible cohort will include patients who meet all CLASP II TR pivotal trial eligibility criteria for the randomized cohort. On a case-by-case basis, the Clinical Screening Committee (CSC) will consider patients for a CAS Registry-eligible cohort who meet the eligibility criteria for the CLASP II TR Registry. Participants will be monitored for outcomes such as mortality, heart failure hospitalizations, and quality of life improvements over a period of 24 months, with follow-ups extending to 5 years.

Expected Enrollment Completion: December 2027

Status: Recruiting

Investments in cath labs, EP labs and hybrid rooms improves capabilities and quality

Significant investments have been made to enhance cardiac care capabilities across the Henry Ford Health. These capital improvements in heart and vascular catheterization labs, electrophysiology labs, and hybrid rooms represent a system-wide commitment to provide physicians with state-of-the-art environments for cardiovascular care. Enhancements also meet the needs of the many communities served in the diagnosis, management and treatment of a variety of conditions that include coronary artery disease, peripheral artery disease, venous disorders and pulmonary embolism, general and advanced heart failure, and cardiac electrophysiological abnormalities. Benefits include:

- Reduced procedure times through streamlined workflows
- Enhanced image quality supporting more precise diagnostics
- Expanded capacity reducing scheduling constraints
- Improved integration with hospital information systems

Henry Ford Health multidisciplinary teams include board-certified interventional cardiovascular medicine specialists, electrophysiologists, vascular surgeons, anesthesiologists, and specially trained nurses and technologists. Integration with hospital-wide digital health records and remote monitoring systems enhances procedural planning and post-procedural care.

To make this possible, significant financial investments made by the system, a federal grant and transformational financial donations have allowed the facilities to stay or be brought up to date through renovation, equipment and software enhancements. Specific hospital highlights include:

Henry Ford West Bloomfield Hospital

The two Henry Ford West Bloomfield Hospital laboratories are equipped with the latest high-resolution digital imaging and interventional technologies, to precisely visualize coronary and peripheral blood vessels, heart chambers, and electrical conduction pathways in 3-dimensional space with application platforms combining imaging, physiology, and co-registration software in optimizing procedural outcomes. These systems integrate seamlessly with advanced hemodynamic monitoring, intravascular ultrasound, fractional flow reserve and coronary flow reserve measurements using CoroFlow Cardiovascular System, ensuring accurate assessment of both coronary and peripheral vascular physiology and pathology.

Significant investments in cath labs, EP labs and hybrid rooms expand capacity and streamline workflow.

These highly integrated laboratories are equipped with specialized devices and equipment to support advanced heart failure services, performing invasive hemodynamic monitoring, including implantation of CardioMEMS sensors for remote tracking of a patient's heart failure condition, along with performing endomyocardial biopsies, and supporting refractory heart failure and cardiogenic shock with catheter-based mechanical circulatory support using intra-aortic balloon pump or direct left and right ventricular assist with Impella axial pump devices.

Cath Lab 1: The latest laboratory renovation permits electrophysiology procedures to be performed with dedicated equipment for advanced 3D electro-anatomical mapping using CARTOTM, intracardiac echocardiography, and radiofrequency or cryoablation systems. With recent certificate-of-need approval, a wide range of arrhythmias can be specifically treated, including atrial fibrillation and supraventricular tachycardia. Device implantation—including standard and micro pacemakers, implantable loop recorders, implantable cardioverter-defibrillators, and cardiac resynchronization therapy systems—is performed with high precision under image guidance.

Cath Lab 2: This lab was refreshed in 2022. The CoroFlow Cardiovascular System, an advanced platform to measure physiological indices: fractional flow reserve and resting full-cycle ratio to assess epicardial vessels; plus coronary flow reserve and index of microcirculatory resistance to assess microcirculation. Patients with coronary microvascular dysfunction can receive a clear diagnosis of CMD and take the first step to improve their quality of life.

Deb Spencer, regional director Heart and Vascular Service Line applied for a $1.15 million federal government grant which was awarded in 2022 and was recently allocated in an HRSA earmark grant to support the improvements.

Henry Ford St. John Hospital

John Surducan, director Cardiovascular Services for the Metro East Region shared that Henry Ford St. John Hospital has several catheterization labs that have been or are in the process of renovation thanks to philanthropic donations:

Cath Labs 1 and 3: These hybrid labs allow for structural heart procedures and or high-risk percutaneous coronary intervention (PCI). These labs are capable of producing live stream video cases, which are broadcast nationally and around the world. A case was recently streamed to Cardiovascular Research Technologies, which is a national conference, where new and advanced procedures are shared. Donations of $2.5 million brought Cath Lab 3 online approximately four years ago.

Cath Lab 4: A $2.5 million donation has been allocated for this hybrid cath lab which is not yet complete, but the work of the engineers and architects is complete and is expected to be completed by Fall 2025. Once open, this lab will also have live streaming capabilities.

EP Lab 10: A $1.7 million donation brought this EP lab online in February 2025. This state-of-the-art lab features advanced imaging technology, including the latest Philips fluoroscopy system. Electrophysiology procedures, including ablations, are performed in this lab using the new Boston Scientific pulse field ablation catheter which reduces procedure times nearly in half while producing the same or better outcomes. The new lab enhances their ability to perform complex catheterization procedures with greater precision, improving efficiency, safety, and outcomes for patients.

Any of the labs can be used for ECMO canulation as a hub in the ECMO process.

Henry Ford Warren Hospital

There are three modernized catheterization labs at Henry Ford Warren Hospital that provide improved workflow design and patient monitoring capabilities. Two of the cath labs are 8 and 10 years old and the third, the department is working to obtain funding for a new lab.

These labs are used as the spoke for ECMO, with Henry Ford St. John Hospital.

Henry Ford Wyandotte Hospital

Christian Fisher, administrator, Cardiovascular Services for Henry Ford Wyandotte and Brownstown Medical Center, explained when planning for the renovation of current cath lab 1, case volumes were such that it made better strategic sense to apply for a Certificate of Need for a third cath lab. This would allow the two existing labs to operate while building for future growth due to Cath Lab 3. Once the new lab 3 was built, then efforts to renovate the oldest Cath Lab 1 could be entertained in 2026. This represents an extraordinary investment in Henry Ford Wyandotte Hospital:

Cath Lab 3: A CON was received to complete this state-of-the-art lab, the previous year's Henry Ford Health capital funds of $4.3 million were provided. This catheterization lab is expected to open in July 2025.

Hybrid Vascular OR: Combining two operating rooms into one, this hybrid vascular OR is expected to open in October 2025 with funding of $4.7 million from Henry Ford Health's strategic capital pool. The volume of thoracic and aortic aneurysms through catheter-based technology, advanced carotid TCAR procedures and others that vascular surgeons have not been able to do locally to meet the needs of the local Henry Ford Wyandotte Hospital community will be possible in late fall.

Henry Ford Hospital

Christa Means, nurse manager, Cardiac Catheterization Services for Henry Ford Hospital, explained that Henry Ford Hospital has a total of 8 catheterization EP rooms, of which 2 are hybrid procedure rooms and two shared-space ORs for the complex cases. Of the 8 cath rooms there are 2 dedicated to EP procedures, 5 are cath rooms and 1 is shared between cath and EP.

The newest cath lab 6, opened in February 2025 and allows for more catheterization procedures and provides three additional days per week for EP. This new room was rebuilt from a shell room both capital and donation funding. State-of-the-art equipment varies among the rooms based on need. For example, equipment includes 5 ultrasound machines capable

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Salvaging a transcatheter tricuspid valve-in-ring procedure: a case study

A case study published in the JACC, reviews an innovative solution for a potentially catastrophic complication during a tricuspid transcatheter valve-in-ring (TViR) procedure performed by interventional cardiovascular medicine specialists at the Center for Structural Heart Disease at Henry Ford Hospital.

Pedro Engel Gonzalez, M.D.

An 84-year-old man with multiple prior cardiac interventions presented with worsening right-sided heart failure symptoms despite maximum medical therapy. His history included:

- Transcatheter aortic valve replacement (2011)
- Bioprosthetic mitral valve replacement, complicated by valve degeneration (2017)
- Tricuspid valve repair with a 32-mm CG Future annuloplasty band (2017)
- Valve-in-valve mitral valve replacement (2022)
- Micra pacemaker placement (July 2024)

The patient who was referred to Henry Ford following severe tricuspid regurgitation (TR) was deemed very high risk for a repeat surgical intervention, with a calculated STS-PROM of 5.25%. Pedro Engel Gonzalez, M.D., interventional cardiovascular medicine specialist explained, "after careful evaluation, the heart team decided to proceed with a TViR procedure using a 29-mm SAPIEN 3 Ultra prosthesis, despite the unfavorable nature of the incomplete [Colvin-Galloway Future Band] CG Future band."

The procedure was complicated by an unexpected balloon rupture during valve deployment when it interacted with the Micra pacemaker anchors. This resulted in incomplete valve expansion and subsequent embolization of the valve into the right atrium.

The team's quick response involved:

1. Successfully deploying a second 29-mm SAPIEN 3 Ultra valve within the tricuspid band, achieving good anchoring with minimal residual regurgitation
2. Maintaining wire position through the embolized valve while advancing a 30-mm NuCLEUS balloon
3. Capturing and withdrawing the balloon, the embolized valve was carried into the superior vena cava (SVC)
4. Precisely deploying the embolized valve at the SVC-right atrial junction using a 28-mm TRUE Dilatation balloon (Bard Vascular),
5. Effectively converting the original ViR into a functional caval valve implantation (CAVI)

Dr. Engel Gonzalez explained, "post-procedure imaging confirmed stable placement of both valves with only mild central regurgitation and a mean tricuspid gradient of 3.5 mm Hg." The patient was discharged the following day with significant improvement in symptoms. Dr. Engel Gonzalez concluded by sharing, "while TViR procedures remain relatively uncommon, this report provides valuable insights into managing a rare but potentially disastrous complication, demonstrating how proper preparation and quick adaptation can lead to successful outcomes even in challenging scenarios can be managed by skilled cardiac interventionalists.

The read the complete article, use this link:
https://www.jacc.org/doi/10.1016/j.jaccas.2025.103237

Alrayes H., Chakfeh, E., Kar Lok Lai, L. Fram, G., Zweig B., Lee, J.C., O'Neill, B., Frisoli, T., O'Neill, W., Villablanca P., Engel Gonzalez, P. *J Am Coll Cardiol Case Rep.* 2025 Apr, 30 (8) 103237. Impromptu SVC Caval Implantation During Tricuspid Transcatheter Valve-in-Ring. DOI: doi.org/10.1016/j.jaccas.2025.103237

Staff update

Fayaz Hakim, M.D.
Cardiac Electrophysiology

Medical School Education
Government Medical College, Srinagar Kashmir, India

Fellowship
Loyola University Medical Center, Clinical Cardiac Electrophysiology, Maywood, IL

Mayo School of Graduate Medical Education, Cardiovascular Disease, Phoenix, AZ

Residency
Mayo School of Graduate Medical Education, Internal Medicine, Rochester. MN

Board Certifications
American Board of Internal Medicine - Cardiovascular Disease

American Board of Internal Medicine - Clinical Cardiac Electrophysiology

The American Board of Internal Medicine - Internal Medicine

Memberships
Midwestern Vascular Society

Society of Vascular Surgery

Clinical Interests
Dr. Hakim's clinical interests are in atrial fibrillation, supraventricular tachycardia and ventricular tachycardia.

Locations
Henry Ford Genesys Heart - Pollock Road


Fayaz Hakim, M.D.

Asaad Nakhle, M.D.
Interventional Cardiology

Medical School Education
Damascus University School of Medicine, Damascus, Syria

Fellowship
Henry Ford Hospital, CHIP Fellowship, Detroit, MI

Tulane University School of Medicine, Interventional Cardiology, New Orleans, LA

Tulane University School of Medicine, Cardiovascular Medicine, New Orleans, LA

Residency
Henry Ford Hospital, Resident, Detroit, MI

Board Certification
American Board of Internal Medicine - Internal Medicine

American Board of Internal Medicine - Cardiovascular Disease

American Board of Internal Medicine - Interventional Cardiology

Certification Board of Nuclear Cardiology - Nuclear Cardiology

National Board of Echocardiography - Cardiology

Registered Physician in Vascular Interpretation – Vascular Medicine

Clinical and Research Interests
Dr. Nakhle's clinical interests are chronic total occlusions, complex coronary interventions, and mechanical circulatory support.

Languages
Dr. Nakhle also speaks fluent Arabic.

Locations
Henry Ford Hospital

Henry Ford Medical Center - Fairlane

Henry Ford West Bloomfield Hospital

Henry Ford Wyandotte Hospital


Asaad Nakhle, M.D.

Kyle Markel, M.D.
Vascular Surgery

Medical School Education
Wayne State University School of Medicine, Detroit, MI

Residency
University of Pittsburgh Medical Center, Vascular Surgery, Pittsburgh, PA

Board Certification
The American Board of Surgery - Vascular Surgery

Clinical Interests
Dr. Markel's clinical interests include open and endovascular management of aortic aneurysms, dissections and occlusive disease. Also open and endovascular management of cerebrovascular disease, peripheral arterial disease, and dialysis access with particular interest in complex limb salvage.

Locations
Henry Ford Hospital

Henry Ford Macomb Hospital

Henry Ford West Bloomfield Hospital


Kyle Markel, M.D.

In the news

First off-the-shelf device for complex aneurysmal disease

Andi Peshkepija, M.D.

Henry Ford Wyandotte Hospital is among the first to use the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE), first used by Vascular Surgeon Andi Peshkepija, M.D. "Patients who have thoraco-abdominal or para-renal aneurysms now have an endovascular repair option. Also, patients with complex anatomy that are at high surgical risk yet an endovascular approach could repair abdominal aortic aneurysm (AAA) are the potential candidates," explains Dr. Peshkepija.

TAMBE is the first FDA-approved, off-the-shelf, endovascular system to be used to exclude the aneurysm from the blood circulation in patients diagnosed with para-renal and thoraco-abdominal aortic aneurysm disease and who have appropriate anatomy including adequate iliac/femoral access.

Dr. Peshkepija explains, that at Henry Ford Wyandotte Hospital, "this means patients who have a complex aneurysm, and an open approach was their only option, now can have an FDA approved, on label device, minimally invasively repair of their para-renal or thoraco-abdominal aneurysms." Also, high risk surgical candidates who may have not been candidates for open surgery, now can have a minimally invasive option to reduce their risk of aneurysm rupture. "This will expand our ability to provide greater care for our patients and reduce risk of aneurysm rupture in complex anatomy that may have otherwise been ignored," he said.

Healthgrades recognition

At the annual TCT 2024 conference the Henry Ford Structural Heart Research Center was designated as the top structural heart research center from the Cardiovascular Research Foundation.

100th commercial tricuspid regurgitation EVOQUE

An important milestone in treatment of patients with severe tricuspid regurgitation (TR), was made by performing our 100th commercial Evoque case. Brian O'Neill, M.D., said, "I cannot thank our industry partners, our administration, and most of all our patients enough for trusting us to help improve their lives. We embrace the challenges ahead and look forward to helping continue to lead the innovation in the field of transcatheter tricuspid valve intervention." Physicians include: Tiberio Frisoli, M.D., Pedro Villablanca Gonzalez, M.D., James Lee, M.D., Herbert Aronow, M.D., Henry Kim, M.D., and William O'Neill, M.D. and support from Steven Kalkanis, M.D., and Adnan Munkarah, M.D.

First patients receive BrioVAD™ LVAD at Henry Ford

The Advanced Heart Failure team, including Hassan Nemeh, M.D., chief of cardiac surgery, implanted three of only a few patients across the United States with the BrioVAD™ system, a left ventricular assist system (LVAS). Henry Ford Hospital is one of only eight centers in the United States to take part in the INNOVATE Trial, making the FDA-approved BrioVAD™ heart pump available.

This device represents a significant advancement in the establishment of technologies available to address advanced heart failure. A novel small MagLev pump with a large diameter rotor and long blades is designed to create a low turbulence blood flow path, which minimizes blood damage while optimizing patient fit. This new pump is under trial for permanent heart support for patients with end-stage heart failure or recalcitrant cardiogenic shock. This trial is important as it provides another option to only one other FDA-approved device.

The surgical PI: Hassan Nemeh, M.D.
The surgical PI: Daizo Tanaka, M.D.
The site PI is: Dr. Gillian Grafton, D.O.
National Leadership Panel: Jennifer Cowger, M.D., MS, FACC

Healthy heart screens nearly 1,000 at 6 Henry Ford locations

For the 20th year, residents took advantage of free, life-saving heart screenings offered at six Henry Ford Health locations on April 26 through the Healthy Heart initiative. Nearly 1,000 received cardiology-related screenings which included an electrocardiogram (EKG), blood pressure screening, body mass index, blood glucose test, heart risk assessment, stroke assessment and consultation with a doctor. "It's Henry Ford Health reaching out to the community to say we are here to support you. We want our community to be healthy and these screenings are an integral part of our mission," said Shukri David, M.D., Chair of Cardiovascular Services for legacy Ascension Michigan.

Healthy Heart will return next year to provide even more much-needed services, all at no cost. Christian Fisher, a cardiology administrator who led operations at the Wyandotte event, said the screenings make a tremendous difference for those who are not insured or may be struggling financially.

By the numbers:

- **985:** Healthy Heart participants in 2025
- **6:** Participating Henry Ford Health locations
- **360:** Southfield participants
- **330:** Participants at new locations in Wyandotte and Macomb
- **10,000+:** Residents screened since 2005

Herbert Aronow, M.D. (left) and Shukri David, M.D. were interviewed by Fox 2 News.

Teams from Henry Ford Rochester Hospital

Henry Ford Wyandotte Hospital supported the screening effort.

Investments in cath labs, EP labs and hybrid rooms improves capabilities and quality *continued from page 11*

of 3D and 4D intracardiac echo, 2 new ultrasound machines were upgraded and 1 pre-existing machine was upgraded from only 2D to 3D/4D capability in addition to 2 previously existing 3/4D capable machines, bringing the count of machines from 2 to 5, to provide better imaging during complex structural heart and EP procedures. The ultrasound machines can be used in any of the rooms. One of the EP labs biplane fluoroscopies for 3D imaging and the second EP room is designated as the magnet room, used specifically for magnet-guided catheter procedures.

Any of the cath labs can be used for new and innovative research procedures, recently the first commercial (non-research) tricuspid valve replacement in Michigan was performed. Specific procedures performed in the cath labs include being the hub for ECMO transfers from hospitals that are the spokes or other hospitals not capable of performing ECMO and LVADS, as well as in- and outpatient heart failure procedures and heart transplant work-ups for patients. The cath labs are also used for PCI, high risk and complex total occlusion program. EP procedures include treatment for patients with ventricular tachycardia and VT storm.

The OR is used for cardiothoracic surgery by EP for lead extractions and structural heart carotid cut-down procedures for valve replacements.

To connect with a Henry Ford physician, call:

Henry Ford Health Heart & Vascular

1-877-434-7470

henryford.com

HENRY FORD HEALTH®
Heart & Vascular

Heart & Vascular
Henry Ford Hospital
2799 West Grand Blvd.
Detroit, MI 48202

In the news

TEAM Heart Failure Trial: LVAD therapy earlier
The TEAM Heart Failure Trial is a novel trial examining LVAD therapy in the less sick and is one of three programs (Cleveland Clinic and MUSC) serving as study leads through National PI representation. The work Gillian Grafton, D.O., has done with heart failure and CardioMEMS™ HF System to identify how pulmonary HTN is a risk factor for adverse outcome in heart failure support this effort. In this trial, CardioMEMS™ will be used to identify high risk patients who may benefit from earlier LVAD.

The excellent outcomes achieved by our surgeons and medical practitioners (including doctors, nurses, APPs, PT, OT, psychology, etc.) is on the map nationally and played a large part in our clinical selection.

Jennifer Cowger, M.D., section head of Advanced Heart Failure, Transplant, and Mechanical Circulatory Support said, "currently, LVADs are only approved for patients who are very ill—in cardiogenic shock in the ICU or requiring inotropes to support their heart. We recognize there are patients with heart failure who have a high risk of death within two years despite being treated as an outpatient. Since LVAD survival has greatly improved over the last decade, we want to see if we improve long-term survival for a subset of patients with heart failure by putting in LVAD before they become critically ill."

The success of this trial will expand the patient candidacy for LVAD and increase LVAD volumes at Henry Ford Hospital and will also impact these numbers nationally.

This team will use all their resources to advance the care they can offer to patients today and tomorrow. They bring hope to patients who otherwise might not receive the best care. As Dr. Cowger said, "our Advanced Heart Failure Program is very special. The talent is fierce. The dedication unwavering. Every team member shines bright. They have worked so hard to get to this point and deserve this recognition."

The surgical PI: Dr. Nemeh, M.D.
The surgical PI: Kyle Miletic, M.D.
The medical PI: Lindsey Aurora, M.D.
National PI: Jennifer Cowger, M.D.