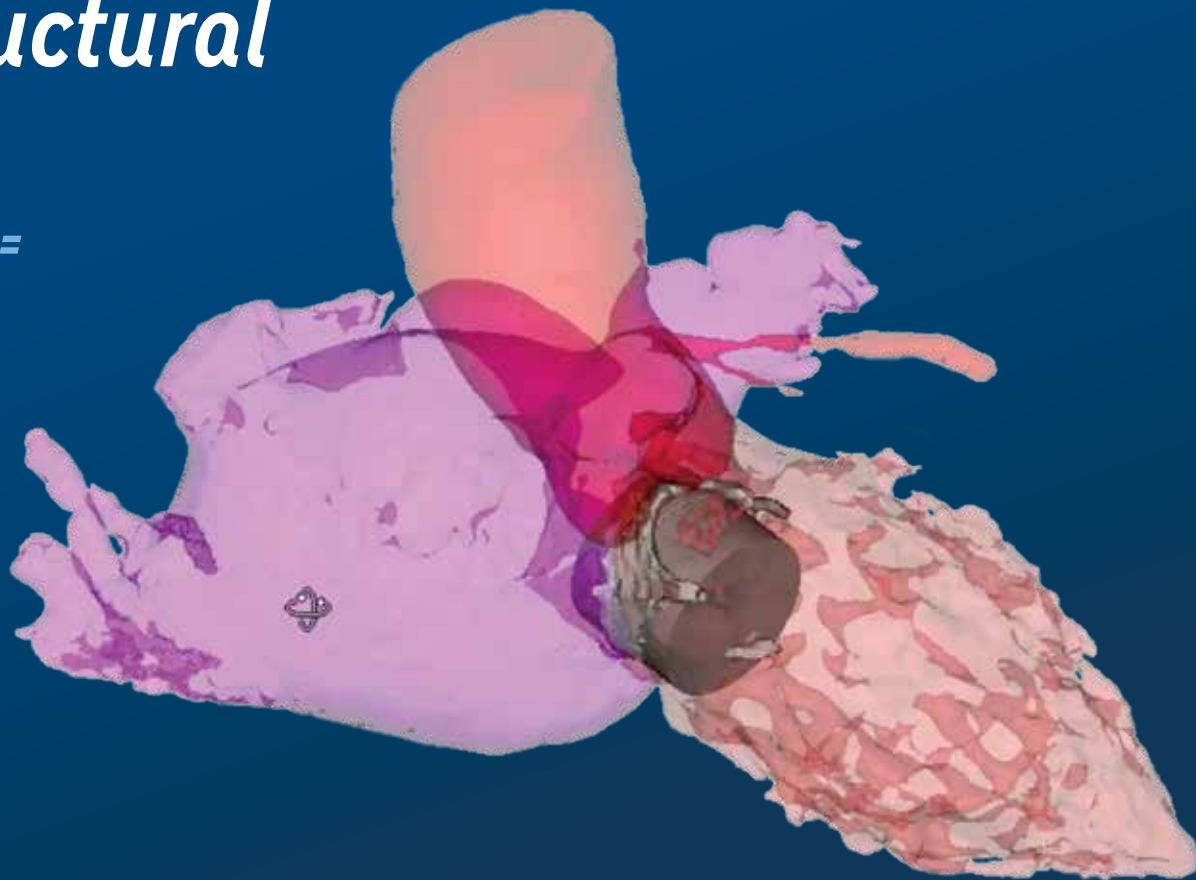


Center for Structural Heart Disease

*Technology + Device =
Precision Fit for
Every Patient*

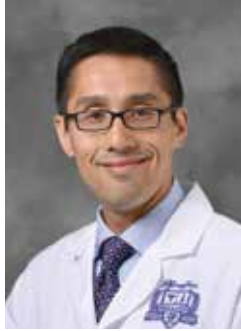
ACTIVITY AND
OUTCOMES 2018



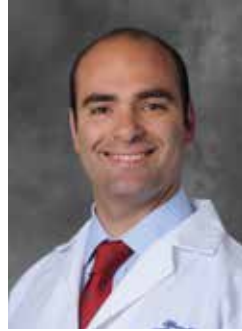
CENTER FOR STRUCTURAL HEART DISEASE TEAM



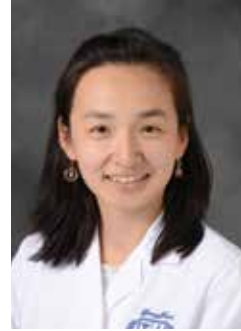
William W. O'Neill, M.D.
Medical Director



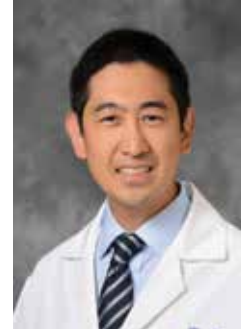
Marvin Eng, M.D.
*Research Director
Fellowship Director*



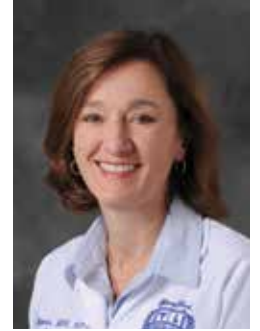
Tiberio Frisoli, M.D.
*Structural Heart
Cardiologist*



Dee Dee Wang, M.D.
*Director, Structural
Heart Imaging*



James C. Lee M.D.
*Advanced Structural
Imaging*



Janet Wyman, DNP, RN-CS
Clinical Manager



Hassan W. Neme, M.D.
*Surgical Director,
Heart and Lung
Transplant*



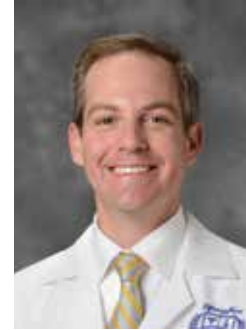
Raed Alnajjar, M.D.
*Cardiothoracic
Surgery*



Dimitrios Apostolou, M.D.
*Cardiothoracic Surgery,
Transplant Surgery*



Michael Isley, M.D.
*Cardiac
Anesthesiologist*



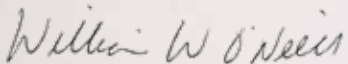
Trevor Szymanski, M.D.
*Cardiac
Anesthesiologist*

FROM THE DESK OF WILLIAM W. O'NEILL, M.D.

Each year the Center for Structural Heart Disease continues its clinical research to advance treatment options for all of our patients, especially those with few options. Our research has provided access to an extraordinary number of mitral valve devices that few programs around the country have achieved.

In addition to presenting our growth in numbers, we also share how the Center for Structural Heart Disease team has enhanced techniques and devices all supported by predictive modeling using 4D CT, 3D printing and computer simulation modeling to ensure the best possible outcomes for our mitral patients.

We acknowledge the importance of partnerships in the care of patients referred from local physicians, across the country, and around the world who allow us to innovate and bring a better quality of life – all for our patients.

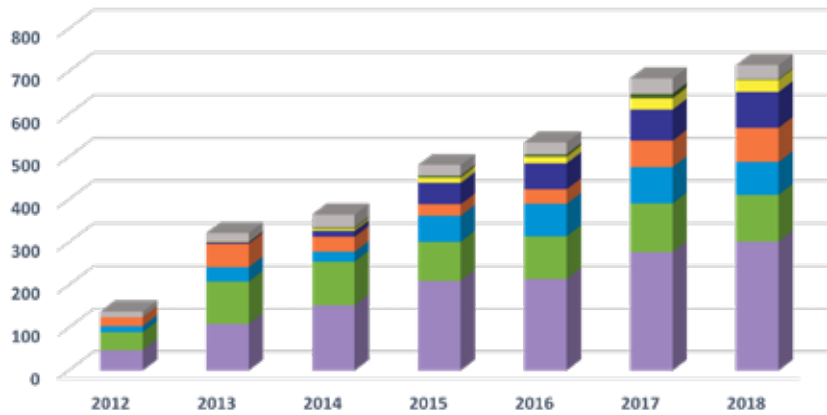


William W. O'Neill, M.D.
Medical Director



William W. O'Neill, M.D.
Medical Director
Twitter: @BillO'NeillMD

CENTER FOR STRUCTURAL HEART DISEASE PROGRAM AT HENRY FORD – GROWTH



*Other: ASA, pulmonic procedures, PVL repairs

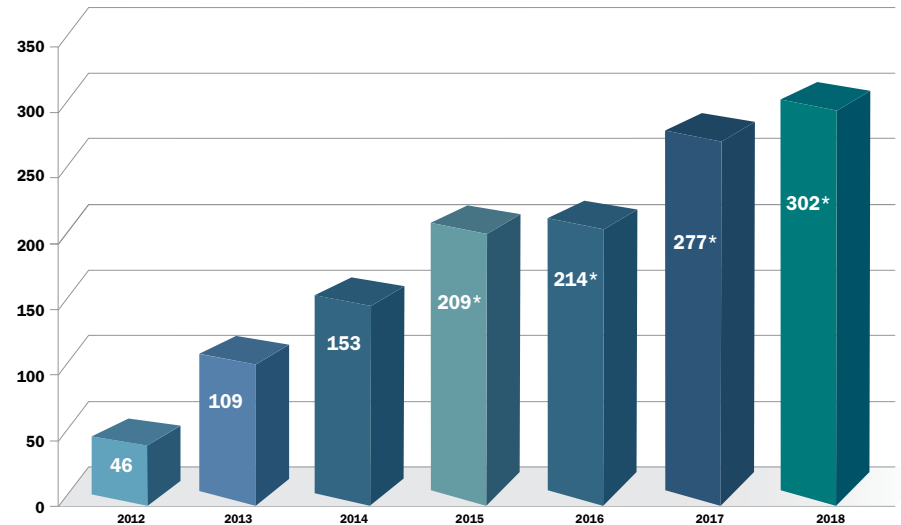
COMMERCIAL PROCEDURES AND DEVICES

The Center for Structural Heart Disease at Henry Ford Hospital offers the following procedures and devices:

- **Transcatheter Aortic Valve Replacements (TAVR)**
 - Native and dysfunctional bioprosthetic valves
 - Edwards: SAPIEN 3 Valves, Medtronic CoreValves
- **Transcatheter Mitral Valve Repair (TMVR) with MitraClip™ device**
- **Perivalvular leak repairs of prosthetic valves**
- **Mitral Valve Replacement (TMVR) Valve-in-Valve**
 - Edwards: SAPIEN 3 Valve-in-Valve
- **Left atrial appendage occlusion with Watchman™ device**
- **Valvuloplasty**
- **Patent foramen ovale, atrial and ventricular septal defect repairs**

Referring physicians have the commitment of the Center for Structural Heart Disease team to return patients for follow-up care. Training to provide follow-up care in referring physician offices is also available.

HENRY FORD TAVR VOLUME GROWTH



*Total Experience

COAPT TRIAL RESULTS: HEART FAILURE PATIENTS HAVE A NEW OPTION

The landmark results of Cardiovascular Outcomes Assessment of the Percutaneous Therapy (COAPT) trial results were shared in September 2018. The Structural Heart physicians at Henry Ford Hospital participated in this trial for the past eight years which made it possible to bring a new treatment option to Henry Ford patients with heart failure.

The results of the COAPT study showed that patients with severe functional MR who received a MitraClip™, when compared to those who underwent medical treatment, experienced:

- a 40 percent reduction in hospital readmission for heart failure;
- improvement in overall quality of life;
- a significant increase in longevity at two-year follow up;
- a decrease in all-cause mortality.

William W. O'Neill, M.D., medical director of the Center for Structural Heart Disease at Henry Ford says, “This is one of the most rigorous studies conducted in recent time. Patients underwent intensive screening, were provided the optimal medical therapy yet still had moderate to severe leaky valves before being enrolled in the randomized study.”

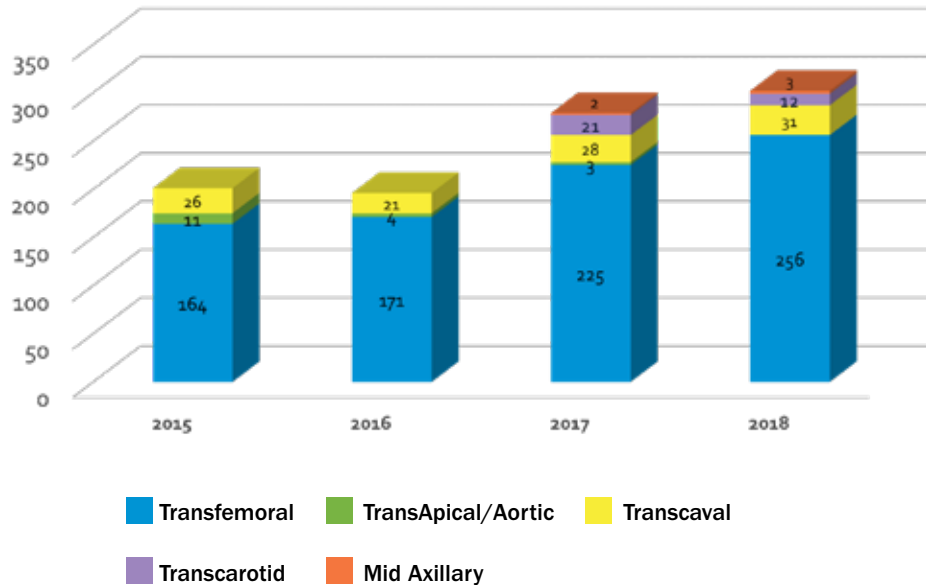
Dee Dee Wang, M.D., director of Structural Heart Imaging at Henry Ford Hospital, explains, “The study is unprecedented in the fact that it brings a mitral valve and heart failure treatment option to patients who had been told in the past their heart failure was no longer treatable.”

Even many doctors involved in the study doubted that fixing the leaky valve would help to achieve the study’s goals, but were pleasantly surprised at the preliminary outcomes when the data was opened.

The preliminary conclusions demonstrate that among patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy, transcatheter mitral-valve repair resulted in a lower rate of hospitalization for heart failure and lower all-cause mortality within 24 months of follow-up than medical therapy alone. The rate of freed from device-related complications exceed a prespecified safety threshold.

[Transcatheter mitral-valve repair in patients with heart failure.](#)
New England Journal of Medicine, 2018 Sept 23. Doi: 10.1056/NEJ-Moa1806640

HENRY FORD 2015–2018 TAVR VOLUMES BY APPROACH



ADVANCING APPROACHES TO TAVR

Transfemoral: In the standard approach for catheterization, access is gained through the femoral vein through the groin to insert the catheter and a wire which is guided to the aorta.

Transcaval: Access is through the femoral vein. The guide wire travels up the inferior vena cava (IVC), crosses through IVC wall into the aorta then up into the heart to implant a new artificial aortic heart valve. After the valve is placed, the catheter “bridge” is removed. A plug closes the holes in the artery and the vein so the two major blood vessels can function as normal.

Transcarotid: A small incision is made in the carotid artery accessed just above the clavicle but below where the artery branches, thus safely allowing collateral blood flow to the brain. From this point, TAVR valve delivery is the same as it would be with the transfemoral approach.

Transaxillary: A small incision, made near the armpit, allows the catheter to be inserted and guided to the heart to perform the TAVR procedure.

ACTIVE ENROLLMENT RESEARCH PROTOCOLS

ExCEED - To establish the safety and effectiveness of the Edwards CENTERA Transcatheter Heart Valve (THV) System in patients with symptomatic, severe, calcific aortic stenosis who are at intermediate operative risk for surgical aortic valve replacement (SAVR).

WATCHMAN and TAVR - To evaluate the safety and effectiveness of the left atrial appendage occlusion with WATCHMAN™ Device in prevention of stroke and bleeding in patients with atrial fibrillation (AF) undergoing transcatheter aortic valve replacement (TAVR).

M3 - Early feasibility study of the Edwards Lifesciences SAPIEN M3 System to evaluate the safety and functionality of the SAPIEN M3 System in patients with symptomatic severe mitral regurgitation.

TRILUMINATE - To evaluate treatment with Abbott Transcatheter Clip Repair System in patients with moderate or greater tricuspid regurgitation.

The CLASP IID Study - To assess the safety and efficacy of the Edwards PASCAL Transcatheter Mitral Valve Repair System compared to the MitraClip™.

TIARA - To evaluate the safety and initial performance of the Neovasc Tiara Mitral Transcatheter Heart valve with the Tiara Transapical Delivery System.

The PARTNER 3 Continued Access Study - To establish the safety and effectiveness of the Edwards SAPIEN 3 Transcatheter Heart Valve in patients with severe, calcific aortic stenosis or failing bio-prosthetic valve who are at low operative risk for standard aortic valve replacement.

Early TAVR - To establish the safety and effectiveness of the Edwards SAPIEN 3 Valve compared with clinical surveillance in asymptomatic patients with severe, calcific aortic stenosis.

Marvin H. Eng, M.D.

Structural Heart Disease Research
and Fellowship Program Director

MEDICAL SCHOOL EDUCATION

Wayne State University School of Medicine

POST-GRADUATE TRAINING

University of Colorado Health Sciences
Center (CO) – Internal Medicine

University of Colorado Health Sciences
Center (CO) – Cardiology

FELLOWSHIP

Scripps Green Hospital (CA) – Cardiology, Interventional

BOARD CERTIFICATION

American Board of Internal Medicine

American Board of Internal Medicine: Cardio Interventional

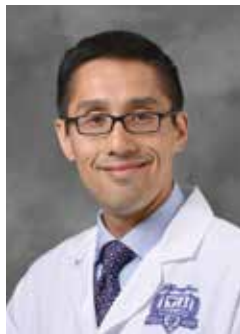
American Board of Internal Medicine: Cardiovascular Disease

American Board of Internal Medicine: Adult Congenital
Heart Disease

Society of Vascular Medicine: Peripheral Vascular Intervention

AREAS OF CLINICAL EXPERTISE INCLUDE

- Minimally invasive catheter-based treatment of advanced heart disease (heart valves, mitral valve, congenital heart defects, heart blood vessels and heart pumps inserted through catheters).
- Integral in developing multiple techniques with National Institutes of Health to treat valvular heart disease.
- Research interests include mitral valve interventions, left atrial appendage closures, minimally invasive percutaneous techniques, structural heart disease interventions, self-expanding stents, and alternative access for transcatheter aortic valve interventions.



Marvin Eng, M.D.
*Research and Fellowship
Program Director*

LARGEST VALVE PORTFOLIO IN THE MIDWEST

Patients experiencing some of the most complex functional and degenerative mitral regurgitation (MR) conditions have new hope. Successful outcomes come from a triad of care – experienced interventional cardiologists using the most advanced procedures, the largest mitral valve device portfolio in the area and expertise and use of 3D and 4D imaging and 3D printing that improves patient outcomes.

Marvin Eng, M.D., research and fellowship program director, and Tiberio Frisoli, M.D., structural heart interventional cardiologist concur when the working environment is collaborative, where colleagues are open-minded and dedicated to advancing minimally invasive procedures using the most advanced technology, a perfect situation emerges to provide patients with the best possible outcomes. “Our center has the highest volume of mitral valve repair and replacement in the Midwest,” explains Dr. Eng. “Because of our clinical expertise, we have been involved in numerous research studies, and as a result we have the knowledge and access to more devices than other centers in our area.”

Henry Ford Center for Structural Heart Disease includes Cardiologist Dee Dee Wang, M.D., director, Center for Structural Heart Disease Interventional Imaging. A leader in 3D transesophageal echocardiography (TEE), 3D-image guidance and 4D printing,

she supports each procedure alongside of her colleagues as they perform the valve repair or replacement. “Because the mitral valve is a complex anatomical structure, we can determine which device is the proper size and how it is best placed in each patient prior to an intervention,” explains Dr. Wang. “With 3D live imaging guidance, the outcomes of our cases are at the highest level.”

2018 Device Portfolio

As leaders in research (see page 9), and expertise in advancing procedures and technologies, the Center for Structural Heart Disease offers its patients the right valve devices for their individual treatment. “We have used the **MitraClip™**, approved by the FDA in 2013, for degenerative mitral valve diseases, which is now under investigation for functional mitral regurgitation,” explains Dr. Eng. “**Pascal** is another device currently being investigated for both functional and degenerative mitral regurgitation.”

Tendyne is a trial device for mitral valve replacement, that comes in multiple sizes to fit the anatomy of various patients. “We are particularly pleased with the investigational **M3** device, that allows implantation through a transseptal approach,” says Dr. Frisoli.

To address functional mitral regurgitation, the percutaneous transfemoral delivery of the **Cardioband** system continues to be evaluated for both performance and safety for functional MR.

Tiara, another trial device, used for degenerative and functional regurgitation, replaces the mitral valve yet preserves the surrounding structures of the heart.

Tiberio Frisoli, M.D.

Structural Heart Interventional Cardiologist

MEDICAL SCHOOL EDUCATION

St. George’s University School of Medicine, Grenada, West Indies

POST-GRADUATE TRAINING

Henry Ford Hospital,
Structural Heart Disease, Fellowship

Henry Ford Hospital,
Interventional Cardiology, Fellowship

Henry Ford Hospital, Cardiovascular
Disease, Fellowship (Chief Fellow)

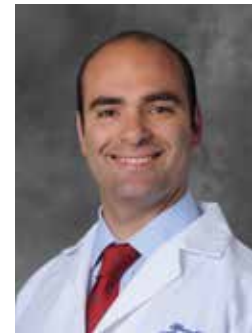
St. Luke’s Roosevelt Hospital Center (NY),
Internal Medicine Residency

BOARD CERTIFICATION

American Board of Internal Medicine – Interventional Cardiology
American Board of Internal Medicine – Cardiovascular Disease
American Board of Internal Medicine – Internal Medicine

AREAS OF CLINICAL EXPERTISE

- Valvular heart disease interventions (e.g. TAVR, MitraClip™, TMVR), alcohol septal ablation for hypertrophic obstructive cardiomyopathy, paravalvular leak repair, left atrial appendage occlusion, and closure of atrial septal defects and patent foramen ovale.
- Coronary artery treatments: complex high risk stenting procedures, use of mechanical heart assist devices, interventions for peripheral artery disease.
- Clinical research published on the evaluation of patients with chest pain in Emergency Department, innovations in structural heart interventions.



Tiberio Frisoli, M.D.
**Structural Heart
Cardiologist**

Dee Dee Wang, M.D.

Director, Center for Structural Heart Disease Interventional Imaging at Henry Ford Hospital

MEDICAL EDUCATION

Wayne State University
School of Medicine

POST-GRADUATE TRAINING

University of Michigan,
Internal Medicine
Chief Resident

FELLOWSHIPS

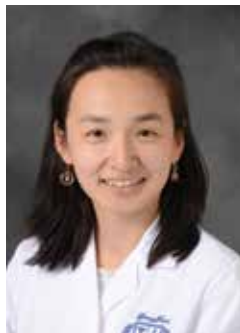
Henry Ford Hospital, General Cardiology
Advanced Cardiac Imaging with emphasis
on Structural Heart Interventions

BOARD CERTIFICATION

American Board of Internal Medicine -
Cardiovascular Disease
American Board of Internal Medicine -
Internal Medicine

AREAS OF CLINICAL EXPERTISE

- Level 3 Cocats trained in Echocardiography (with 3D TEE), Nuclear, Cardiac CTA.
- Level 2 Cocats trained in Cardiac MRI and Cardiac PET.
- Interventional Echocardiography in Structural Heart Interventions including mitral clip, complex TAVRs/mitral cases, and ASD/PFO closures.
- Extensive research in advancing Structural Heart periprocedural planning utilizing 3D and 4D imaging and 3D printing.



Dee Dee Wang, M.D.
Director, Structural Heart Disease Imaging

Joyce Lewis, a patient who experienced mitral regurgitation, is an example of why access to various valve devices makes a difference. In 2000 Joyce's mitral valve procedure was an open procedure. When the mitral valve began leaking in 2018, a walk to the kitchen was exhausting leaving her struggling to breathe. At the age of 84, she had the option of a replacement or repair of the leaking valve. "I didn't want to go through another open procedure, going through my groin and inserting the mitral clip was the right option for me," said Joyce. She chose the mitral clip procedure, performed by Dr. Frisoli, and stated: "Immediately when I woke after the procedure, I could breathe better, it was like daylight in the dark. I'm so very, very pleased with the results."

"Our expert knowledge of 3D imaging and printing translates to a safer, more effective treatment with better outcomes for our patients," explains Dr. Wang. The 3D and 4D CT scans produce a cross-sectional image of the heart. Once the team reviews the 3D imaging and heart models, a customized treatment for each patient is developed. "By the time we are all assembled to perform the procedure, the uniqueness of each patient's case is known and rehearsed," says Dr. Wang.



In a 2017 published study, Dr. Wang and her colleagues validated that computer-aided design (CAD) prediction modeling tools prevent complications such as valve embolization, leaking around the valve and left ventricular outflow tract (LVOT) obstruction for valve replacement.

"Dr. Wang and her team operate one of the most advanced 3D Imaging Centers in the country, and the outcomes show our patients benefit," says Dr. Frisoli.

VALVE REPAIR DEVICES

MitraClip™ is used for degenerative mitral valve disease and is being investigated for functional mitral regurgitation. It has been approved for use in the United States by the FDA since 2013.

Tendyne is a percutaneous mitral valve replacement trial device that is implanted via a small thoracotomy and apical access. It is anchored by an apical tether and will be undergoing evaluation in a pivotal trial. There are a multitude of sizes to accommodate various patient anatomy.

Tiara, a trial device, is delivered through the apex of the heart to replace the mitral valve while preserving the integrity of the surrounding structures of the heart. (NEOVASC)

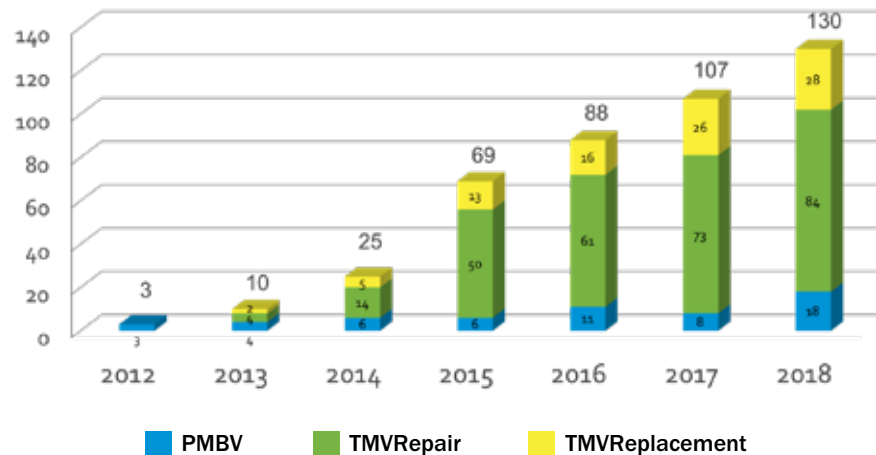
Cardioband system is in trial to evaluate performance and safety. The Cardioband Adjustable Annuloplasty System repair addresses functional mitral regurgitation, using a percutaneous transfemoral delivery system.

Pascal is a device similar to MitraClip™ current in clinical investigation for treating both degenerative and functional mitral regurgitation.

M3 is a device that allows for percutaneous mitral valve implantation through the transseptal approach and does not require a thoracotomy. It is currently undergoing clinical investigation at Henry Ford.

Regurgitation	Degenerative	Functional
MitraClip™	X	X (COAPT study)
Tendyne Valve (study)	X	X
TIARA Valve (study)	X	X
Cardioband		X
Pascal	X	X
M3	X	X

HENRY FORD TRANSCATHETER MITRAL VALVE PROCEDURES



CENTER FOR STRUCTURAL HEART DISEASE 2018 PUBLICATION LIST

Loehn T, O'Neill WW, Lange B, Pfluecke C, Schweigler T, Mierke J, Waessnig N, Mahlmann A, Youssef A, Speiser U, Strasser RH, Ibrahim K. Long term survival after early unloading with Impella CP® in acute myocardial infarction complicated by cardiogenic shock. *Eur Heart J Acute Cardiovasc Care*. 2018 Nov 20;20:2048872618815063. doi:10.1177/2048872618815063. <https://www.ncbi.nlm.nih.gov/pubmed/30456984> [Epub ahead of print]

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Wang DD, Eng MH, Greenbaum AB, Myers E, Forbes M, Karabon P, Pantelic M, Song T, Nadig J, Guerrero M, O'Neill WW. Validating a prediction modeling tool for left ventricular outflow tract (LVOT) obstruction after transcatheter mitral valve replacement (TMVR). *Catheter Cardiovasc Interv*. 2018 Aug 1;92(2):379-387. doi: 10.1002/ccd.27447. <https://www.ncbi.nlm.nih.gov/pubmed/29226591> Epub 2017 Dec 11.

Eng MH, Wang DD. Transcatheter Mitral Valve Therapy: Defining the Patient Who Will Benefit. *Curr Cardiol Rep*. 2018 Sep 12;20(11):107. doi: 10.1007/s11886-018-1058-8. <https://www.ncbi.nlm.nih.gov/pubmed/30209638> Review.

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CENTER FOR STRUCTURAL HEART DISEASE 2018 PUBLICATION LIST

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STRUCTURAL HEART PROGRAM FOR REFERRING PHYSICIANS

Meet Kristin Sexton, RN, Outreach Coordinator. Kristin is available to assist physicians who choose to refer patients to the Center for Structural Heart Disease at Henry Ford Hospital in Detroit. Contact Kristin directly with questions about the program or to connect with one of the physicians.

Kristin can assist with facilitating outpatient consultations, inpatient transfers, enrolling patients into a clinical trial and can also assist physicians who are interested in observing procedures at Henry Ford Hospital. Kristin will arrange for concierge services for referred patients and helps with guest housing for patients who will require an inpatient stay.

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