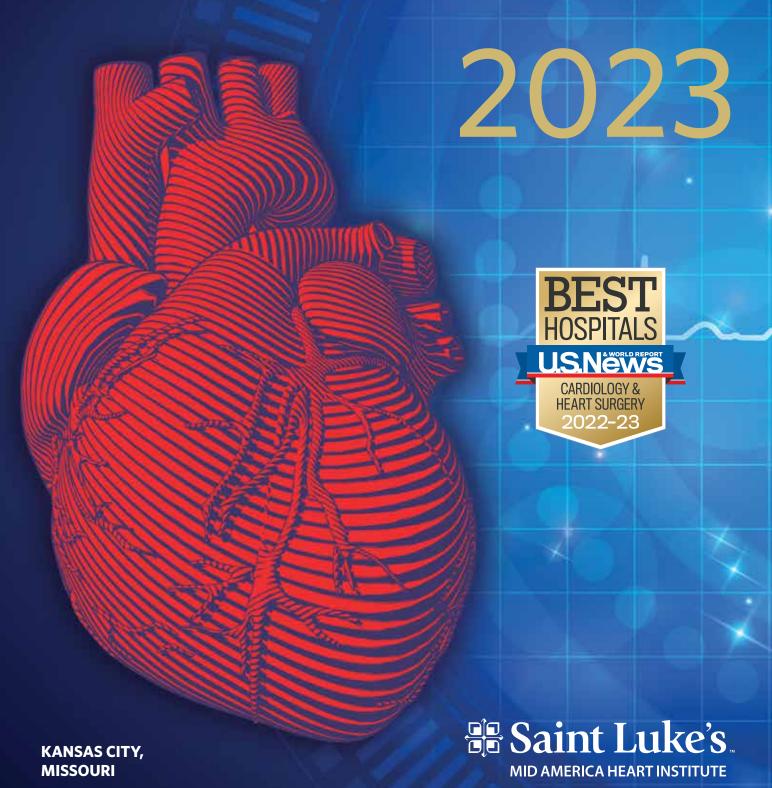
# SAINT LUKE'S MID AMERICA HEART INSTITUTE VALVULAR HEART DISEASE AND STRUCTURAL INTERVENTION



## Saint Luke's: The Intersection of Innovation and Hope

In 1981, Saint Luke's Mid America Heart Institute opened its doors as the world's first free-standing, dedicated heart hospital, focused specifically on caring for patients with cardiovascular disease.

Today, our nearly 200 board-certified specialists and cardiovascular experts provide world-class care to more than 80,000 patients annually.















Comprehensive Cardiac Center Certification



Advanced Heart Failure Certification



Cardiac Valve Repair and Replacement Certification



Advanced Ventricular Assist Device Certification



Acute Myocardial Infarction Certification



One of 75 hospitals in the world to earn four consecutive Magnet Designations



MATTHEW G. DEEDY, MD, FACC



J. RUSSELL DAVIS, MD, FACS

Dear Colleague,

Saint Luke's Mid America Heart Institute's Valve Center of Excellence plays a critical role in achieving and maintaining the esteemed Comprehensive Cardiac Center Certification from The Joint Commission.

Saint Luke's provides the full range of high-quality valve care, including clinics dedicated to optimizing medical management, transcatheter intervention, traditional surgical intervention, and minimally invasive surgical options.

The Valve Center's team includes dedicated structural interventionalists, structural echocardiographers, and surgeons who are supported by our cath lab clinical team, research coordinators, and advanced practice providers—all experts in valvular heart disease.

In this book, we highlight our valve team's extensive experience, multidisciplinary approach to patient care, and intensive commitment to research and innovation. Some of our program highlights include:

- **Saint Luke's Valvular Heart Disease Program** in 2008, was among the first in the nation to perform transcatheter aortic valve replacement (TAVR) and participated in landmark PARTNER trials. We have since performed more than 1,500 TAVR procedures.
- Saint Luke's Transcatheter Aortic Valve Replacement Program offers our patients an exceptionally higher quality of life at one year compared to the national rate, as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ).
- **Saint Luke's Cardiac Surgery's** minimally invasive program continues to grow. In 2019, 40% of all isolated mitral surgeries performed were minimally invasive. In 2021, more than 70% of all mitral and tricuspid surgeries were minimally invasive.
- Saint Luke's Mitral Valve Intervention Program is in the top 10% for MitraClip™ volume in the nation.
- Saint Luke's Pulmonic Valve Intervention Program is a leader in the field—one
  of the first hospitals in the region to implant a Harmony™ TPV and SAPIEN® 3 system.
- **Saint Luke's Tricuspid Valve Intervention** team continues to participate in the next series of landmark studies, such as the CLASP II TR and TRISCEND II trials.
- **Saint Luke's Structural Heart Disease** team is a national leader in both left atrial appendage closure (LAAC) and transcatheter paravalvular leak closure research.

These are just a few of the impressive reasons why **U.S. News & World Report ranks**Saint Luke's among the top 25 hospitals for Cardiology and Heart Surgery.

Sincerely,

Matthew G. Deedy, MD, FACC

Co-Executive Medical Director, Saint Luke's Mid America Heart Institute; Clinical Assistant Professor of Medicine, University of Missouri-Kansas City School of Medicine J. Russell Davis, MD, FACS

Co-Executive Surgical Director, Saint Luke's Mid America Heart Institute; Clinical Associate Professor of Surgery, University of Missouri-Kansas City School of Medicine

# **VALVULAR HEART DISEASE**

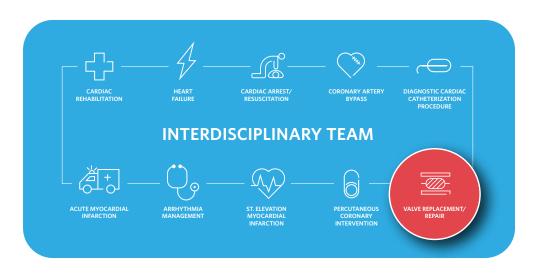
Mitral valve therapy is more complex than aortic valve disease, and tricuspid valve therapy is proving to be even more complicated. In line with our reputation for clinical research and our expertise in transcatheter aortic valve replacement, we are participating in several landmark national trials focused on both mitral and tricuspid valve disease.

In 2016, Saint Luke's Mid America Heart Institute established the first Valve Center of Excellence in the region. This Center was built on our successful cardiac valve program that embraced the ideals of excellence in patient care, leadership in research, and a commitment to education.

In 2018, we became the third institution in the country to receive The Joint Commission certification as a Comprehensive Cardiac Center, due to the quality of our valve program.

In 2018, we received a more specific certification from The Joint Commission for Cardiac Valve Repair and Replacement, which is a testament to our mission statement: Accuracy in Diagnosis, Excellence in Care.





## Recognized as the region's only Valve Center of Excellence since 2016:

- Among the first in the nation and first hospital in Kansas City to perform transcatheter aortic valve replacement (TAVR) in 2008
- Participated in landmark PARTNER trials and have since performed more than 1,500 TAVR procedures
- Performed the first transcatheter pulmonic valve replacement in 2015 in collaboration with Children's Mercy Hospital, Kansas City

- Participated in the landmark COAPT trial in 2017
- Performed the region's first transcatheter tricuspid valve replacement in 2022
- TAVR and mitral TEER volumes have grown by more than 20%, even with the challenges of the COVID-19 pandemic
- First in the nation to perform transcatheter paravalvular leak closure using the novel AVP III device in 2020

As we enter the second decade of this rapidly evolving field of transcatheter valve intervention, Saint Luke's remains at the forefront of this exciting subspecialty.

## Team-based approach

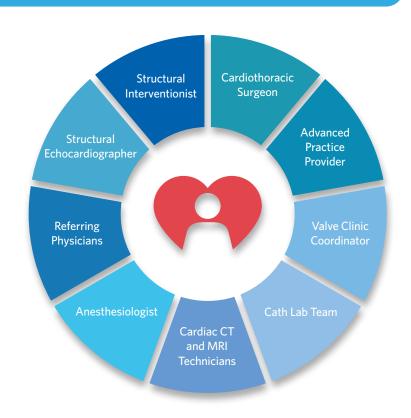
## **Complex patient management**

is becoming the norm, and coordination of care is now of paramount importance.

## **Our team-based approach**

to coordinated care leads to better outcomes and a better patient experience.





## **COMMITMENT TO RESEARCH**



SUZANNE ARNOLD, MD Clinical Scholar; Professor of Medicine, UMKC

Our team of clinical scholars have published more than 150 peer-reviewed valvular heart research papers. Saint Luke's Mid America Heart Institute remains on the leading-edge of transcatheter valvular intervention research.

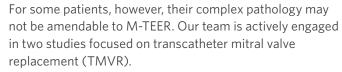
#### **Aortic Stenosis**

Our research extends beyond patients with symptomatic, severe aortic stenosis. We are involved in:

- EARLY TAVR trial: Evaluating the role of transcatheter aortic valve replacement (TAVR) for patients with severe aortic stenosis who are not yet symptomatic
- **PROGRESS trial:** Evaluating the potential benefits of TAVR in patients with moderate aortic stenosis and symptoms of cardiac dysfunction

#### **Mitral Regurgitation**

Mitral transcatheter edge-to-edge repair (M-TEER) with MitraClip<sup>™</sup> is a proven and effective therapy for patients with degenerative or functional mitral regurgitation. We are expanding the understanding of M-TEER by participating in the CLASP II TR trials involving edge-to-edge repair with the PASCAL® device, an alternative to MitraClip.



- SUMMIT trial: Evaluating TMVR with the Tendyne<sup>™</sup> valve via transapical access
- ENCIRCLE trial: Evaluating TMVR with the SAPIEN® Ultra system via transseptal approach

#### **Tricuspid Regurgitation**

Our team is involved in two studies aimed at reducing the degree of tricuspid regurgitation without open-heart surgery, and improving patients' survival, symptom status, and quality of life:

- CLASP II TR trial: Evaluating a tricuspid leaflet edge-to-edge repair procedure using the PASCAL device
- TRISCEND II trial: Evaluating a tricuspid valve replacement using the EVOQUE valve



SUMMIT



**ENCIRCLE** 



**CLASP II TR** 



TRISCEND II

## **COMMITMENT TO EDUCATION**

As early adopters of innovative treatments, we are uniquely qualified to share our earned knowledge. Our Heart Institute team members:

- Helped pioneer and now teach the technique of surgical bioprosthetic valve fracture to facilitate valve-in-valve TAVR
- Established an interventional fellowship program in 2016 dedicated to structural heart disease
- Are routinely invited to moderate scientific sessions or speak at local and national cardiology and surgery conferences
- Host several annual events to educate our medical staff and community about valvular heart disease



Jonathan Enriquez, MD, Program Director, Cardiovascular Fellowship (front row fifth from the left) leads one of the top 10 cardiology fellowship programs in the country.



Mohammed Saghir, MD, is reviewing an upcoming procedure with colleagues, residents, and fellows.

Saint Luke's recognizes the important intersection of education and research to **enhance patient care.** 

# TRANSCATHETER AORTIC VALVE **REPLACEMENT (TAVR)**



ADNAN K. CHHATRIWALLA, MD Medical Director, Structural Intervention; Professor of Medicine, UMKC

Transcatheter aortic valve replacement (TAVR) has revolutionized the treatment of patients with symptomatic, severe aortic stenosis. And we are proud to have participated in this journey since the beginning. Our first TAVR procedure was in 2008.

#### **Outcomes that matter**

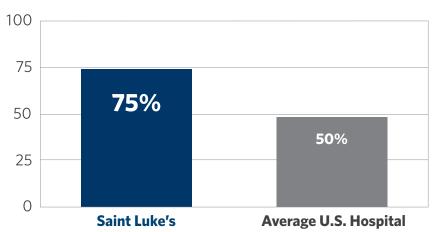
Our valve team's dedication to innovation and continuous quality improvement puts us at the forefront of metrics such as mortality, acute kidney injury, and quality of life, all of which positively affect the patient.



(Kansas City Cardiomyopathy Questionnaire)



KEITH ALLEN, MD Surgical Director, Structural Intervention; Clinical Associate Professor of Surgery, UMKC



Q2 2018 - Q1 2021 STS/ACC TVT Registry™



ANTHONY HART, MD Director, Cardiac Intensive Care Unit; Clinical Assistant Professor of Medicine, UMKC



The Kansas City Cardiomyopathy Questionnaire (KCCQ) was developed by John A. Spertus, MD, MPH; Director, Outcomes Research, Saint Luke's Mid America Heart Institute.

KCCQ is a self-administered, 23-item questionnaire that quantifies physical limitations, symptoms, self-efficacy, social interference, and quality of life.

## **PULMONIC VALVE INTERVENTION**



JOHN SAXON, MD Co-Medical Director, Adult Congenital Heart Disease Program; Associate Professor of Medicine, UMKC

Although it is the least common valve to need intervention in adults, the pulmonic valve is the most common valvular intervention in adults with congenital heart disease.

At Saint Luke's, we partnered with interventional specialists from Children's Mercy Hospital in Kansas City to develop the pulmonic valve intervention program. In 2015, we performed our first transcatheter valve replacement using the Melody™ transcatheter pulmonary valve in a failed surgical right ventricular-to-pulmonary-artery conduit. In many cases, this technology allows patients to have a minimally invasive pulmonic valve replacement rather than a repeat open heart surgery for failed pulmonary valves or conduits.

Since the inception of the pulmonary valve replacement program, the options available to patients have continued to expand at a remarkable pace. We now have four FDA-approved transcatheter valve options for the pulmonic position—a striking breadth of innovation compared to what was offered less than a decade ago.

#### Managing severe pulmonic insufficiency

- 2020: First adult hospital in Kansas City region to implant a Harmony™ transcatheter valve
- 2021: First hospital in the region, and one of the only adult hospitals in the country, to implant a SAPIEN® 3 Transcatheter Pulmonary Valve System with Alterra

## TRICUSPID VALVE INTERVENTION

The valve team at Saint Luke's continues to be leaders in the tricuspid valve intervention field. Building on our surgical experience in tricuspid valve surgery and more than a decade's worth of clinical trial experience with transcatheter valve interventions, we are participating in the next series of landmark studies focused on transcatheter tricuspid valve repair and replacement.

#### First-of-their-kind clinical trials

Our team is involved in two studies aimed at reducing the degree of tricuspid regurgitation without open-heart surgery, and improving patients' survival, symptom status, and quality of life:

- CLASP II TR trial: Evaluating a tricuspid leaflet edge-to-edge repair procedure using the PASCAL device
- TRISCEND II trial: Evaluating a tricuspid valve replacement using the EVOQUE valve





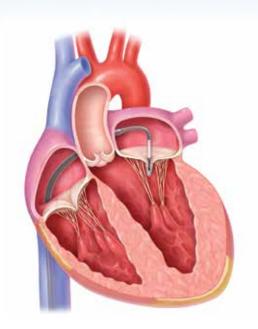


TRISCEND II

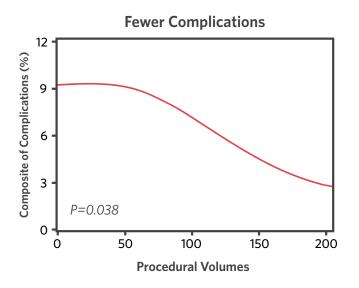
## MITRAL VALVE INTERVENTION

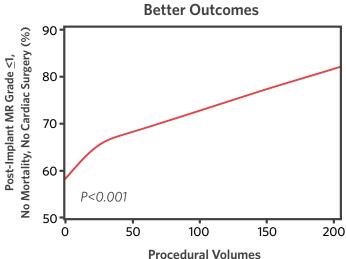
Not every patient is a candidate for surgical intervention to address symptomatic mitral regurgitation. Continuing our commitment to innovation, we began a mitral transcatheter program with the MitraClip<sup>™</sup> system in 2015. Like with TAVR, our team participated in national clinical trials to establish the role of MitraClip as an option for patients with significant mitral regurgitation.

While mitral transcatheter edge-to-edge repair (M-TEER) is a proven therapy, fewer than 120 U.S. hospitals have substantial experience and volume with this procedure. As with most interventional procedures, studies continue to demonstrate a relationship with higher M-TEER volume and better clinical outcomes.

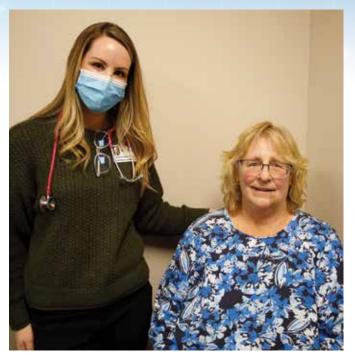


## **Experience Matters**





Saint Luke's is in the **top 10% for MitraClip** volume in the nation.





Sarah Heavey, RN, AGACNP, was instrumental in Barb's recovery, while her husband Christopher provided unconditional support. Barb lost 60 pounds after receiving a Tendyne valve through the SUMMIT clinical trial.

Mitral valve replacement helped Barb lose 60 pounds and her wheelchair.

#### **Great Care in Action**

#### Clinical Trial Helps Barb Get Back on the Move

Barb Settele was looking after everyone in her life—except herself. Even a heart attack in 2010 wasn't enough to convince her that her obesity and smoking were taking a severe toll on her physical and mental health. Not being able to move around freely was just part of her life. She had resigned herself to using a wheelchair.

By age 65, Barb's low energy and shortness of breath convinced her to seek help. She was diagnosed with mixed mitral valve disease with both stenosis and regurgitation. She had mitral annular calcification, and her surgical risk was prohibitive.

When she learned that the condition was life-threatening, Barb was scared but determined to find a way to keep living. Fortunately, she was an ideal candidate for the SUMMIT clinical trial. After extensive testing, she underwent a catheter-based intervention to replace her mitral valve and had a Tendyne™ valve implanted. In just a few months after the procedure, she was able to lose 60 pounds. Her energy returned and she is much more mobile. Best of all, her quality of life improved dramatically.

## CARDIAC SURGERY FOR VALVE DISEASE



J. RUSSELL DAVIS, MD, FACS Co-Executive Surgical Director; Clinical Associate Professor of Surgery, UMKC



MICHAEL GIBSON, MD Director of Thoracic Surgery; Clinical Assistant Professor of Surgery, UMKC

The surgical valve program at Saint Luke's Mid America Heart Institute is the most comprehensive in the region. Our surgical team has performed approximately **700 valve surgeries in the last three years,** ranging from isolated valve repair or replacement to complex multi-valve procedures.

We understand that not all patients have an anatomy that is favorable to TAVR. For some patients, TAVR can be a riskier procedure compared to surgical aortic valve replacement. Our broad expertise gives patients comprehensive options when needed.

It is clear from large studies that the quality of surgical mitral valve repair is related to surgical experience, and mitral valve repair is strongly preferred to valve replacement. However, the surgical skills needed to successfully repair mitral regurgitation are not universal. At Saint Luke's, the valve repair rate for appropriate anatomy is greater than 90%. Our surgical program maintains a high volume of mitral valve repair procedures, and that benchmark continues to represent a differentiator for success.

The minimally invasive program also continues to grow at Saint Luke's. The advantage of this surgical approach centers on a shorter hospitalization and a faster return to normal physical activity. In 2019, 40% of all Saint Luke's isolated mitral surgeries were minimally invasive. In 2021, more than 70% of all mitral and tricuspid surgeries were minimally invasive.



**Performed 700 valve surgeries** over the past three years.





Elisa now has the energy to run her donut shop thanks to a minimally invasive mitral valve repair by cardiothoracic surgeon J. Russell Davis, MD.

In 2021, more than 70% of all mitral and tricuspid surgeries at Saint Luke's were minimally invasive.

### **Great Care in Action**

# Minimally Invasive Surgery Gives Elisa the Energy to Fully Live

After a day working in her doughnut shop, 65-year-old Elisa Breitenbach barely had the energy to climb the stairs and go to bed. Over the years, her heart had gone into atrial fibrillation (AFib) seven times. Finally, her husband had had enough and convinced her to do something about it.

Tests showed she had a severe mitral regurgitation. Elisa was resistant to the idea of major surgery, but her heart condition was ideal for a minimally invasive approach to repair her leaky mitral valve. This surgical technique shortened her hospital stay and allowed for a faster return to normal physical activity.

Elisa's procedure was performed via a small incision on the right side of her torso, avoiding the common approach of opening the chest via the sternum. She also received cryoablation to treat her AFib.

Elisa feels great and has much more energy. For the first time in years, she feels like she can live a full life.

# **CARDIAC IMAGING**



RANDALL C. THOMPSON, MD Medical Director, Cardiac CT Imaging; Professor of Medicine, UMKC



NICHOLAS M. ORME, MD Medical Director, Cardiac MRI; Co-Director, Echocardiography; Assistant Professor of Medicine, UMKC



ADAM M. FLEDDERMANN, MD Multimodality Imaging



ARUN M. IYER, MD Multimodality Imaging; Assistant Professor of Medicine, UMKC



MOHAMMED K. SAGHIR, MD Medical Director, Cardiac Rehabilitation; Associate Professor of Medicine, UMKC

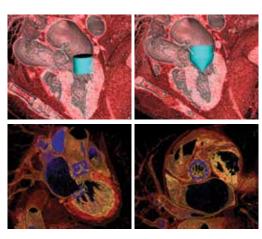
# **COMPUTED TOMOGRAPHY** AND MAGNETIC RESONANCE

With state-of-the-art equipment, the cardiac CT and MRI programs at Saint Luke's provide complementary information to diagnose and manage complex cardiac conditions. We have a dedicated team of board-certified CT and MRI cardiologists who review all these respective studies.

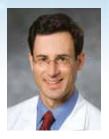
CT imaging is indispensable in evaluating patients for transcatheter aortic, mitral, and tricuspid valve replacement. It provides a detailed assessment of cardiac structure and is instrumental in ensuring the appropriate-size device is implanted—whether it is for a transcatheter valve or left atrial appendage closure (LAAC). CT imaging is also critical for assessing potential prosthetic valve dysfunction, paravalvular defects, subclinical leaflet thrombosis, and LAA thrombus.

Cardiac MRI technology provides more precise volumetric chamber assessment and flow quantification, which is essential in the management of patients with complex myocardial and valvular disease. For example, parametric mapping offers greater insight to the etiology of cardiomyopathies. And advanced 4D flow technology allows us to achieve highly accurate cardiac flow quantification for patients with complex valvular pathology.

With the addition of a second dedicated MRI scanner, recent volume has doubled. We completed more than 1,300 scans in 2022.



State-of-the-art 3D/4D capable CT scanners help guide management of structural heart disease. Transcatheter mitral valve replacement procedure planning (top) and bioprosthetic valve leaflet thrombosis (bottom).



**DAVID SKOLNICK, MD**Medical Director, Valve Program;
Director, Echo Laboratory;
Professor of Medicine, UMKC



**KYLE R. LEHENBAUER, MD**Structural Echocardiologist



**ANTHONY MAGALSKI, MD**Co-Medical Director, Heart Failure
Program; Professor of Medicine, UMKC



MICHAEL L. MAIN, MD Senior Vice President, Saint Luke's Health System; CEO, Saint Luke's Physician Group; Professor of Medicine, UMKC



MARTIN H. ZINK III, MD Medical Director, Anticoagulation Clinic; Assistant Professor of Medicine, UMKC

## **ECHOCARDIOGRAPHY**

At Saint Luke's Mid America Heart Institute, the bar for quality is set extraordinarily high. Every Saint Luke's cardiologist who interprets echo studies has not only passed the initial National Boards of Echocardiography, but also passes the re-certification examination every 10 years. Few hospitals achieve this goal.

Patient care is further enhanced when the current echo is compared side-by-side with the previous set of images. No other health system in the region invests the additional time and effort to assess for incremental change in left ventricular volume, ejection fraction, and severity of valve disease.

For patients with valvular heart disease, our echo reports now include recommendations from the American College of Cardiology and American Heart Association for obtaining the next study. This 2020 initiative was designed to reduce variation in care and to ensure patients are appropriately monitored for a disease state that very often requires timely intervention.

As we continue to participate in landmark clinical trials on all four valves, our echo team gains a deeper understanding of valvular pathology. In turn, our patients receive more accurate diagnoses. As part of our commitment to education and quality, we host a monthly echo physician conference to review updated imaging guidelines and new research.



The cornerstone for a precise and accurate cardiac diagnosis rests on sophisticated imaging. Patients at Saint Luke's have access to **world-class imaging in echocardiography** (echo), **computed tomography** (CT), and **magnetic resonance** (MRI).

# STRUCTURAL HEART DISEASE

## LEFT ATRIAL APPENDAGE CLOSURE



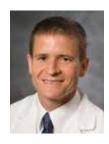
CHETAN P. HUDED, MD, MSC Medical Director, LAAC Program; Assistant Professor of Medicine, UMKC



**SANJAYA GUPTA, MD**Director of Electrophysiology
Fellowship; Associate Professor of Medicine, UMKC



**JESSICA KLINE, DO**Electrophysiologist



**ALAN WIMMER, MD**Medical Director, Electrophysiology;
Professor of Medicine, UMKC

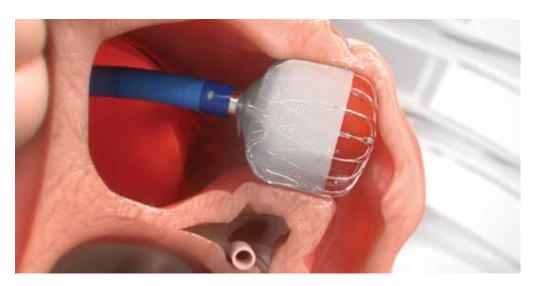
Transcatheter left atrial appendage closure (LAAC) is a safe and effective alternative to long-term anticoagulation for the prevention of stroke in patients with atrial fibrillation.

## Our team participated in the:

- Trial design and conduct of pivotal trials for nearly 20 years
- Landmark PROTECT-AF trial in 2005 and PREVAIL trial in 2010, which helped establish this procedure for everyday practice
- Echocardiographic core laboratory for the ASAP-TOO and SALUTE studies
- Echo sub-study in the pivotal PROTECT-AF trial
- Latest CHAMPION-AF trial

Saint Luke's has been a national leader in left atrial appendage closure research for nearly two decades.

Recognized as a leader in the region, our team has performed more than 800 successful procedures since commercial approval of the WATCHMAN™ device by the FDA in 2015.



The WATCHMAN™ device is a safe and effective alternative to long-term anticoagulation for patients with atrial fibrillation.

## PARAVALVULAR LEAK

Paravalvular leak (PVL), due to an unintended gap between a prosthetic valve and native tissue, is a difficult problem to treat. Patients with PVL can have significant hemodynamic compromise and/or struggle with issues of hemolysis. Most of these patients are not good candidates to undergo repeated open heart surgery, so the advent of transcatheter solutions to treat PVL has significantly altered the treatment options for many of our patients.

In 2014, our team at Saint Luke's developed a dedicated, collaborative paravalvular leak closure program. Patients are best treated when evaluated by a multidisciplinary team including structural cardiologist, cardiac surgeon, and advanced dedicated structural imagers in the field of echocardiography and computed tomography.



Amplatzer Valvular Plug III

In 2020, Saint Luke's performed the very first paravalvular leak closure in the U.S. using the Amplatzer™ Valvular Plug III, a novel, purpose-built PVL closure device, during a specially approved, one-time case.

In 2021, Saint Luke's became one of only 25 international sites to participate in PARADIGM, a clinical trial of the AVP III device. We continue to be one of the leading U.S. centers for enrollment, which will ultimately afford patients FDA-approval of a tailored device for this unique anatomic problem.







PVL can be a challenging diagnosis, resulting in symptoms of heart failure, hemolysis, or both. At experienced centers like Saint Luke's, **transcatheter PVL closure is now first-line therapy as an alternative to surgery.** 

In 2022, Saint Luke's performed the first transcatheter tricuspid valve replacement in the Kansas City region.







Frank is living his best life thanks to the TRISCEND II study and the experts at Saint Luke's Mid America Heart Institute.

#### **Great Care in Action**

Valve Replacement Has an 81-Year-Old Ready to Get Back to Work

At 81, Frank Stathopoulos had been living with atrial fibrillation (AFib) most of his life. He thought he was used to it. But he was finding it harder and harder to breathe—even waking up at night and having to sit up to get a deep breath. Frank was struggling with decompensated heart failure. An echocardiogram revealed that he had tricuspid regurgitation.

Having had open heart surgery for a cardiac mass nearly 40 years ago, Frank decided one major operation was enough. An extensive search for a less invasive procedure lead him to Saint Luke's Mid America Heart Institute. Once established as an ideal candidate, his cardiologist enrolled him in the TRISCEND II study to receive a transcatheter tricuspid valve replacement.

The procedure only took about an hour, and Frank felt the results immediately. He was able to breathe easily and had more energy. He regained his health and is back to running every day and feels like he is 40 years old again. In fact, the twice-retired man says he has so much energy, he's thinking about going back to work.

## **THANK YOU, DONORS**

Support from our community enables Saint Luke's Mid America Heart Institute to serve as one of the nation's leading heart hospitals.

Saint Luke's Foundation works with grateful individuals to create philanthropic opportunities that greatly benefit Saint Luke's and our patients.

Our donors' gracious generosity in support of our vision allows us to grow our nationally recognized programs, purchase leading-edge medical technology, and enhance our commitment to education and research.

In addition, philanthropy directly supports innovation at the Heart Institute, enabling our researchers to investigate, identify, and provide safe, innovative technologies and state-of-the-art treatments.

Combined, these efforts contribute to our cardiovascular knowledge and ability to provide world-class patient care.

On behalf of our patients and their families, we are honored and thankful for our donors' support.





the intersection of
INNOVATION \* HOPE

4401 Wornall Road Kansas City, MO 64111 816-931-1883 saintlukeskc.org/heart