FRANKEL CARDIOVASCULAR CENTER
MICHIGAN MEDICINE

Multidisciplinary TAVR Program

On behalf of the Aortic Valve Team, we welcome you to the University of Michigan Frankel Cardiovascular Center. Severe **Aortic Stenosis** is narrowing of the aortic valve in the heart. It is often not preventable and may be related to:

- Age
- Buildup of calcium deposits on the aortic valve
- Radiation therapy
- Medications
- History of rheumatic fever
- High cholesterol
- Condition you were born with

Signs and symptoms of severe aortic stenosis can include:

- Chest pain or tightness
- Feeling faint or fainting with activity
- Dizziness
- Fatigue
- Shortness of breath
- Heart palpitations
- Heart murmur

How is severe aortic stenosis treated?

There are several established treatments for people with severe aortic stenosis. Your health care team meets after each of your evaluations to review and discuss the best treatment plan for you based on your overall health.

Heart valve treatment options

❖ **Medical management**

Medicines for severe aortic stenosis focus on treating problems that can

occur as a result of your diseased aortic heart valve. For example, people with severe aortic stenosis may take medicines to help control irregular heartbeats or prevent blood clots. These medicines may help control your symptoms for a period of time, however without aortic valve replacement severe aortic stenosis could worsen to a more serious condition.

- **Balloon aortic valvuloplasty**
  In addition to medications, your doctor may recommend a procedure called a balloon valvuloplasty. It is a minimally-invasive (nonsurgical) procedure that is performed to open your narrowed valve. This procedure does not require open heart surgery. However, the benefits last only a short period of time, usually 3-6 months.

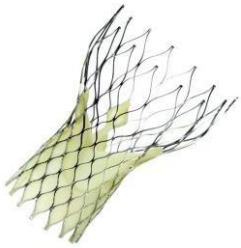
- **Open- heart surgical valve replacement**
  Open-heart aortic valve replacement surgery is an effective, life-saving treatment option for certain people with severe aortic stenosis. With open-heart aortic valve replacement, your chest is opened to allow the surgeon access to your heart. During surgery your diseased aortic valve is removed and a new valve is inserted.

- **Transcatheter Aortic Valve Replacement (TAVR)**
  TAVR is a heart valve replacement option for people with severe aortic stenosis who may not qualify for open heart aortic valve replacement surgery. The TAVR is a procedure that inserts a new valve inside your diseased aortic valve, and does not require your chest to be opened. Talk with your doctor about the risks associated with transcatheter aortic valve implantation.

There are several types of transcatheter valves used at the University of Michigan Frankel Cardiovascular Center. Below are two of the most commonly used valves for aortic stenosis. Your care team will determine the right valve for you based on your medical condition and other factors.

Edwards Lifescience®

Edwards Sapien Valve®



Medtronic, Inc®

Corevalve®

Visit the valve company websites to view animations of the TAVR procedure:

- Edwards: https://tinyurl.com/vs6lr2r
- Medtronic: https://tinyurl.com/yx7sae3f

How do I know if I am a candidate for TAVR?

People with severe aortic stenosis who are at low risk to very high risk for standard open heart surgery may qualify as candidates for this procedure. Prospective TAVR candidates must be evaluated by a TAVR cardiac surgeon and TAVR interventional cardiologist.

Additionally, further testing is required to determine your eligibility. This testing includes an echocardiogram, CT scan of the aorta, cardiac catheterization, carotid ultrasound, pulmonary function tests, lower extremity arterial ultrasound and dental evaluation. After careful consideration and presentation to the TAVR multidisciplinary committee, our team will determine the best way to treat your aortic valve disease.

TAVR is not an appropriate treatment option for everyone but you may be a candidate for one of our clinical trials. The transcatheter valves have not been approved by the FDA for patients with Aortic Valve Insufficiency (leaky valve). **Aortic valve insufficiency** occurs when the aortic valve does not completely close, causing blood to flow backward from the aorta in to the heart (also known as "regurgitation"). It has many of the same signs and symptoms of aortic stenosis.

We are participating in a clinical trial that will look at the use of a transcatheter valve specifically designed to help treat severe aortic valve insufficiency in people who are at high risk for open heart surgery. Our team will discuss with you whether or not you are a good candidate for this trial.

Are there safeguards in place to protect people who take part in research studies for medical devices?

The United States government and, specifically, the Food and Drug Administration (FDA) have strict regulations and safeguards in place to protect people who choose to participate in clinical trials. Additionally, clinical trials must be reviewed by an Institutional Review Board (IRB). The purpose of an IRB is to protect the rights and safety of people who volunteer to take part in research studies. Before participating in a trial, a person must agree to sign an informed consent form, which provides detailed information about the study and study procedures.

How do I prepare for my appointment?

In order to expedite the care process and better serve you as our patient, bring the following helpful medical information to your appointment:

1. **List of all current medications**
2. **Enclosed documents in this letter**
    a. Please fill these out before your appointment
3. **Current list of medical diagnoses and surgeries**

4. **Dental clearance is required for all TAVR patients.** Please take the enclosed dental clearance letter to your dentist. All patients must be evaluated within 6 months of TAVR procedure and have dental clearance (patients with full upper and lower dentures are exempt from this).

What should I expect at my initial visit?

On the day of your visit, be sure to take all your regular scheduled medications and have a good breakfast. Your initial visit will be comprehensive and will last a long period of time. We do suggest you bring a snack, especially if you are diabetic. On the day of your visit, you may have to complete testing, such as a blood draw or **ECG** (a device used to record the electrical activity of the heart), before your appointment.

The expected length of time for your initial visit is approximately 2 to 6 hours with our team.

Meet our core team:

As a patient, it is important to know the members of your care team. We have provided a list of individuals you may have contact with before, during, or after your clinic visit.

Multidisciplinary Team:

- *Stanley Chetcuti, MD*
  Interventional Cardiology
- *P. Michael Grossman, MD*
  Interventional Cardiology
- *Daniel Menees, MD*
  Interventional Cardiology
- *Devraj Sukul, MD*
  Interventional Cardiology
- *G. Michael Deeb, MD*
  Cardiac Surgery
- *Sarah Gualano, MD*
  Interventional Cardiology
- *Himanshu Patel, MD*
  Cardiac Surgery
- *Bo Yang, MD*
  Cardiac Surgery
- *Shinichi Fukuhara, MD*
  Cardiac Surgery
- *Karen M. Kim, MD*
  Cardiac Surgery
- *Gorav Ailawadi, MD*
  Cardiac Surgery

Clinic Team:

- *Hallie Casper, RN*
  Clinical Care Coordinator
- *Kelly Hodges, ACNP*
  Nurse Practitioner
- *Todd Dowe, RN*
  Clinical Care Coordinator
- *Angela Stamper*, ACNP
  Nurse Practitioner
- *Marianne Gaylor, AGPCNP*
  Nurse Practitioner
- *Julia Roberts, AGACNP*
  Nurse Practitioner

Support Team:

- *Laurie Linton*
  Patient Financial Counselor
- *Erica Long*
  Clinic Scheduler

Research Team:

- *Shradha Bhatt*
  Regulatory Specialist
- *Jessica Oakley, BS, CCRP*
  Clinical Research Project Manager
- *Wendy Warshall, BSN*
  Clinical Research Coordinator

Who do I contact if I have questions?

If you have any questions or concerns regarding this information, please contact our Patient Coordination Team at**: (888) 287-1082**

Visit this web resource site to learn more and watch the ***"Introduction to TAVR at the University of Michigan"*** **video:**
http://www.uofmhealth.org/media/29726

We strive to provide seamless, compassionate and safe care to both you and your family. We look forward to participating in your care and meeting both you and your family.

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