💎 Heart **Valve** Surgery.com



MEDTRONIC TAVR PROCEDURE

What 7 Facts Should You Know?

Sponsored by Medtronic

Table of Contents

Introduction The Transcatheter Aortic Valve Replacement (TAVR) Transformation
Fact 1: Aortic Stenosis Is Deadly and Under-Treated5
Fact 2: Medtronic TAVR Treats Aortic Stenosis Without Open-Heart Surgery
Fact 3: A Heart Team Can Determine If Medtronic TAVR Is Right For You
Fact 4: New Research For Medtronic TAVR Is Encouraging13
Fact 5: What Makes the Medtronic TAVR Unique?15
Fact 6: Over 600,000 Patients Have Been Implanted With Medtronic TAVR
Fact 7: Medtronic Has A Long History With Heart Valve Disease and TAVR

Introduction: Transcatheter Aortic Valve Replacement (TAVR) Has Transformed the Treatment of Aortic Stenosis

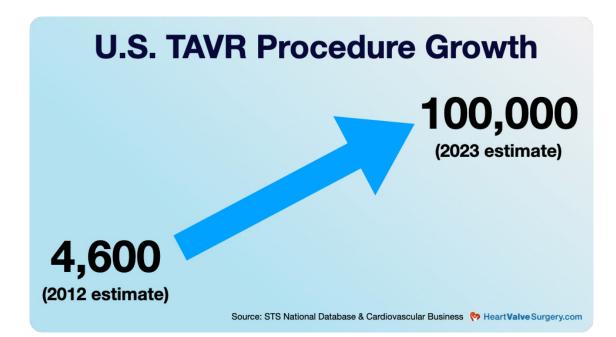
Patients diagnosed with aortic stenosis have important, life-long considerations about their treatment options. Today, there are several therapies designed to restore normal valve function, enhance quality-of-life, and help patients return to active living.

Two common approaches for treating diseased aortic valves include surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR).

- **SAVR** is an open-heart procedure that requires surgeons to make an incision to the patient's chest (or ribs) and replace the diseased aortic valve with a mechanical or a biological valve.
- **TAVR** is a minimally-invasive procedure that does not require an incision to the patient's chest or ribs. Instead, catheters are used by heart teams to implant a biological valve.



During the past 10 years, there has been a significant increase in the use of TAVR for aortic stenosis patients. The number of TAVR procedures performed in the United States has increased from 4,600 procedures in 2012 to over 100,000 procedures in 2023.¹







Fact 1: Aortic Stenosis Is Deadly and Under-Treated

Aortic stenosis prevents your aortic valve leaflets from opening-and-closing properly. This makes your heart work "over time" to pump blood to the rest of your body.



As you can see above, a normal aortic valve has three thin leaflets. An aortic valve may become stenotic due to age, calcium build-up, radiation therapy and/ or infections. Patients with aortic stenosis can be symptomatic or asymptomatic (without symptoms). Common symptoms of aortic stenosis are chest pain, dizziness, fatigue, shortness of breath and an irregular heartbeat.



Unfortunately, patients with severe aortic stenosis who do not get treatment have a 50% chance of dying just 24 months after the onset of symptoms.²

"Aortic stenosis slowly develops over years, however, it becomes very deadly when diagnosed as severe and the patient becomes symptomatic." states Dr. G. Michael Deeb, Inaugural Herbert Sloan Professor of Cardiac Surgery at University of Michigan Health.



"Aortic Stenosis slowly develops over years, however, it becomes <u>very deadly</u> when diagnosed as severe and the patient becomes symptomatic."

Dr. G. Michael Deeb, Inaugural Herbert Sloan Professor of Cardiac Surgery at University of Michigan Health





Even though there are many different safe-and-effective therapies for the treatment of aortic stenosis, this disease is significantly under-treated.

"Aortic Stenosis is grossly under-treated," states Dr. Kendra Grubb, Surgical Director of the Emory Structural Heart & Valve Center. "When you look at the number of patients with severe aortic stenosis who meet the guidelines for treatment, approximately 40%[†] of patients do not get treatment for this disease -- which is like a cancer of the heart." ³



"Aortic Stenosis is grossly under-treated. Approximately 40%[†] of patients do not get treatment."

Dr. Kendra Grubb, Surgical Director, Emory Structural Heart and Valve Center

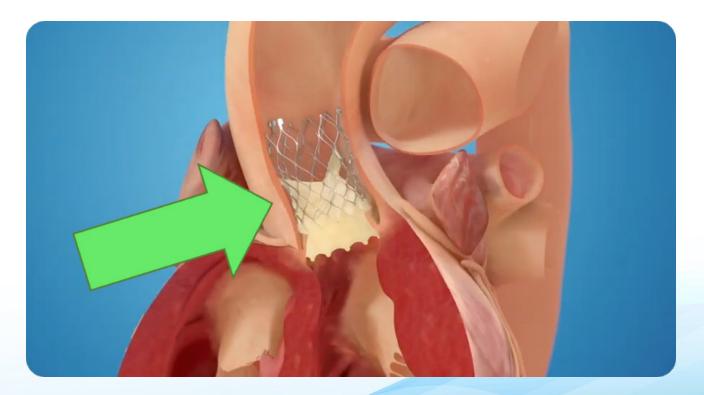
[†] Reflects total number of patients who could receive an aortic valve replacement.



Fact 2: Medtronic TAVR Treats Aortic Stenosis Without Open-Heart Surgery

There are many differences between TAVR and open-heart surgery. The main differences are (i) TAVR procedures typically do not require an incision to the patient's chest or ribs, (ii) patients who undergo TAVR are not required to go on the heart-lung machine, and (iii) patients who undergo TAVR often are not required to have general anesthesia.

For patients with symptomatic severe aortic stenosis who are candidates, a Medtronic TAVR procedure can replace a diseased aortic valve in approximately one to two hours depending on your health.







At the start of the procedure, your doctor will make a small cut in the groin, the neck, or a space between your ribs to guide a thin, flexible tube with the new heart valve into your artery and to your diseased valve. Your new valve will work immediately. Your doctor will remove the tube and close the small cut.

Many patients who had the Medtronic Evolut TAVR procedure go home the next day and get back to their everyday activities faster than open-heart surgery.⁴



Fact 3: A Heart Team Can Help Determine If Medtronic TAVR Is Right For You

The Medtronic TAVR procedure is currently approved by the United States Food & Drug Administration (FDA) for:

- Patients with heart disease due to symptomatic severe aortic stenosis; and
- Patients with a failing surgical aortic valve who are at high risk or extreme risk for complications during surgery.

As shown below, a <u>"Heart Team"</u> is comprised of aortic stenosis specialists including cardiologists, cardiac surgeons, and imaging experts - can collectively work together to determine if a Medtronic TAVR is the best treatment option for you.



Medtronic

To determine your best treatment option, you may undergo a series of tests including a cardiac catheterization, a CT scan, an echocardiogram, a carotid ultrasound, blood tests, a physical exam, and a pulmonary function test.

Diagnostic Tests Performed by Heart Teams



When meeting with your heart team, it is important for you to feel empowered and ask questions specific to your heart and your treatment options. Key questions to ask your doctors include:

11

- Why is treatment necessary?
- How effective are my treatment options?
- How do I know what the best treatment is for me?
- What are the risks associated with the treatment options?
- Am I a candidate for a less invasive procedure?
- How will treatment of my heart valve disease impact my life?





"Do not assume that all Heart Teams are the same. Research your care provider team. Learn what options are available to you."

Natalie Kelley, RN, Valve Program Coordinator, CHRISTUS Trinity Mother Frances Health System

To find a leading TAVR Heart Team, please <u>click here</u>.



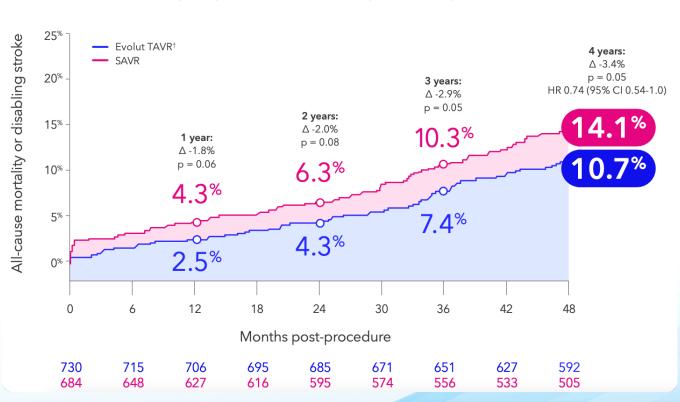


Fact 4:

New Research For Medtronic TAVR Is Encouraging

The Medtronic TAVR is the only TAVR with proven durability including less structural valve deterioration versus surgical valves at 10 years.⁵

In a 2023 clinical study, the Medtronic TAVR demonstrated superior hemodynamics (blood flow) at one year compared to surgery and remained excellent through four years. In that same study, the Medtronic TAVR also showed numerically lower death rates or disabling stroke rates compared to surgery (see chart below).⁶



Primary Endpoint: All-Cause Mortality or Disabling Stroke



"New clinical trial research shows that the minimally-invasive Medtronic TAVR outperforms surgery with sustained valve performance."

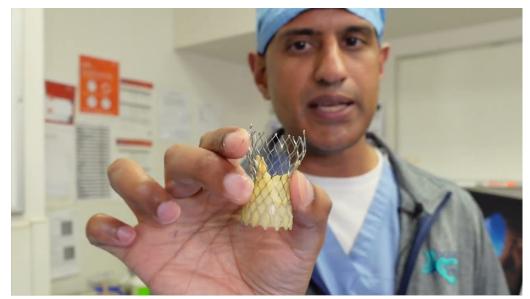
Dr. Michael Reardon, Chairman of Cardiovascular Research, Professor of Cardiovascular Surgery, Methodist Health





Fact 5: What Makes the Medtronic TAVR Unique?

The self-expanding Medtronic TAVR provides patients excellent hemodynamics (blood flow) across their aortic valve, which can which can help keep patients alive and out of the hospital.⁷

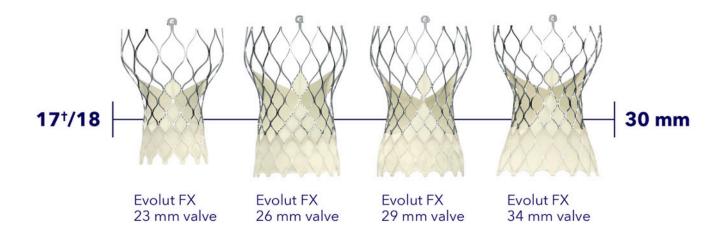


Source: Boulder Community Hospital

The metal frame is a blend of nickel and titanium (called nitinol). This material allows the frame to shape itself to the patient's anatomy. The tissue leaflets and the outer wrap of a Medtronic TAVR are made from pig heart tissue.



The Medtronic TAVR has been shown to have lower rates of valve dysfunction than surgical valves out to five years, resulting in lower risk for death and rehospitalization for valve disease or heart failure.⁷



† Measurement is for TAV-in-SAV only.

Medtronic TAVR Sizes (23mm to 34mm)

To ensure the best possible fit and to avoid prosthesis patient mismatch (valve too small for patient body size), the Medtronic TAVR is available in four different sizes ranging from a 23 millimeters to 34 millimeters.

Fact 6: Over 600,000 Patients Have Been Implanted With Medtronic TAVR ³

According to a survey of more than 3,000 heart valve patients, 49% of respondents reported a "quick return to active living" as a key factor in their treatment option selection.⁸

Here are what actual aortic stenosis patients are saying about their experience with Medtronic TAVR and their return to active living.



"I can walk. I can dance. I can cook. I can drive. I can do anything I want to do after my Medtronic TAVR. I live life to the fullest every day."

- Darian, 80 years old, aortic stenosis patient





"If I didn't have the Medtronic TAVR procedure, I don't think I would be playing golf and gardening. TAVR gave me a new lease on life."

-Gary, 69 years old, aortic stenosis patient



"I'm amazed because I can do anything I want to. I'm living a new life after TAVR."

-Julia, 74 years old, aortic stenosis patient

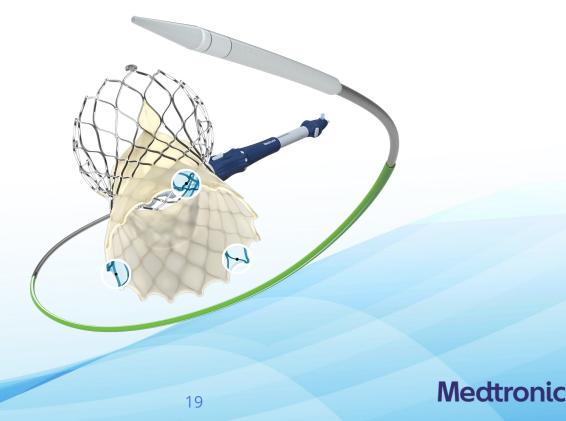
Fact 7: Has A Long Hig

Medtronic Has A Long History With Heart Valve Disease and TAVR

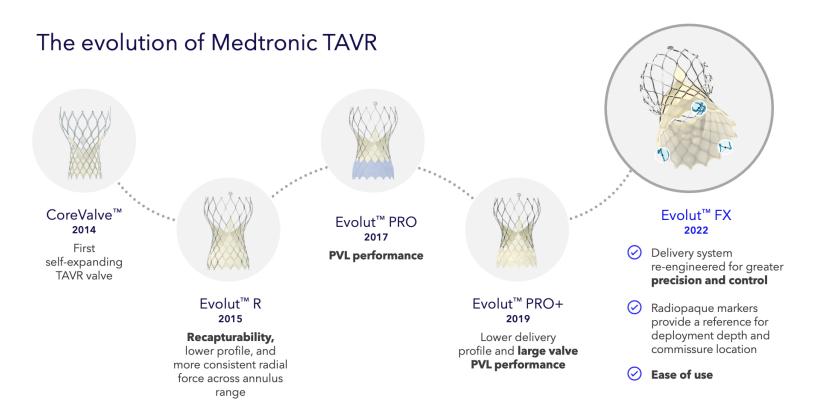
Founded in 1949, Medtronic is one of the world's largest medical device companies with over 95,000 employees in 150 countries. In 2024, Medtronic was named one of the World's Most Ethical Companies by Ethisphere for a second year. Out of 136 honorees, spanning 44 industries in 20 countries, Medtronic was one of only two honorees in its industry.

Specific to heart valve disease, Medtronic's first heart valve replacement device, the Medtronic-Hall Mechanical Heart Valve, was released in 1977.

Since then, Medtronic has continued to research and develop new innovations for the treatment of aortic stenosis. An important medical breakthrough by Medtronic was the development of a self-expanding TAVR device.



As you can see below, Medtronic's ongoing commitment to advancing aortic stenosis therapy has generated four innovations of its TAVR procedure to enhance the performance of this less-invasive treatment option.



Thanks to this unique technology, patients with severe aortic stenosis can undergo aortic valve replacement without an incision to the patient's chest or ribs, without the use of the heart-lung machine and, at times, without the use of general anesthesia.

After receiving a Medtronic TAVR, patients have reported benefits like having more energy, breathing normally, experiencing less pain, experiencing fewer symptoms, and feeling less anxiety.

Backed by proven performance, continually advancing technology, the Medtronic TAVR has been implanted in more than 600,000 patients worldwide.³



"At Medtronic, we are committed to helping aortic stenosis patients benefit from durable, minimallyinvasive devices that consider the lifetime management of heart valve disease."

Nina Goodheart, Senior Vice President and President, Structural Heart & Aortic, which is part of the Cardiovascular Portfolio at Medtronic.





For more information, please visit:

www.TreatAorticStenosis.com

To find a Heart Team that specializes in TAVR, click here.

Important Safety Information.

References:

- 1. Society of Thoracic Surgeons National Database and Cardiovascular Business, Presented by Dr. Michael Mack at Controversies & Advances in the Treatment of Cardiovascular Disease Conference, December, 2023.
- 2. Ross J Jr, Braunwald E. Aortic stenosis. Circulation. July 1968;38 (1 Suppl):61-67.
- 3. Medtronic data on file.
- 4. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. New England Journal of Medicine, 2019;380(18):1706-1715.
- 5. Thyregod HGH, Jorgensen TH, Ihlemann N, et al. Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial. Eur Heart J. Feb 7 2024.
- Forrest JK, Deeb GM, Yakubov SJ, et al. Evolut Low Risk Trial Investigators.
 4-Year Outcomes of Patients With Aortic Stenosis in the Evolut Low Risk Trial.
 J Am Coll Cardiol. 2023 Nov 28;82(22):2163-2165.
- 7. Yakubov S, et al. Five-Year Incidence of Bioprosthetic Valve Dysfunction in Patients Randomized to Surgery or TAVR: Insights From the CoreValve US Pivotal and SURTAVI Trials. Presented at CRT; February 2023.
- 8. Pick, Adam, "Heart Valve Patient Survey Reveals 'Active Living' a Top Priority for Patients Seeking Treatment", HeartValveSurgery.com, 2020.



Medtronic

Medtronic is the sponsor of this educational eBook.

© 2024 HeartValveSurgery.com. All Rights Reserved