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CARDIO DEVICE COMPANIES SPECIAL REPORT

INSIDE:

- The 5 largest cardiovascular device companies
- The top cardiovascular tech stories at TCT 2025
- Lessons from Medtronic's Define AFib study of implantable cardiac monitors

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COVER IMAGE: ADOBE STOCK

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INTRODUCTION

Cardiology remains one of the most exciting areas of medtech, producing a host of meaningful technologies.

From atrial-fibrillation-treating pulsed-field ablation to heart pumps to transcatheter heart valves, cardio devices have saved countless lives in recent decades, and the innovation continues.

In *MassDevice*'s inaugural Cardio Device Companies Special Report, I turned to SEC filings to rank the five largest. What especially stood out to me was how cardiovascular technology innovation is driving growth in all five. Saving lives makes for a good business, too.

Senior Editor Sean Whooley expands on the innovation theme with a roundup of top stories out of this year's Transcatheter Cardiovascular Therapeutics (TCT) conference. We round out this report with some of the greatest hits from *Medical Design & Outsourcing* Managing Editor Jim Hammerand's features on cardio tech innovations.

I hope you find this report helpful. Thanks again for being loyal followers of *MassDevice* and *MDO* — and keep on innovating.

CHRIS NEWMARKER
Editor-in-chief

THE 5 LARGEST CARDIOVASCULAR DEVICE COMPANIES

COMPANY	ANNUAL REVENUE
Medtronic – Cardiovascular	$12.481B
Abbott - Cardiovascular businesses *	$11.219B
Boston Scientific - Cardiovascular	$10.755B
Johnson & Johnson MedTech - Cardiovascular	$7.707B
Edwards Lifesciences	$5.440B

* Abbott's cardiovascular businesses inside its medical devices segment include rhythm management, electrophysiology, heart failure, vascular, and structural heart.

THESE 5 CARDIO DEVICE COMPANIES ARE THE LARGEST

By Chris Newmarker, Editor-in-chief

Pulsed-field ablation (PFA), leadless pacemaking, transcatheter heart valves, and intravascular lithotripsy (IVL) are among the top technologies driving success at the world's largest cardiovascular device companies.

Cardiovascular businesses are part of much larger businesses for four of the companies on this list, but they are standout performers for all of them.

HERE ARE THE WORLD'S FIVE LARGEST CARDIOLOGY TECH COMPANIES:

MEDTRONIC – CARDIOVASCULAR

Annual revenue: $12.481B

Corporate headquarters: Galway, Ireland (Operational HQ in Fridley, Minnesota)

Top executives: Geoff Martha, CEO; Skip Kiil, EVP and Cardiovascular portfolio president

www.medtronic.com

Cardiovascular technology is a major growth driver for the world's largest medical device company. In just its second quarter ending Oct. 24, 2025, Medtronic's Cardiac Ablation Solutions revenue increased 71% year-over-year, including 128% in the U.S., driven by the success of Affera pulsed-field ablation technology to treat atrial fibrillation (AFib).

"We're winning share as our PFA franchise grew over 300% in the U.S., as well as in international markets. This was based on the strength of our Affera mapping system and our Sphere-9 dual-energy and high-density mapping catheter," said CEO Geoff Martha.

Next up is the Affera Sphere-360, an investigational single-shot mapping and PFA catheter for paroxysmal AFib. Medtronic has submitted an application for an investigational device exemption (IDE) with the FDA. Add in the success of Medtronic's Micra leadless pacemakers, and its Cardiovascular business grew 10.8% in the quarter.

In many ways, Medtronic's cardiology success represents the company returning to its roots. Co-founders Earl Bakken and Palmer Hermundslie pioneered battery-powered pacemakers in the late 1950s. These days, Medtronic's Cardiovascular portfolio is made up of its Cardiac Rhythm & Heart Failure, Structural Heart & Aortic, and Coronary and Peripheral Vascular divisions. Medtronic recently promoted Jim Peichel, who had been the head of its Cardiac Implantables Technology Development Center, to be its new chief technology officer.

More from Medical Design & Outsourcing:

- How Medtronic developed OmniaSecure, the world's smallest defibrillation lead
- Medtronic tech takeaways on PFA, RDN, M&A and R&D from top executives
- Medtronic's Affera Sphere-9 dual-energy ablation and mapping catheter uses nitinol in a new way
- Medtronic launches study to address health disparities in structural heart disease

ABBOTT - CARDIOVASCULAR BUSINESSES

Annual revenue: $11.219B

Corporate headquarters: Abbott Park, Illinois

Top executives: Robert Ford, CEO; Lisa Earnhardt, EVP and Medical Devices group president; Randel Woodgrift, SVP, Cardiac Rhythm Management; Uri Yaron, SVP, Electrophysiology; Sandra Lesenfants, SVP, Structural Heart; Julie Tyler, SVP, Vascular

www.abbott.com

Five of the seven businesses within Abbott's Medical Devices segment are related to cardiology, with Electrophysiology, Rhythm Management, Heart Failure and Structural Heart reporting double-digit growth during the company's third quarter, which ended Sept. 30, 2025. Analysts see growth opportunities around Abbott pulsed-field ablation technology. Its Volt PFA catheter already has a CE mark and is described by the company as next-gen technology featuring a balloon-in-basket catheter with the EnSite X EP heart mapping system. (There's also a recent FDA breakthrough nod for the TactiFlex Duo Sensor-Enabled catheter for the treatment of ventricular tachycardia using PFA.)

Other top cardiology device news for Abbott this year included:

- FDA investigational device exemption (IDE) approval for its coronary intravascular lithotripsy (IVL) system, which represents another bid to compete in a fast-growing market;
- The FDA approval and U.S. launch of Tendyne, a transcatheter mitral valve replacement system that doesn't require open-heart surgery.
- A CE mark for an expanded indication for Abbott's Navitor TAVI system.
- Positive data on Abbott's Aveir dual-chamber (DR) leadless pacemaker system.
- A CE mark for the company's Esprit BTK everolimus-eluting resorbable scaffold system.

Abbott's HeartMate 3 is presently the only durable left ventricular assist device available in the United States.

More from Medical Design & Outsourcing:

- Design for access, says Abbott's Lisa Earnhardt, medtech's most powerful woman
- How Abbott dialed in the waveform for its Volt PFA system
- Why Abbott went with a balloon-in-basket design for its Volt PFA catheter
- Do PFA microbubbles matter? We asked Abbott's top doc in electrophysiology

BOSTON SCIENTIFIC - CARDIOVASCULAR

Annual revenue: $10.755B

Corporate headquarters: Marlborough, Massachusetts

Top executives: Michael Mahoney, CEO; Joseph Fitzgerald, EVP and Cardiology group president

www.bostonscientific.com

Boston Scientific could become the top player in electrophysiology as it battles Medtronic and Johnson & Johnson MedTech in the fast-growing pulsed-field ablation (PFA) market.

"Pricing has been stable, and the company intends to continue innovating to maintain its market leader status in PFA even as competitor systems come to market," BTIG analysts recently said.

Future launches for the Farapulse PFA system include the Farapoint and Faraflex catheters. Farapoint is expected to launch by the end of 2025, while the Faraflex mapping and ablation remains in the pipeline with ongoing clinical trials.

Complementing Farapulse is Boston Scientific's Watchman FLX left atrial appendage closure (LAAC) device. It reduces the risk of thromboembolism from the LAA in patients with non-valvular AFib. The company continues to report growth there as well, with patients scheduled for Watchman procedures proactively asking for ablations, the analysts say. The company has pushed to deliver the two offerings in concomitant procedures.

More from Medical Design & Outsourcing:

- Brad Sutton on Boston Scientific's PFA advantage and advice for medtech pros
- First Look: Boston Scientific's next-gen Faraflex PFA and mapping catheter

JOHNSON & JOHNSON MEDTECH - CARDIOVASCULAR

Annual revenue: $7.707B

Corporate headquarters: New Brunswick, New Jersey

Top executives: Joaquin Duato, CEO; Tim Schmid, EVP and worldwide chair, MedTech

www.jnj.com

Johnson & Johnson MedTech's cardiovascular technologies continue to lead the company's growth, said Tim Schmid, the company's worldwide chair of MedTech, during our DeviceTalks West event in October 2025.

"We made a distinctive decision to say we're going to play a bigger role in the cardiovascular space," he said. "These are the sickest patients. … They're also patients that create the greatest burden on health systems around the world."

Johnson & Johnson MedTech's Cardiovascular business was up more than 17% year-over-year during the first nine months of 2025, driven by growth from major acquisitions in recent years.

Those deals include the $13.1 billion purchase in 2024 of Shockwave Medical and its intravascular lithotripsy (IVL) technology that uses sonic waves to treat calcified arterial plaque. J&J continues to report positive data on Shockwave technology.

The Shockwave purchase followed J&J's $400 million acquisition of left atrial appendage (LAA) device maker Laminar in 2023 and the $16.6 billion purchase of Abiomed and its catheter-delivered Impella heart pumps to treat heart failure in 2022. New data recently enabled upgraded recommendations for Impella in recent multi-society guidelines.

Expect Johnson & Johnson MedTech's focus on cardiology to grow even more now that it plans to separate its DePuy Synthes Orthopaedics business.

More from Medical Design & Outsourcing:

- How Shockwave Medical sealed the deal that could put Johnson & Johnson back on top
- J&J's Shockwave wants to take IVL to the next level with next-gen devices
- Beyond IVL, there's one place Shockwave wants to restrict blood flow
- J&J MedTech is growing Shockwave's R&D budget by double digits

EDWARDS LIFESCIENCES

Annual revenue: $5.440B

Corporate headquarters: Irvine, California

Top executives: Bernard Zovighian, CEO

www.edwards.com

Edwards Lifesciences' primary focus is on structural heart devices, including its well-respected transcatheter aortic valve replacement (TAVR) and transcatheter mitral and tricuspid technologies. Edwards boosted its concentration on structural heart technologies even more in 2024, selling its Critical Care business to BD.

"Our focus on structural heart, including extending into heart failure and aortic regurgitation, represents a tremendous opportunity with the potential to drive differentiated long-term value," Edwards CEO Bernard Zovighian said when releasing the company's results for the third-quarter, which ended Sept. 30, 2025.

The company further boosted its portfolio in September by buying the remaining stake in Vectorious Medical Technologies and its miniature heart pressure sensor implant called V-LAP. Edwards is still seeking to complete a $1.2 billion acquisition of JenaValve and the Trilogy transcatheter heart valve (THV) system, even as the Federal Trade Commission seeks to block the deal.

More from Medical Design & Outsourcing:

- Edwards Lifesciences engineers Darshin Patel and Hengchu Cao discuss minimally invasive device development in the MDO Min-Vasive Medtech Series
- The Edwards Lifesciences Sapien M3 transcatheter mitral valve replacement system uses nitinol in a new way
- Q&A with nitinol expert Ming Wu, former SVP of engineering at Edwards Lifesciences

Our focus on structural heart, including extending into heart failure and aortic regurgitation, represents a tremendous opportunity with the potential to drive differentiated long-term value."

– Edwards CEO Bernard Zovighian

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THE TOP CARDIOVASCULAR TECH STORIES OUT OF TCT 2025

By Sean Whooley, Senior Editor

At the end of October, medtech's biggest names gathered in San Francisco for the 2025 Transcatheter Cardiovascular Therapeutics (TCT) conference.

These companies develop a range of cardiovascular therapeutics, devices and systems. Those include replacement heart valves, heart pumps, drug-eluting implants, renal denervation (RDN) systems and more.

Last year's TCT 2024 event highlighted significant trends in the cardiovascular space, following up on the previous year's developments.

Several companies reported positive study results and significant advances for their platforms at TCT 2025 this time around. Here are the biggest stories out of this year's event.

Medtronic has multiple studies backing its Symplicity Spyral RDN

At TCT 2025, Medtronic shared findings that included new long-term results from its final report of the SPYRAL HTN-ON MED trial and the first results from the high cardiovascular risk cohort of its SPYRAL AFFIRM study.

Symplicity Spyral delivers radiofrequency energy to nerves near the kidneys in a minimally invasive procedure to treat hypertension. These nerves can become overactive and contribute to high blood pressure. The RDN system holds approval for commercial use in more than 80 countries.

Medtronic's Symplicity Spyral RDN system delivered consistent, durable hypertension treatment in the SPYRAL HTN-ON MED study. [Image courtesy of Medtronic]

Medtronic received a landmark approval for the system in November 2023.

SPYRAL HTN-ON MED demonstrated the consistent and durable effects of the Symplicity blood pressure procedure, with the most long-term data presented and published to date.

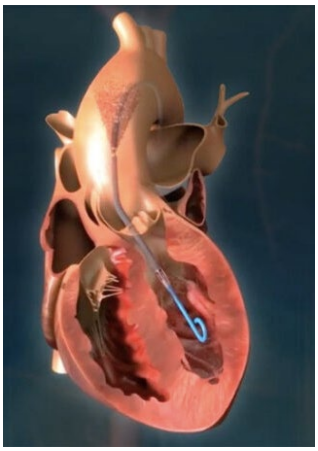
In the data shared for SPYRAL AFFIRM, investigators saw significant, safe and sustained blood pressure reductions with the RDN system. This occurred with no increase in anti-hypertensive medication use at six months.

Read the full SPYRAL HTN-ON MED story here.
Read the full SPYRAL AFFIRM story here.

Impella study, new guidelines boost J&J MedTech at TCT 2025

Johnson & Johnson MedTech announced new data confirming the benefits of its Abiomed Impella CP system.

Impella CP is the world's smallest heart pump. It's inserted into the heart to temporarily take over the heart's pumping function, allowing the heart to rest and recover while maintaining the flow of oxygenated blood throughout the body.



This screen shot from an Abiomed video demonstrates placement of the Impella 2.5 and Impella CP. Delivered in a minimally invasive way, Impella pumps actively unload the heart, aiding native heart recovery. [Image courtesy of Abiomed]

Findings from the DanGer Shock trial included an absolute mortality reduction of 16.3% compared to standard care at 10 years. On average, Impella CP patients gained approximately 600 additional days alive at 10 years.

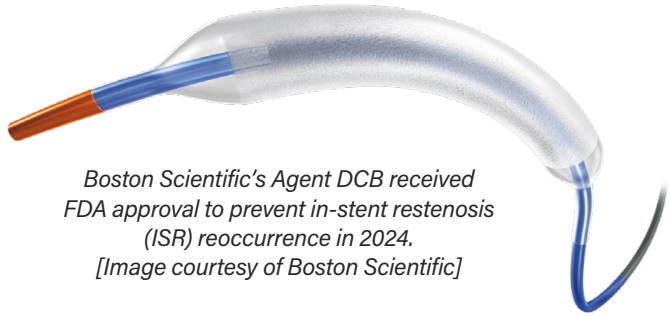
J&J MedTech also shared that its evidence led to upgraded recommendations for Impella in recent multi-society guidelines. The guideline updates, which include ACC/AHA, cover the treatment of cardiogenic shock patients. They come on the back of evidence from the DanGer Shock trial.

Read the full story here.

Boston Scientific's Agent drug-coated balloon performs well in study

Boston Scientific shared findings from new analyses of its Agent drug-coated balloon (DCB) at TCT 2025.

Agent is an alternative to traditional therapies like balloon angioplasty, additional layers of stenting or radiation. The paclitaxel-coated balloon transfers a therapeutic dose of drug to the vessel wall, helping to prevent in-stent restenosis (ISR) reoccurrence. The FDA approved the balloon in March 2024.



Boston Scientific's Agent DCB received FDA approval to prevent in-stent restenosis (ISR) reoccurrence in 2024. [Image courtesy of Boston Scientific]

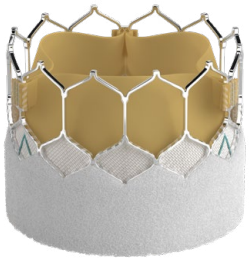
First, an observational, prospective, nonrandomized, multi-center registry used real-world data from the CathPCI registry. It evaluated more than 12,000 patients treated with the Agent DCB during a two-year enrollment period (April 2024-June 2025). The study took place across more than 700 U.S. sites.

Boston Scientific also reported findings from the ALLIANCE registry looking at 1,800 Agent patients in Japan. It assessed the safety and effectiveness of Agent for real-world PCI. Patients received either standalone DCB or a hybrid drug-eluting stent and DCB strategy.

Read the full story here.

Edwards Lifesciences touts multiple studies for its heart valves at TCT 2025

At TCT 2025, Edwards shared new data demonstrating long-term benefits with its Sapien heart valve system, then added more study findings demonstrating successful outcomes with its mitral and tricuspid therapies.



The Sapien 3 Ultra Resilia TAVR system demonstrated strong long-term outcomes at TCT 2025. [Image courtesy of Edwards Lifesciences]

Seven-year data from the PARTNER 3 trial reaffirmed the early and sustained patient benefits of Edwards' transcatheter aortic valve replacement (TAVR) system. Data outlined superior clinical outcomes at one year, too, and demonstrated strong long-term valve performance and durability.

Separately, 10-year results from PARTNER 2 intermediate risk studies reinforced the company's valve's lasting performance and outcomes across all risk profiles and generations.

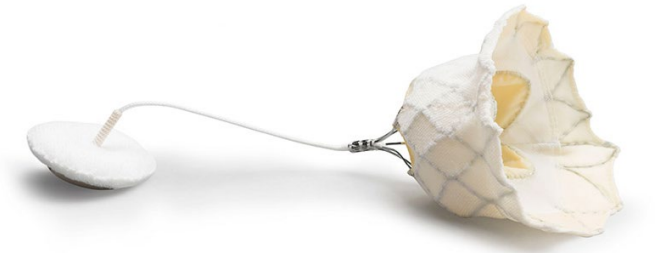
Edwards also shared one-year data from the ENCIRCLE single-arm pivotal trial and 30-day data from the EVOQUE STS/ACC TVT registry.

Read about long-term TAVR results here.
Read about the Evoque and Sapien M3 results here.

Abbott reports positive results for its Tendyne mitral valve replacement

New study findings supporting the use of Abbott's Tendyne transcatheter mitral valve replacement (TMVR) system were shared at TCT 2025.

Tendyne offers an option for patients with mitral valves that fail to function properly due to severe mitral annular calcification (MAC). MAC stiffens the annulus ring-like structure that supports the mitral valve. This can lead to mitral regurgitation or stenosis, disrupting the heart's ability to effectively pump blood.



Abbott's Tendyne system is an option for patients with mitral valves that fail to function properly due to severe mitral annular calcification (MAC). [Image courtesy of Abbott]

Some patients with severe MAC at high risk for open-heart surgery can't have their valve repaired with Abbott's MitraClip. For this population, Tendyne delivers an alternative, minimally invasive way to replace the leaky (mitral regurgitation) or narrowed (stenosis) valve.

Findings from the SUMMIT-MAC pivotal trial were shared at TCT 2025, marking the first prospective, multi-center trial evaluating the system's safety and effectiveness with core-lab adjudication and prespecified endpoints.

Read the full story here.

FastWave Medical reports first-in-human findings for Sola laser IVL system

FastWave Medical shared first-in-human and pre-clinical data for its Sola coronary laser intravascular lithotripsy (L-IVL) system at TCT 2025.

Minneapolis-based FastWave designed Sola to treat cardiovascular calcium with sleek, rupture-resistant balloon catheters. Its custom laser energy source produces actuating, circumferential sonic pressure waves. Sola enables improved operator control to safely and effectively modify calcium.

First-in-human results demonstrated the safety, efficacy and procedural success of the FastWave Medical next-generation Sola IVL system. [Image courtesy of FastWave Medical]

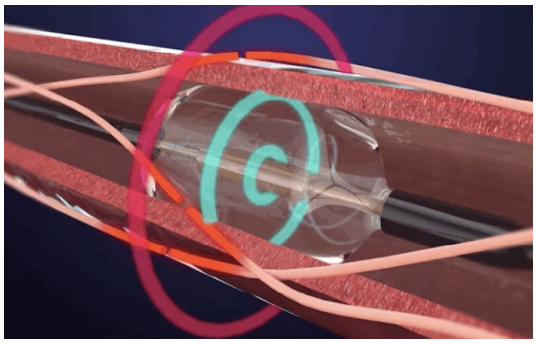
FastWave's study for which results were shared at TCT 2025 evaluated Sola in patients with complex calcified coronary lesions. The first-in-human results demonstrated the safety, efficacy and procedural success of the next-generation system.

Primary endpoints include 30-day major adverse cardiac events (MACE, defined as cardiac death, myocardial infarction or target-vessel revascularization) and procedural success, defined as successful stent delivery with <50% residual stenosis and no in-hospital MACE.

Read the full story here.

Recor Medical shares positive renal denervation data at TCT 2025

Rivaling Medtronic's Symplicity Spyral system, Recor Medical has its own RDN system: the Paradise ultrasound RDN (uRDN) platform.



This ReCor Medical illustration shows the Paradise renal denervation catheter during the procedure. The red circle indicates ultrasound-generated energy producing heat for denervation, while the blue circles illustrate cooling from circulating water within the artery to protect the artery from heat. [Image courtesy of Recor Medical]

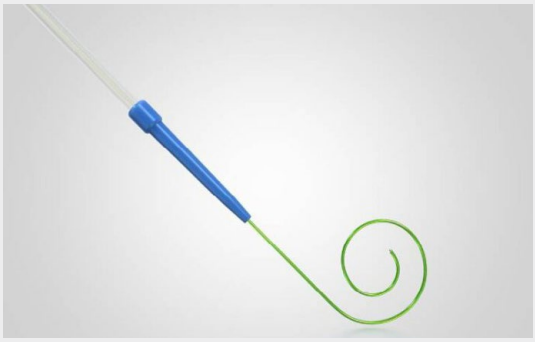
Recor Medical received a landmark FDA nod for its Paradise system in November 2023. It also holds a CE mark for the technology. The first-of-its-kind Paradise system denervates the sympathetic nerves surrounding the renal arteries. This lowers blood pressure by reducing the overactivity that can lead to hypertension.

At TCT 2025, the company announced results from two clinical studies evaluating the system. Recor shared findings from its Global Paradise System (GPS) registry and a pooled analysis of data from its RADIANCE global clinical trial program. The positive data presentation came days after the company picked up a significant Medicare win as well.

Read the full story here.

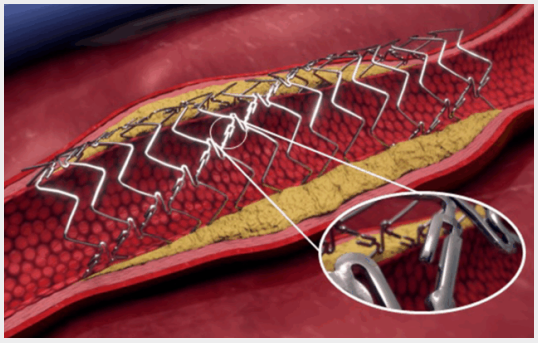
The rest of the big stories out of TCT 2025

- Medtronic launches new guidewire to support TAVR procedures
- Philips study backs immediate narrowed artery treatment in heart attacks
- Philips unveils new cath lab data integration platform for Azurion
- Anteris reports positive biomimetic heart valve study results
- Surmodics reports real-world Pounce thrombectomy system findings
- Study shows significant risk reduction with Elixir Medical bioadaptor
- Penumbra study backs mechanical thrombectomy for treating pulmonary embolism
- Multiple studies back Cordis Selution SLR drug-eluting balloon
- Venus Medtech's Cardiovalve completes enrollment in tricuspid valve replacement trial



The Stedi guidewire [Image courtesy of Medtronic]

IFR technology used in the iMODERN study [Image courtesy of Philips]



Elixir Medical's DynamX [Image courtesy of Elixir Medical]

Lessons from Medtronic's Define AFib study of implantable cardiac monitors

JIM HAMMERAND
MANAGING EDITOR

Medtronic's study of Linq implantable cardiac monitor (ICM) devices in atrial fibrillation (AFib) patients offers important lessons for other device developers, says the cardiac electrophysiologist who chaired the Define AFib clinical study steering committee.

Dr. Jonathan Piccini, a professor of medicine and population health at Duke University Hospital and the Duke Clinical Research Institute, has been involved with the first-of-its-kind app-based study — which enrolled its first patients in 2021 — for more than five years.

"Define AFib is not only a really important study to help us understand how atrial fibrillation behaves in patients, but it's also a building block for the clinical trials of the future," Piccini said in an interview with *Medical Design & Outsourcing*.

The following has been lightly edited for space and clarity.

MDO: What's the significance of the Define AFib study for patients and for the technology?

Piccini: "There are a lot of different ways you can think about Define AFib. On one hand, you could say it's a study about implantable loop recorders and the information they bring that can be used for monitoring patients and understanding their disease trajectory as well as management and treatment of their conditions. Another way to look at the study is as a first-in-class innovative study design, where as much information as possible is sourced from patients in their usual routine and not under the auspices or in the settings of dedicated research visits where we intermittently collect information. Define AFib was very unusual in that patients who got one of these implantable loop recorders as part of their regular clinical care were invited to participate, and once they were informed about the study and they agreed to participate, essentially everything was remote. It wasn't a sightless study, because a sightless study truly means they never stepped foot in a brick-and-mortar facility. >>

Medtronic developed the Reveal Linq implantable cardiac monitor for long-term monitoring of patients with infrequent symptoms.
Photo courtesy of Medtronic

Medtronic's Linq II implantable cardiac monitor (featuring AccuRhythm artificial algorithms) is for long-term heart monitoring. [Image courtesy of Medtronic]

In this case, they were in a brick-and-mortar facility for that original implant, but everything after that was really all remote. As a result it had as minimal a burden as possible on patients. More than that, the study was designed largely through patient feedback. The study team reached out to patients and said, 'You have this implantable monitor. What type of information do you find helpful for managing your illness?' The entire app that the patient had displayed information in a very patient-centered way."

What about this study made it different than more traditional clinical trials?

Piccini: "The concept was wearables are becoming more and more common. They're collecting a significant amount of information on patient health. Smartphones are becoming more and more common. They too are collecting lots of information, not just necessarily health information, but also information like someone's location. So if someone goes into a healthcare facility, does that mean they've been hospitalized? There's so many different pieces of innovation. One was making sure that patients were informed and that when they agreed to participate, they understood what information the study was going to use to help us understand the disease better. For example, part of this geofencing was that if a patient provided permission and their phone was in a healthcare facility for a certain period of time, that launched a query to see if the patient had been hospitalized. There were quality of life surveys that if a patient's device picked up atrial fibrillation at a certain interval, it would send a patient a questionnaire that assessed how their quality of life activity levels were, those types of things. There's so many things we learned, and it would be hard to go through all of them, but some of the highlights are that we definitely did see that when patients had more AFib, they tended to have reductions in their quality of life. We learned that the information from the devices was not overwhelming to patients or their healthcare providers. We often hear concerns about information overload, but by and large the feedback we received was the additional information was helpful and not overly burdensome."

"WE OFTEN HEAR CONCERNS ABOUT INFORMATION OVERLOAD, BUT BY AND LARGE THE FEEDBACK WE RECEIVED WAS THE ADDITIONAL INFORMATION WAS HELPFUL AND NOT OVERLY BURDENSOME."

What was the major takeaway for AFib from this study?

Piccini: "The main scientific finding presented at the AF Symposium is when you take basic information about someone's atrial fibrillation combined with information about their medical conditions — do they have heart failure, do they have diabetes, do they have high blood pressure — and you combine that with continuous information about their heart rhythm and how often they're in atrial fibrillation, how long the episodes of atrial fibrillation are, all of that information together, you can begin to be able to predict how likely someone is to need care for their atrial fibrillation. Why is that important? When they need care, won't they just show up for it?

That's one view you could take. But a much better way to deliver healthcare is to make sure the right treatment gets to the right patient at the right time. So it would be much better if we can anticipate that someone's going to need a change in their medication so we can avoid them needing to come in for an urgent last-minute clinic visit or avoid them going to the emergency room or being hospitalized."

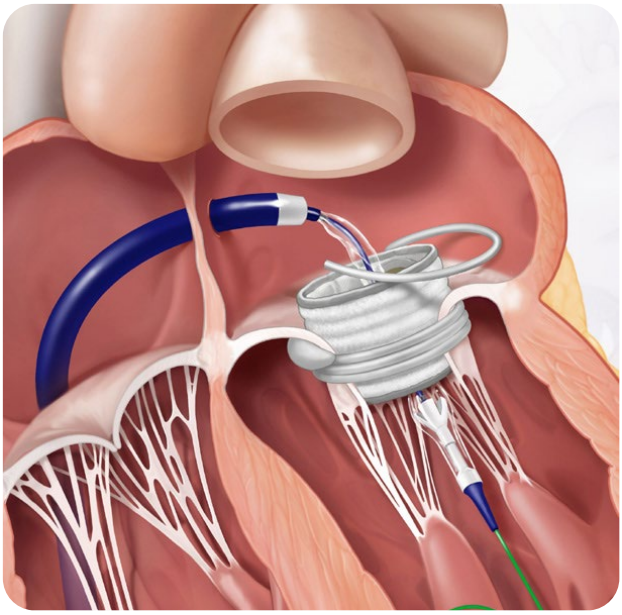
What did you learn from this study that could be helpful for device developers planning their own trials?

Piccini: "One worry we had was if you're in a study and your phone every now and then asks you to answer some questions for the study, are you really going to do it? We were very pleasantly surprised. Our survey response rates were very high throughout the study. We think that's a reflection of the fact that these are patients who really wanted to help improve our knowledge of atrial fibrillation so in the future we get even better at treating the illness. That was one pleasant surprise. I wouldn't say it was a disappointment, but something I think we need to continue to work on is that the vast majority of individuals have a smart device, but they may not have the specific smart device that a given study is using. In the future we need to focus on interoperability so no matter what type of device someone has, they can still participate in the study. And it is true that remote studies still have barriers. If you have a hard time navigating electronic enrollment or setting up things on your phone, those can be barriers in these types of studies. No matter what type of information you're collecting, you still want to be able to validate things in individuals medical records. If a patient says they have this condition or that condition or they went to the emergency room, you want to be able to verify that and the technologies we have to do that are still very labor intensive. Having ways to quickly validate things electronically is something else we're going to need to pay close attention to in the future."

How did you achieve such a high response rate?

Piccini: "There's three reasons. The first is we really leaned heavily into patient engagement. The study team aggressively sought out patient opinion, asking, 'Will this be burdensome? Do you think your peers will react favorably to this?' There was a lot of engagement to get advice from patients in the very beginning. The second reason is we used validated surveys that are designed to collect the maximal amount of information while avoiding survey fatigue to every extent possible. And then the third reason is — and this is something we often don't talk about — these are patients who said, 'I want to help.' They were highly motivated to make sure the study could learn as much about atrial fibrillation as possible. And we have just an incredible amount of data, thousands and thousands and thousands of observations and data points from the study participants that we hope is going to continue to contribute to the body of knowledge around AFib for a very long time to come."

Professor of Medicine and Population Health at Duke University Hospital
Dr. Jonathan Piccini



Q&A with Darshin Patel, who led the Edwards Lifesciences Sapien M3 TMVR system's development

Edwards Lifesciences VP of Engineering Darshin Patel discusses the first-of-its-kind Sapien M3 TMVR system's design, development and lessons for other medical device developers.

By Jim Hammerand
Managing Editor

(ABOVE) *The Edwards Lifesciences Sapien M3 transcatheter mitral valve replacement (TMVR) system uses a nitinol dock to anchor the replacement valve, with both implants delivered via a minimally invasive catheter. [Image courtesy of Edwards Lifesciences]*

Edwards Lifesciences VP of Engineering Darshin Patel led the development of the new Sapien M3 transcatheter mitral valve replacement (TMVR) system from the very beginning.

This transfemoral TMVR system recently won the world's first-of-its-kind approval with a CE mark for treating symptomatic (moderate-to-severe or severe) mitral regurgitation in patients who are deemed unsuitable for surgery or transcatheter edge-to-edge (TEER) therapy. (This minimally invasive system has not yet been approved by the FDA for use in the U.S.)

The Sapien M3 system uses nitinol, but not in the catheter-delivered replacement heart valve's frame. Instead, the dual-implant system uses nitinol's shape memory properties for the dock implanted inside the heart to anchor the replacement valve.

In an interview with *Medical Design & Outsourcing*, Patel discussed the M3 Sapien system's design, development and lessons for other medical device developers. The responses below have been lightly edited for clarity and space.

MDO: Are there modifications to the valve or is it essentially a Sapien 3?
Patel: "The Sapien M3 valve was modified to be compatible with the dock and mitral valve anatomy by replacing the Sapien 3 paravalvular leak (PVL) skirt with a full-frame outer skirt and frame apex covers to respect the native mitral anatomy."

How is nitinol used in the Sapien M3 dock and did your team learn any lessons about nitinol that might be helpful for other device designers and engineers?
Patel: "The Sapien M3 dock is made from a nitinol wire that is shape-set to obtain the intended configuration. In the early days, a laser-cut nitinol tube was also explored. However, the team chose to utilize a wire to simplify the manufacturing process. One of the key learnings was to continually look for opportunities to reduce the complexity of the design and find ways to borrow design elements from other Edwards devices that have already been proven. For material-specific learnings, understanding the repositionability of the implant is key in making sure the design and raw material specifications are robust to the intended number of reposition cycles."

What was the biggest technical/engineering challenge with this new system and how did the team solve it?

Patel: "The biggest technical challenge was designing a dock and valve that were able to anchor to the mitral valve apparatus without damaging the native anatomy. >> This was achieved through numerous iterations varying different parameters of the dock and valve (i.e., dock wire diameter, dock shape set diameter, dock cover materials, valve cover materials) and evaluating them in various models through trial and error. Resilience in the early stages is critical."

Were there other anchor approaches that didn't pan out, and can you share any lessons learned from those attempts?

Patel: "While other anchoring approaches exist, the team focused on developing a method to anchor the Sapien 3 valve in the mitral position where an anchor did not already exist, leveraging the extensive experience of the Sapien valve in the mitral position."

How did Edwards design the Sapien M3 system to minimize the risk of physician error during implantation?

Edwards Lifesciences
VP of Engineering
Darshin Patel

Patel: "Edwards partnered with numerous key opinion leaders (KOLs) prior to human experience to provide feedback on the device and procedure and apply learnings from previous therapies in addition to extensive usability studies with the appropriate user groups. Once in the clinic, when new learnings arose, the team diligently investigated the findings to understand the root cause. The team then shared with the physicians and incorporated those learnings into procedure or patient screening updates."

Were there other materials/manufacturing processes that unlocked this solution for TMVR, and was there anything the team learned that could be helpful for others in medtech?

Patel: "The innovation was really in the application of existing materials and manufacturing processes, leveraging ideas and processes from other Edwards products versus reinventing the wheel."

Is it too soon to talk about the next generation of this system?

Patel: "The team continues to iterate the Sapien M3 system to further enhance patient outcomes and procedural ease of use, as well as expand the treatable population."

What advice or guidance would you offer to device designers/engineers and other technical roles at device developers and manufacturers?

Patel: "If you are afraid to fail, you will never learn. As the saying goes, fail often and fail quickly, especially in the early days of product design. And engineers cannot fall in love with their designs. They need to look for continual improvement, even if they made the original design."

"Finally, it's critical for the engineers that designed the product to participate in the early human experience with their clinical counterparts so they can understand how the device is being used and what opportunities there may be to design out any potential problems. Many times, we wait for aggregate data to tell us what the areas of improvement may be, however, to innovate quickly, we need to almost predict the problem and start developing solutions in parallel to gaining clinical experience. This expedites the development pathway by running innovation and evidence generation in parallel, rather than in series, preventing a start and stop of clinical experience. Engineers working side-by-side with clinicians prior to human use can accelerate development."

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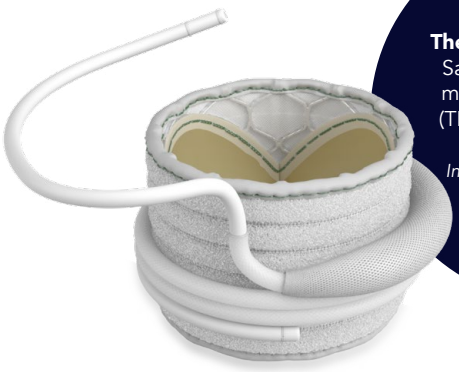

The Edwards Lifesciences Sapien M3 transcatheter mitral valve replacement (TMVR) system, including the dock and valve
Image courtesy of Edwards Lifesciences