



Table of Contents

- 1 **A Tried-and-True Innovation Process Applied to Pediatric Congenital Heart Disease**
Beverly Tang, PhD;
Kathryn Olson, MEng;
Mark Juravic, MEng
- 6 **PICS 25th Anniversary Symposium Chicago – Together Again**
- 8 **Medical News**
 - Atrium Health Sanger Heart & Vascular Institute Marks Milestone Surgery
 - Aortic Valve Replacement Market Size is Projected to Reach USD 33.51 Billion by 2030, Growing at a CAGR of 14%, According to Straits Research
 - American Society of Echocardiography Elects New Board President

12 Meeting Calendar

A Tried-and-True Innovation Process Applied to Pediatric Congenital Heart Disease

Beverly Tang, PhD; Kathryn Olson, MEng; Mark Juravic, MEng

Introduction

Starlight Cardiovascular was founded in 2020 by a team of dedicated MedTech industry veterans to serve the unmet needs of pediatric patients born with Congenital Heart Disease (CHD). The company's mission is to help babies born with CHD by developing best-in-class devices alongside pediatric cardiologists and surgeons. Starlight is currently developing a purpose-built Ductus Arteriosus Stent System and a percutaneous Pulmonary Flow Restrictor. In this article, we present a case study of how the Stanford Biodesign Innovation Process was applied to this clinical space to develop a device for the ductus arteriosus.

The Stanford Biodesign Innovation Process

The Stanford Biodesign Innovation Process is a tried and true clinical-needs-first methodology that was developed, practiced, and improved over the last 20+ years by physician entrepreneurs Drs. Paul Yock, Josh Makower, Tom Krummel, and a team of others to advance health outcomes. The program trains over 300 people each year through courses, executive education, faculty and global training, and the flagship Biodesign Innovation Fellowship program. Millions of patient lives have been impacted by the solutions developed within the program. At the core of Biodesign is the idea that **impactful innovation begins with a well-validated unmet clinical need**. Many MedTech companies often start their innovation process with a technology solution already in mind, trying to fit this technology into solving a clinical need and resulting in a mismatched solution. By starting with a well-validated clinical need instead, innovators can save time, money, and resources in designing a solution that is uniquely suited to address the unmet needs before going down the arduous path of developing a technical solution.

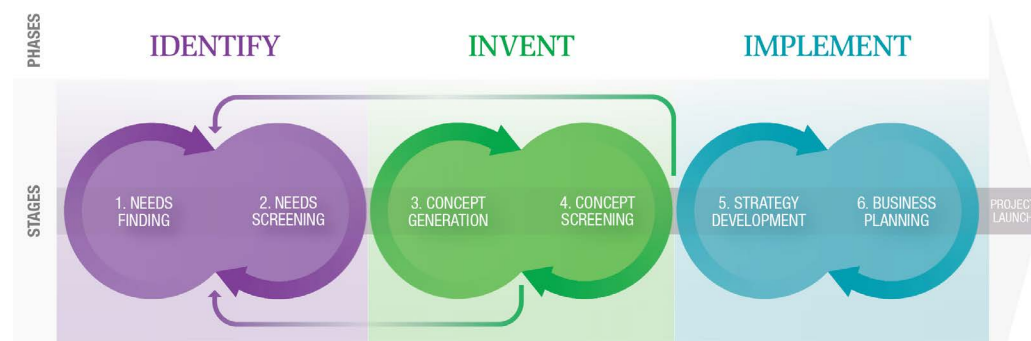


FIGURE 1 Stanford Biodesign Innovation Process

TABLE OF CONTENTS

- 1 **A Tried-and-True Innovation Process Applied to Pediatric Congenital Heart Disease**
Beverly Tang, PhD; Kathryn Olson, MEng; Mark Juravic, MEng
- 6 **PICS 25th Anniversary Symposium Chicago – Together Again**
- 8 **Medical News**
 - Atrium Health Sanger Heart & Vascular Institute Marks Milestone Surgery
 - Aortic Valve Replacement Market Size is Projected to Reach USD 33.51 Billion by 2030, Growing at a CAGR of 14%, According to Straits Research
 - American Society of Echocardiography Elects New Board President
- 12 **Meeting Calendar**



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What is an unmet clinical need? Oftentimes, it is easy to confuse a solution with an unmet need (“We all need a bioresorbable stent!”). A true unmet need, in its purest form, consists of a recurring problem, the population that the problem affects, and the desired outcome that would be achieved with a new solution. The need is completely solution-agnostic and drives toward an insight that results in more effective concept generation.

How are unmet needs found? At Stanford, the needs-finding process starts with clinical observation. This ethnographic research technique allows innovators to watch problems directly and develop empathy for the challenges faced by patients and providers. Starlight was founded in March of 2020, when the world locked down due to the COVID-19 pandemic. Getting into hospitals for case observations was not possible, so our team watched live cases from conferences, attended clinical webinars, scoured the clinical literature, spoke to a number of interventional cardiologists and cardiovascular surgeons, and reviewed individual cases with these physicians, leading to finding over 50 unmet clinical needs in the area of pediatric CHD. (We know now that there are plenty more!)

What do you do with all of these needs? Once a set of compelling unmet needs are identified, a needs screening process is undertaken to ensure an unbiased process of narrowing down to the most impactful needs to be solved.

One of the true merits of the Biodesign process is the ability to remove bias from innovation: it is easy to fall in love with a certain need or solution, but to be worth working on, it should make it through the rigorous “competition” that the process requires. Starlight started with those 50+ unmet clinical needs and used filters such as patient impact, clinical risk, and opportunity size to prioritize the list of needs and decide on which ones to address first.

But how do I know it really is a good need? Another major component of the process is constant validation of one’s understanding of the needs. Need validation ensures that the clinical need that has been identified is relevant to a large enough number of cases and clinicians to warrant solving the problem and that the root cause of the problem is well enough understood to identify a feasible solution. This need validation can be done through a broader set of clinical interviews, surveys, and/or a more systematic literature review. As an example of need validation, we present herein some of the results from a ductus arteriosus stenting survey conducted by Starlight in 2021. The process of need validation often brings out some of the true insights surrounding a need and can result in changing the details of the need, such as the applicable patient population or the specifics of the desired outcome.

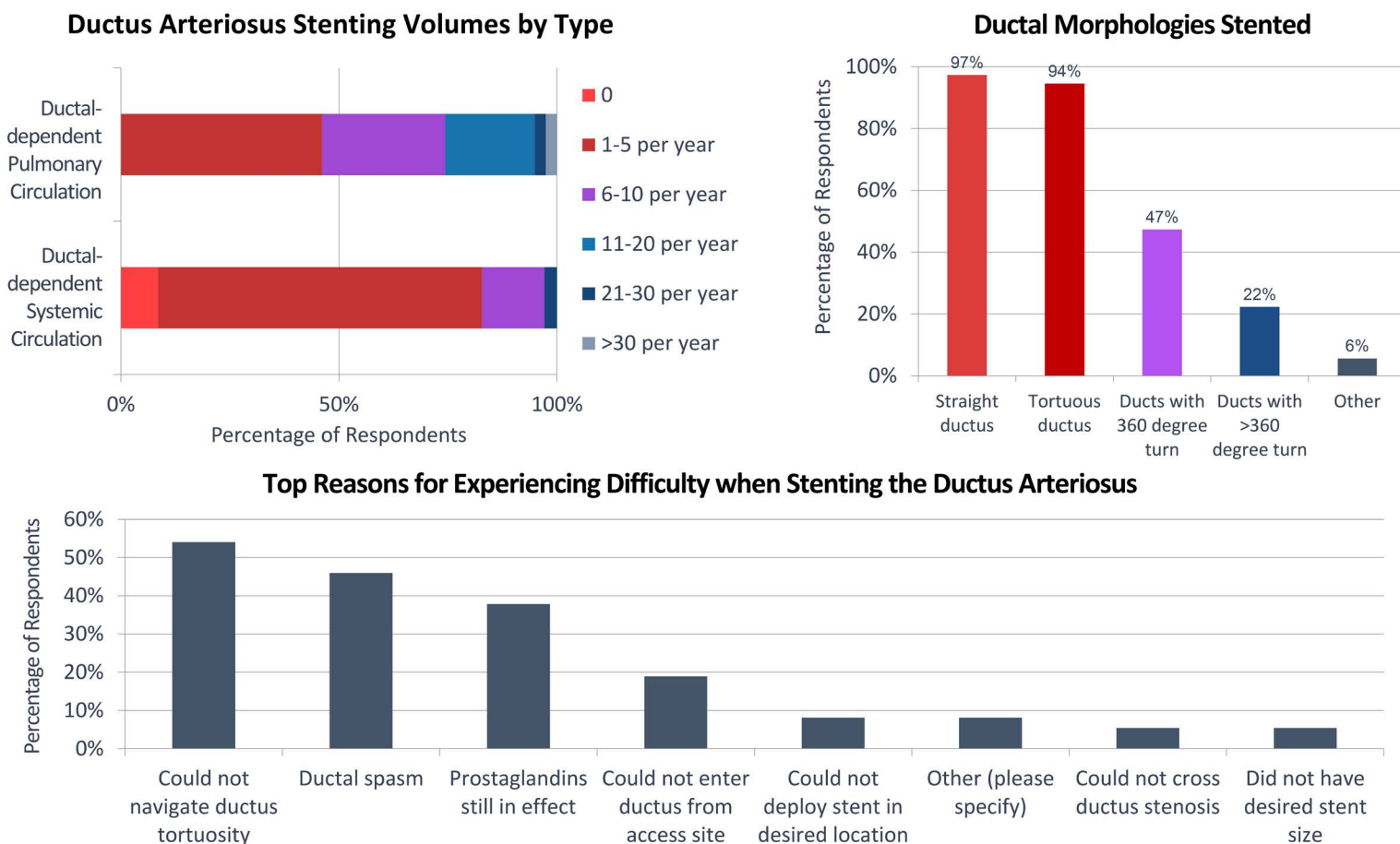


FIGURE 2 Results from a 2021 survey conducted amongst 45 interventional cardiologists regarding their PDA stenting practice.

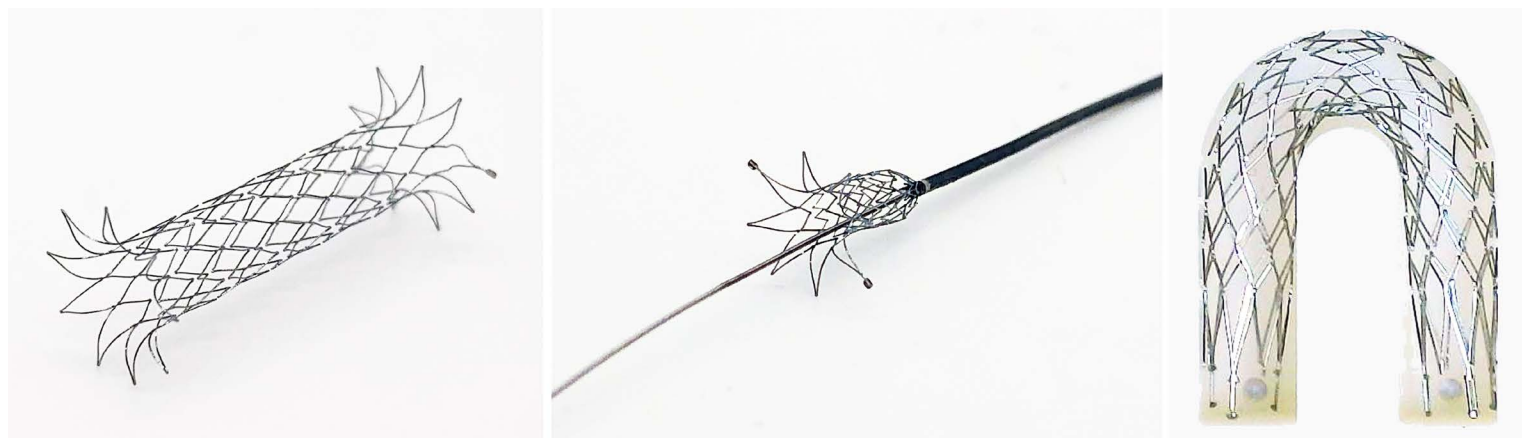


FIGURE 3 Starlight prototype self-expanding ductus arteriosus stent [left]. Stent being delivered through a 0.027" microcatheter [middle]. Stent flexibility / kink resistance [right].

Need Validation Example: Ductus Arteriosus Stenting Survey Results

To validate the clinical need for developing a solution to provide systemic or pulmonary blood flow in a way that reduces the morbidity associated with surgical procedures such as BTT shunting, a survey of 45 pediatric interventional cardiologists was conducted via the CCISC listserv. The results of the survey illustrated that this problem was important to address and that the technical needs among operators performing ductal stenting were similar.

Of the interventional cardiologists surveyed (84% US, 16% from outside the US), almost half of them were stenting between one and five patients with ductal-dependent pulmonary circulation per year, with slightly lower stenting volumes for ductal-dependent systemic circulation. Almost all were stenting straight and tortuous PDAs, and 47% were stenting ducts with a full 360 degree turn. The top reasons that were given for experiencing difficulty when stenting were the ability to navigate ductus tortuosity, ductal spasm, and the presence of prostaglandins.

I have a great need – now what? Once a need has been identified, prioritized via unbiased screening, and validated, concept generation can begin. Based on the Biodesign process and the survey results, Starlight started to narrow down that a ductus arteriosus stent system that is easier and safer to deliver would be a good problem for this small start-up to tackle. Through the iterative process of concept generation, screening, design, and testing, we determined that many of the identified challenges with ductal stenting could be addressed with a self-expanding stent delivered through a microcatheter. This type of design could enable safer and more precise stent delivery by facilitating navigation through tortuous vessels, providing a flexible stent that matches the stent length to the ductus length more precisely, and having stent anchoring features that could allow for stent delivery while the patient is still on prostaglandins. To test these theoretical benefits in the wide range of possible PDA anatomies, we partnered with Stanford, UCSD, and Nationwide to build a library of patient-specific 3D

anatomic models from pre-op CTs of stented patients. These 3D anatomic models represent the most common tortuosities and ductus origins identified by Qureshi et al¹. In addition, an acute animal study in a neonatal lamb model was recently performed that demonstrated early proof-of-concept.

Conclusion

It is well known that less than 25% of MedTech start-ups succeed,² and bringing a novel device to market is a formidable task. While using the Biodesign Innovation Process does not guarantee success, it does provide a framework that reduces risk and prevents misdirected efforts at the earliest stages of MedTech innovation. It is a process that can be learned, taught, and continuously practiced; and physician innovators and seasoned entrepreneurs alike have reaped the benefits of the process. Because Starlight's mission is to help babies born with Congenital Heart Disease by developing best-in-class devices **alongside** pediatric cardiologists and surgeons, we openly welcome engagement and feedback. It is imperative to us that we have identified important clinical needs, that these needs are well-validated, and that our solutions will serve the patient and physician for whom they were designed.

The development of Starlight's Ductus Arteriosus Stent System was supported in part by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as a part of three Financial Assistance Awards (FAIN) totaling \$90,000 and the National Heart, Lung, and Blood Institute of the National Institutes of Health under award number R43HL158304 with funding totaling \$492,571. The content is solely the responsibility of the authors and does not necessarily represent the official views of, nor an endorsement by, the FDA/HHS, National Institutes of Health, or U.S. Government.

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KATHRYN OLSON, MEng

Starlight Cardiovascular



BEVERLY TANG, PhD

Starlight Cardiovascular
9710 Scranton Road, Suite 100
San Diego, CA 92121
bev@starlightcardio.com



MARK JURA VIC, MEng

Starlight Cardiovascular



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PICS 25th Anniversary Symposium Chicago – Together Again



PICS Founder & FPICS Member #1, Ziyad M. Hijazi, MD, MPH, FPICS.



Prof. Hijazi with Fellows/Early Career Course Directors Drs. Darren Berman and Vivian Dimas. Advanced training for the profession's future leaders.



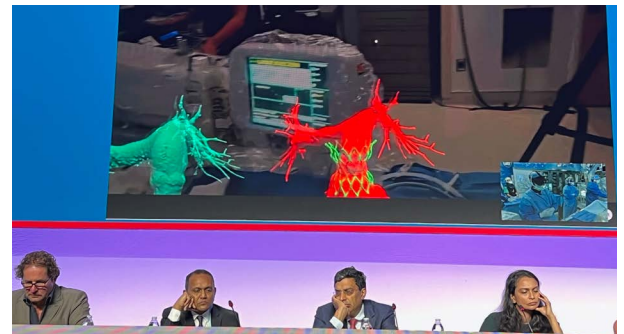
Dr. Alan Ligon and Fellows/Early Career physicians. This year's Symposium featured many hands-on "learn by doing" opportunities via simulators and technology demonstrations.



Thank you Fellows-in-Training & Early Career Course participants, and thank you to the world class faculty and to our visionary sponsors.



Dr. Maiy H. El Sayed, Aim Shams University Cairo, leading the first PICS live case from Egypt. Thank you Dr. El Sayed and your distinguished team for a superb teaching & learning experience!



This year's live cases featured the latest technologies and techniques to provide the best patient care possible. Virtual reality advances (shown here) to model and prepare for highly complex procedures.



Members of the 25th Anniversary Symposium Planning Committee. Honored to recognize this year's PICS Achievement Award Winners (with plaques): Professors Mazen Alwi, Bharat Dalvi and Carlos Pedra. Congratulations and thank you all!



PICS Society Board member Dr. Jacqueline Kreutzer and Early Career Committee Chair Dr. Aimee Armstrong, 3DI3 Advanced Imaging Program Co-Chair.



New PICS Working Group on Humanitarian Activities. Dedicated to the Society's mission: A world where anyone who can benefit from minimally invasive techniques to treat CHD has access to safe, effective care. From left: Drs. Bharat Dalvi (Chair), Zahid Amin, Sir Shakeel Qureshi and Mario Carminati.



Faculty of this year's well-attended Nursing & Associated Professionals Program. From left: Jamil Aboulhosn MD, Sharon Cheatham PhD, Gregor Krings MD, Emily Kish BSN RN and Curtis (Terry) Alford MSN.



After more than two years of virtual meetings and limited travel, this year's Symposium provided countless opportunities for friends to reunite. Shown: Sir Shakeel Qureshi (London, England) and Dr. Makram Ebeid (Jackson, MS USA).



Simone Pedra, Alejandro Peirone, MD, and Carlos AC Pedra, MD, PhD.



The PICS Society is so grateful for the partnership of the Congenital Cardiology Today (CCT) team, Loraine Watts, Kate Baldwin and Tony Carlson. CCT is the official News & Information Partner of the PICS Society.



Congratulations to Dr. Sharon Borik, co-recipient of the 2022 PICS Young Leadership Award. (Not shown: Dr. Arash Salavitarab, 2022 co-recipient).



PICS Special Recognition Award to our Senior Patient Advocate, Natalie Poli, Ed. S., who has worked tirelessly to advocate on behalf of CHD patients and their families worldwide. Thank you, Natalie! With (from left) Drs. Terry King, Damien Kenny, Ziyad Hijazi, Carlos Pedra and Tom Jones.



We were honored to have Prof. Ahmet Çelebi (on left, Chief of Cardiology, Siyami Ersek Hospital) as a distinguished faculty member of the PICS Chicago Symposium. On to PICS Istanbul 2023 (March 15th-18th).



The work never stops! Thank you to our hard-working staff led by PICS Deputy Executive Director Kimberly Ray, RN. Ms. Michaelleen "Mike" Wallig (PICS Financial Director) shown here at Symposium 2022 Mission Control. Mike has staffed all 25 PICS Symposia!



Dr. Manuel Ricardo Tellez Alvarez (on left, Bogota, Colombia), the winner of this year's "My Nightmare Case in the Cath Lab." Thank you Doctor and all the contestants for your honesty and dedication to excellence in patient care.



The team that made it happen. Middle row, 4th from left: our MVP, Ms. Kimberly Ray—thank you Kim for your hard work!



Chicago was the perfect setting for our "back together again" meeting. See you all at PICS 2023, August 28th-31st in Washington DC.



Atrium Health Sanger Heart & Vascular Institute Marks Milestone Surgery

Minimally invasive alternative to open heart surgery offering hope to more patients

Atrium Health Sanger Heart & Vascular Institute has hit a milestone in heart care, having performed 2,022 transcatheter aortic valve replacements (TAVR). This procedure allows the TAVR team to replace the patient's aortic valve using a catheter-based approach instead of open-heart surgery.

Aortic stenosis, a condition that can require a TAVR procedure, occurs when calcium deposits form on the aortic valve, causing a buildup in the heart and lungs. The condition tends to affect patients over the age of 65, but it can also affect those who are middle-aged. Historically, the calcified valve was replaced using open-heart surgery.

"The problem is that many elderly patients aren't healthy enough for open-heart surgery," said Dr. Michael Rinaldi, interventional cardiologist and Medical Director of the Structural Heart Program at Atrium Health Sanger Heart & Vascular Institute. "Most patients want to avoid heart surgery when they can because it's a big commitment, with a lot of risk and recovery time involved."

TAVR has become the preferred therapy for patients with aortic stenosis, particularly for those over 70 years of age. The procedure is associated with low rates of mortality, stroke, bleeding and kidney failure. In addition, most TAVR patients can return home the next day to complete their recovery, which is much quicker compared to surgical recovery.

In addition to helping patients who do not qualify for heart surgery, TAVR can help patients who could have heart surgery, but would likely have a higher

mortality rate and spend considerable time in the hospital. It's also an alternative procedure for younger, healthier patients who are good surgical candidates, but want to return to their everyday lifestyles immediately after a valve replacement.

During the milestone procedure, the new valve was placed in a stent, which was inserted into the patient's leg artery using a catheter. The TAVR team, which included Rinaldi and cardiovascular surgeon Dr. Eric Skipper, tracked the catheter's pathway through the patient's circulatory system using X-ray cameras and placed it across from the narrowed aortic valve. Once in place, the stent was expanded, propping open the new valve.

Sanger Heart & Vascular Institute has been performing TAVR procedures for the past decade. The TAVR team pioneered technology that protects a patient from having a stroke during a procedure. By filtering out small particles during the valve replacement, the team at Sanger Heart & Vascular has been able to reduce strokes by 50%, leading to better patient outcomes within 30 days of the procedure.

"Aortic stenosis touches a lot of people's lives, and TAVR can dramatically improve their survival rate," said Rinaldi. "We've refined this therapy over time to become something that is very safe and effective."

Dr. John Fredrick, Chief of the Division of Cardiovascular Surgery at Sanger Heart & Vascular Institute, says they have been the busiest TAVR center in the Carolinas since the valve became commercially available 10-years ago.



Atrium Health

"That's important because a multitude of studies show that higher volumes translate to better quality and a lower risk of complications," said Fredrick.

Because of this experience, the TAVR team was selected by Edwards Lifesciences to host a training course for providers from other regional valve replacement programs. During the course, the providers learned how to improve the efficiency of TAVR procedures.

Atrium Health Sanger Heart & Vascular Institute's TAVR program has earned the 5-star program rating from U.S. News & World Report, making it one of only three centers to receive this designation in the Carolinas. It also received a 3-star rating, the highest possible designation from the Society of Thoracic Surgeons/ American College of Cardiology Transcatheter Valve Therapy Registry. The TAVR program is one of only a small number of programs in the U.S. to receive the highest ratings from both organizations.



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Aortic Valve Replacement Market Size is Projected to Reach USD 33.51 Billion by 2030, Growing at a CAGR of 14%, According to Straits Research

Europe is leading the global aortic valve replacement market with a market value of USD 3,535 million in 2021 and is expected to grow to USD 9,117 million by 2030 at a CAGR of 11%. The global aortic valve replacement market size was valued at USD 10,722 million in 2021 and is expected to grow at USD 33,516 million by 2030. The market is expected to grow at a CAGR of 14% during the forecast period (2022–2030).

The main thing driving the aortic valve replacement market is the growing number of valvular diseases like aortic stenosis and aortic regurgitation, as well as technological advances in the heart valve market. Aortic stenosis is the most common disease of a valve that affects older people.

A big reason why this market segment is growing is because there are more and more older people. The number of older people is expected to grow from 962 million in 2017 to 2.1 billion in 2050, which is how many people are expected to live on Earth at that time. The market is also expected to grow in the next few years because of the rise of minimally invasive surgeries like TAVR and the development of valves that do not need stitches. Several things are being done to let people know about aortic valve replacement, which is expected to have a positive effect on the market in the coming years.

Rising Prevalence of Valvular Diseases and Initiatives for Creating Awareness of Valve Replacement with Favorable Reimbursements to be the Key Drivers for the Market Growth

Aortic regurgitation is another valve disease that can only be fixed with surgery (Aortic Valve Replacement, or AVR). This problem happens more often as people get older. Aortic regurgitation is usually caused by rheumatic heart disease. Rheumatic heart disease is a type of heart inflammation that goes on for a long time. The World Health Organization (WHO) says that about 2% of people with cardiovascular diseases (CVDs) have rheumatic heart diseases. So, the growing number of rheumatic heart diseases is likely to have a positive effect on the market in the coming years.

With the new techniques and treatment options available to cure or operate on a patient, more people are learning about them and getting referred to better care. Based on the numbers released by Medicare and Medicaid, the number of people over 65 with aortic stenosis is growing quickly. In 1989, there were only 2,500 people with this condition, but in 2011, there were over 32,000. One of the main things that will drive the aortic valve replacement market in the next few years is the growing number of aortic valve surgeries done on older people.

Along with this, good insurance and reimbursement policies are expected to be one of the most important things that will drive the market in the coming years. For instance, the Centers for Medicare and Medicaid Services (CMS) said that the Medicare National Coverage Determination policy would cover TAVR. When it comes to how much they will pay for different procedures, different insurance companies have different rates. A heart valve replacement is a serious illness. How much you get back depends on how much are insured. Because of these and other things that make people aware of it, the market is growing.

Development of Sutureless Valves to Create Huge Opportunities in the Global Aortic Valve Replacement Market

Transcatheter aortic valves are used a lot because more and more people want surgeries that are not as invasive. Transcatheter valves are getting more research and development, and more people all over the world are learning about TAVR. Key players in this market have done a number of clinical studies to test the safety, effectiveness, and range of interventions. Even though sutureless valves are not used very often, they offer a big chance for growth because they have so many benefits. Sutureless valves show good hemodynamic and post-surgery results and have a lower death rate.

Only the Enable 3F, the Perceval, and the Edwards Intuity Valve System have been put on the market without sutures. But there are a number of sutureless valves in development that could help the field of sutureless valves grow even more. The rest of the valves are made of tissue valves and valves that are made of metal. There are already a lot of these valves on the market, but their growth is limited because new technologies like TAVR are coming out. With mechanical and tissue heart valves, developing economies have more room to grow than economies that are already doing well, which opens up huge opportunities.

Regional Analysis of the Global Aortic Valve Replacement Market



The global aortic valve replacement market is mostly split into North America, Europe, and Asia-Pacific. Europe has the largest market share among the other regions and is the leader in regional segmentation.

North America

After Europe, North America is the second most important region for the aortic valve replacement market in terms of revenue. North America is known for having the most advanced healthcare facilities, and it is expected to grow at a rate of 10% over the next few years.

Europe

Europe leads the world market for aortic valve replacement. In 2021, the market in Europe was worth USD 3535 million, and it is expected to reach USD 9117 million by 2030, at a CAGR of 11%. The high number of people with aortic stenosis, the development of effective treatments like TAVR, and more efforts to raise awareness about valve replacement surgeries are some of the main reasons why this market is growing.

Asia-Pacific

The Asia-Pacific region is third on the list, with a CAGR of 14% from 2022 to 2030. This means that the Asia-Pacific region has the highest growth rate of all the regions. With this rate of growth, the Asia-Pacific region will soon lead the global aortic valve replacement market by bringing in the most money.

Key Highlights

- The global aortic valve replacement market to grow at USD 33,516 million by 2030 at a CAGR of 14% from the early figures of USD 10723 million in 2021.
- Minimal invasive surgery is the major dominant segment in the by-surgery type segmentation that accounts for a market value of USD 5,838 million in 2021 and is expected to grow to USD 21,860 million by 2030 at a CAGR of 16%.
- The hospital segment in the by end-use category contributes the major share of the market with USD 3,953 million in 2021 and would reach USD 11,410 million by 2030 at a CAGR of 13%.

- Europe is leading the global aortic valve replacement market with a market value of USD 3,535 million in 2021 and is expected to grow to USD 9,117 million by 2030 at a CAGR of 11%.

Competitive Analysis of the Global Aortic Valve Replacement Market

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American Society of Echocardiography Elects New Board President

The American Society of Echocardiography (ASE) is pleased to announce the appointment of Stephen H. Little, MD, FASE, FRCPC, FACC, as the organization's new Board of Directors President, effective July 1, 2022.

Dr. Little has a strong understanding of the needs of ASE and its diverse membership from his nearly 20-year career dedicated to clinical, educational and research activities in cardiovascular ultrasound, and the numerous leadership and volunteer positions he's held within the Society.

During the 33rd Annual Scientific Sessions in Seattle, Washington, June 10th-13th, Dr. Little shared his vision as ASE's 2022-2023 President. ASE brings together cardiovascular ultrasound imaging experts, enthusiasts and multidisciplinary partners from across the globe, and he explained that a varied and active membership not only makes ASE stronger, but also improves the field and ultimately patient care.

"ASE attracts all users of cardiovascular ultrasound and each member's professional needs and concerns may differ," said Dr. Little. "During my term as President, I want to communicate the many opportunities members have to become fully engaged based on their professional interests and areas of expertise. In the 'big tent of echo,' each ASE member should feel valued and connected to leadership and to each other."

Dr. Little also mentioned the importance of highlighting ASE's quality initiatives, and education and advocacy efforts.

"For ASE to continue to lead in this field, we must: recognize that our members are professionally diverse, identify their needs, act quickly and educate thoroughly. The current strategic goals of ASE focus our efforts where they are most needed. These include developing

strategic partnerships to support research, being indispensable in the development of new technology, meeting the educational needs of a growing variety of clinicians, and being the voice of and embracing all cardiovascular ultrasound users," he said.

Dr. Little earned his medical degree from McMaster University in Ontario, Canada, and completed two clinical and research fellowships in echocardiography at the University of Ottawa Heart Institute in Ontario and Baylor College of Medicine in Houston, Texas. He is a cardiologist at Houston Methodist Hospital and holds leadership positions as the director for the cardiology fellowship training program and is the system director for Structural Heart Disease. He is also Professor of Medicine at Weill Cornell Medical College and an Adjunct Professor at Rice University in the Department of Bioengineering. In each of these roles, he's honed his skills in effective communication, consensus building and strategic action.

Dr. Little is an active member and longtime leader in a variety of healthcare-related organizations, including ASE. He initially joined ASE as a cardiology fellow more than 20 years ago and has been a member of multiple committees—Information Technology, Research, Industry Relations and Public Relations, among others. He was also Chair and Co-Chair of both the Structural Heart Disease Task Force and the Committee on Guidelines and Standards. Most recently, he served on the Executive Committee on ASE's Board of Directors as the 2021-2022 President-Elect.

ASE membership also elected ten new Board members to serve the Society starting July 1st, 2022. The 2022 Executive Committee welcomes: newly elected Vice President Theodore Abraham, MD, FASE, University of California at San Francisco, San Francisco, CA; Council Representative Keith Collins, MS, RDCS,

FASE, Northwestern Medicine, Chicago, IL; and Secretary Kelly Thorson, DHSc, MSRS, ACS, RDCS, FASE, Lucile Packard Children's Hospital Stanford, Palo Alto, CA.

In addition to the new officers, the following new Board of Directors members were elected to serve two-year terms: Jose Banchs, MD, FASE, FACC, University of Colorado Anschutz Medical Campus, Aurora, CO (Member at Large); Akhil Narang, MD, FASE, Northwestern Medicine, Chicago, IL (Member at Large); Fadi Shamoun, MD, FASE, Mayo Clinic Arizona, Scottsdale, AZ (Council on Circulation & Vascular Ultrasound Steering Committee Chair); Neha Ringwala Soni-Patel, MD, RDCS, RDCS (AE/PE), FASE, Cleveland Clinic Children's, Cleveland, OH (Member at Large); and G. Monet Strachan, ACS, RDCS, FASE, UCSD Medical Center, San Diego, CA (Council on Cardiovascular Sonography Steering Committee Chair). Sujatha Buddhé, MD, MS, FASE, Seattle Children's Hospital, University of Washington, Seattle, WA (Leadership Academy Representative) and Arthur Labovitz, MD, FASE, Naples Cardiac & Endovascular Center (Retired), Naples, FL (Council on Critical Care Echocardiography Steering Committee Chair) will each serve a one-year term.

Learn more about ASE by visiting, [ASEcho.org](https://www.asecho.org).





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The 7th Annual Advances in Congenital Heart Disease Summit:

Transposition of the Great Arteries: The Master Class

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<https://www.clevelandclinicmeded.com/live/courses/CongenitalHeart23/>

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- Contact information at each hospital for Chief of Pediatric Cardiology & Fellowship Director
- Lists each hospital's Pediatric Cardiologists & Cardiothoracic Surgeons
- Lists Pediatric Cardiology Fellowships
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CORPORATE TEAM

**PUBLISHER &
EDITOR-IN-CHIEF**

Kate Baldwin
kate.f.baldwin@gmail.com

**CO-FOUNDER &
MEDICAL EDITOR**

John W. Moore, MD, MPH
jwmmoore1950@gmail.com

**FOUNDER &
SENIOR EDITOR**

Tony Carlson
tcarlsonmd@gmail.com

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Tarek S. Momenah, MBBS, DCH

John W. Moore, MD, MPH
Shakeel A. Qureshi, MD
P. Syamasundar Rao, MD
Carlos E. Ruiz, MD, PhD
Hideshi Tomita, MD
Sara M. Trucco, MD
Gil Wernovsky, MD

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