

Structural Heart Devices- Market Insights, Competitive Landscape and Market Forecast-2026

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Abstracts

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Structural Heart Devices Market By Product Type (Repair Devices [Occluders, Annuloplasty Devices, Valvuloplasty Devices, Others] And Replacement Devices [Mechanical Heart Valves And Tissue Heart Valves]), By Application (Atrial Spetal Defect, Aortic Valve Stenosis, Patent Foramen Ovale, Ventricular Septal Defects, Mitral Regurgitation, And Others) And By End User (Hospitals, Ambulatory Surgical Centers, And Others), by geography is expected to grow at a steady CAGR forecast till 2026 owing to increasing prevalence of structural heart diseases and the development of new products.

Global Structural Heart Devices Market was valued at USD 8.82 billion in 2020, growing at a CAGR of 11.23% during the forecast period from 2021 to 2026 to reach USD 16.70 billion by 2026. The demand for structural heart devices is primarily being boosted by the rapid growth in the prevalence of structural heart diseases, growing popularity of minimally invasive interventions, increase in the research and development activities in product development, the approval of new and advanced products, and the inclusion of structural heart devices in various reimbursement & insurance programs.

Structural Heart Devices Market Dynamics:

As per the Global Burden of Diseases Study published in the Lancet journal in 2020, titled "Global, regional, and national burden of congenital heart disease, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017", congenital heart disease caused 261,247 deaths across the globe in 2017, of which 180,624 were infants. Even though the mortality rates associated with CHD have decreased over the

years due to increasing socio-demographic index, the prevalence of congenital diseases have witnessed an increase over the years with 11,998,283 people living with it in 2017.

According to the factsheet by the British Heart Foundation, 2021, about one in 50 births are diagnosed with heart defects in the UK, which averages to about 13 babies each day in the UK with more diagnoses later in life. Estimates suggest that in total as many as 1-2 per cent of the population in the country may be affected with CHD.

As per the study published in the Journal of the American Heart Association by Grave et al in 2020 titled “Epidemiological Features of Aortic Stenosis in a French Nationwide Study: 10-Year Trends and New Challenges”, aortic stenosis (AS) is the most common form of valvular heart disease in Europe, and the second most common indication in the United States. The prevalence of aortic stenosis is estimated to increase exponentially with age and has been estimated at 0.2% of the US population before the age of 65 years and 2.8% after the age of 75 years.

Moreover, the rising popularity of minimally invasive procedures such as transcatheter repair and replacement techniques in treating structural heart diseases, have further provided great landscape for the structural heart devices market growth.

However, the number of product recalls and rigid regulatory norms for product approval may restrain the growth of the structural heart devices market during the forecast period.

Structural Heart Devices Market Segment Analysis:

Structural Heart Devices market by Product Type (Repair Devices [Occluders, Annuloplasty Devices, Valvuloplasty Devices, Others] and Replacement Devices [Mechanical Heart Valves And Tissue Heart Valves]), Structural Heart Devices market by Application (Atrial Septal Defect, Aortic Valve Stenosis, Patent Foramen Ovale, Ventricular Septal Defects, Mitral Regurgitation, And Others) Structural Heart Devices market by End User (Hospitals, Ambulatory Surgical Centers, And Others), and Structural Heart Devices market by Geography (North America, Europe, Asia-Pacific, and Rest of the World)

In product segment of the structural heart devices market, the repair devices category is expected to account for the larger market share compared to the replacement devices. This can be attributed to the preference of surgeons to repair procedures over

replacement ones as the first choice. These is due to the several benefits associated with the repair procedures in treating structural heart defects such as repairing strategies tend to preserve the strength, and function of the heart muscle, reduces the chances of post-surgery infections such as endocarditis, offers better prognosis compared to replacement devices, and comparatively less dependency on blood-thinners.

In the repair category, annuloplasty devices are expected to amass significant market share due to their significant importance in valve repair, specifically the mitral valve. An annuloplasty ring is considered essential as it helps in restoring the shape and the size of the native annulus of the valve, it prevents future dilation of the annulus, and offers functional support to the annulus. Furthermore, these devices offer the flexibility to be administered as a treatment both via an open heart surgery or minimally invasive approach.

In October 2020, Genesee BioMedical Inc received the FDA approval for their TruForm Sievers Annuloplasty Ring, Model TRH for the treatment of the correction of mitral valvular insufficiency where the lesions are not so severe as to require total valve replacement.

However, the rising popularity of minimally invasive interventions such as transcatheter-based approaches for valve repair such as Edwards Cardioband Mitral Reconstruction System, MitraClip and Carillon Mitral Contour System are expected to witness a faster growth in demand in the forecast period.

North America is expected to dominate the Overall Structural Heart Devices Market:

Among all the regions, North America is expected to amass the largest share in the structural heart devices market. The growing prevalence of structural heart disease, better healthcare facilities coupled with the presence of major market players as well as supportive reimbursement programs in the region are predicted to be the major influencing factors in driving the overall growth of the structural heart devices market over the forecast period.

In North America, the US is expected to account for the largest share of the North American Structural Heart Devices market. This can be attributed to the increasing cases of structural heart diseases. According to the Centers for Disease Control and Prevention (CDC) data (2021), congenital heart diseases affect approximately 40,000 births per year in the country. It has been estimated that about one in 4 babies suffer

from a critical form of CHD. The commonest type of heart defect is the ventricular septal defect.

As per the data provided by the CDC (2021), near about 2.5% of the US population suffers from valvular heart disease and it is more commonly observed in the older population.

Aortic stenosis is one of the commonest and serious valve disease problems and is one of the type of valvular heart diseases. The aortic valve opening becomes narrow in this indication which results in the restricted blood flow from the left ventricle to the aorta. As per the factsheet provided by the American Heart Association (2021), about 20% of the people in the United States over the age of 65 suffer from aortic stenosis.

Moreover, the large presence of key market players namely Abbott, Edwards Lifesciences Corporation, Livanova plc in the country as well as the launch of new products in the country also provide favorable conditions for the growth of the structural heart devices market.

In September 2020, the US Food and Drug Administration expanded the product approval for the The SAPIEN 3 and SAPIEN 3 Ultra THV System by Edwards Lifesciences Corporation to include the replacement of a failing (narrowed, leaky, or both) use previously implanted transcatheter aortic valve. The device has been previously approved to be used in the treatment of aortic stenosis as well as a replacement for the replacement of a failing (narrowed, leaky, or both) previously implanted surgical artificial aortic or mitral heart valve in patients who are too high risk for open-heart surgery. Such frequent revisions of the device applications and safety assessment by the country's regulatory authorities also play a key role in instilling faith in device manufacturers and end users.

Therefore, the market for structural heart devices in the United States and North America is predicted to witness significant growth in the forecast period.

Structural Heart Devices Market Key Players:

Some of the key market players operating in the structural heart devices market includes Medtronic, Boston Scientific Corporation, Braile Biomedica, JOTEC GmbH, Edwards Life Sciences Corporation, Valcare Medical, W. L. Gore & Associates, Inc, Abbott, Cardiovascular Systems, Inc., XELTIS BV, JenaValve Technology, Inc, Biomerics, Lepu Medical Technology (Beijing) Co. Ltd, Livanova plc, Comed B.V.,

TORAY INDUSTRIES INC, Occlutech International AB, Microport Scientific Corporation and others.

Recent Developmental Activities in Structural Heart Devices Market:

In August 2021, Medtronic received the 510k clearance from the US Food and Drug Administration for their new-generation, self-expanding transcatheter aortic valve replacement (TAVR) system- Evolut FX TAVR system. This device is aimed at treating patients with symptomatic severe aortic stenosis while maintaining the features offered by their Evolut platform such as hemodynamics and durability.

In August 2021, Occlutech Holding AG was granted an Investigational Device Exemption (IDE) by the US FDA for their Flex II PFO Occluder. This IDE would allow the company to conduct a clinical study to gather safety and efficacy data for their device to support their premarket approval in order to access the US markets.

In March 2021, Medtronic received the 510k approval by the US FDA for their Harmony Transcatheter Pulmonary Valve System. This system is the first-ever non-surgical valve replacement device in the world for the treatment of certain types of congenital heart disease in both adult and pediatric populations.

Key Takeaways from the Structural Heart Devices Market Report Study

Market size analysis for current structural heart devices market size (2020), and market forecast for 5 years (2021-2026)

The effect of the COVID-19 pandemic on this market is significant. To capture and analyze suitable indicators, our experts are closely watching the structural heart devices market.

Top key product/services/technology developments, merger, acquisition, partnership, joint venture happened for last 3 years

Key companies dominating the global structural heart devices market.

Various opportunities available for the other competitor in the structural heart devices market space.

What are the top performing segments in 2020? How these segments will perform in

2026.

Which is the top-performing regions and countries in the current structural heart devices market scenario?

Which are the regions and countries where companies should have concentrated on opportunities for structural heart devices market growth in the coming future?

Target Audience who can be benefited from this Structural Heart Devices Market Report Study

Structural Heart Devices products providers

Research organizations and consulting companies

Structural Heart Devices-related organization, association, forum, and other alliances

Government and corporate offices

Start-up companies, venture capitalists, and private equity firms

Distributors and Traders dealing in structural heart devices

Various End-users who want to know more about the structural heart devices market and latest technological developments in the structural heart devices market.

Frequently Asked Questions for Structural Heart Devices Market:

1. What is are Structural Heart Devices?

Structural heart devices are various types of devices that are used in the treatment of structural heart defects. Depending upon the degree of the defect, different types of structural heart devices can be employed either in the repair of the defect or replacement, such as replacement of a heart valve.

2. What is the market for Global Structural Heart Devices?

Global Structural Heart Devices Market was valued at USD 8.82 billion in 2020, growing at a CAGR of 11.23% during the forecast period from 2021 to 2026 to reach USD 16.70

billion by 2026.

3. What are the drivers for Global Structural Heart Devices Market?

The major factors boosting the demand for Structural Heart Devices in the market the rising prevalence of structural heart diseases, increasing popularity of minimally invasive interventions, and favourable reimbursement programs related to these procedures.

4. What are the key players operating in Global Structural Heart Devices?

Some of the important market players operating in the the structural heart devices market includes Medtronic, Boston Scientific Corporation, Braile Biomedica, JOTEC GmbH, Edwards Life Sciences Corporation, Valcare Medical, W. L. Gore & Associates, Inc, Abbott, Cardiovascular Systems, Inc., XELTIS BV, JenaValve Technology, Inc, Biomerics, Lepu Medical Technology (Beijing) Co. Ltd, Livanova plc, Comed B.V., TORAY INDUSTRIES INC, Occlutech International AB, Microport Scientific Corporation and others.

5. What region has the highest share in Structural Heart Devices market?

North America is projected to dominate the structural heart devices market in terms of revenue in the during the forecast period. This can be related to the high number of cases of structural heart diseases, better healthcare system, and presence of major market players in the region, primarily in the US.

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