

Annuloplasty System Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, Segmented By Application (Mitral Valve Repair, Tricuspid Valve Repair, Aortic Valve Repair), By End Use (Hospitals, Ambulatory Surgical Centers and Others), By Region and Competition, 2020-2030F

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Abstracts

Global Annuloplasty System Market was valued at USD 486.38 Million in 2024 and is expected to reach USD 681.10 Million by 2030 with a CAGR of 5.73% during the forecast period. The global annuloplasty system market is driven by several key factors, including the rising prevalence of heart valve diseases, particularly in the aging population, which leads to an increased demand for effective treatment solutions. According to Centers for Disease Control and Prevention, 75% percent of U.S. adults have limited or no knowledge about heart valve disease.¹ Even among those most at risk, individuals aged 65 and older, awareness remains low.¹ Each year, over 5 million people in the U.S. are diagnosed with heart valve disease. Advancements in medical technology, such as the development of minimally invasive surgical techniques and enhanced materials for annuloplasty devices, have also contributed to market growth. Growing awareness and better diagnostic capabilities have led to earlier detection of heart valve issues, further propelling the market. Increased healthcare spending, particularly in emerging markets, and the availability of advanced surgical options are supporting this growth. The development of more cost-effective, patient-friendly devices and the expanding number of clinical studies are expected to continue to drive the market in the coming years.

Key Market Drivers

Rising Prevalence of Heart Valve Diseases

The growing prevalence of heart valve diseases is one of the most significant drivers of the global annuloplasty system market. Heart valve disorders, including conditions like mitral regurgitation, aortic stenosis, and valve prolapse, are becoming increasingly common worldwide, particularly as populations age. A Centers for Disease Control and Preventioreport released in October 2024 reveals that a cardiovascular-related death occurs every 33 seconds, emphasizing the urgent need for advanced medical devices to effectively prevent, diagnose, and treat heart conditions. This critical demand extends to the treatment of heart valve disorders, where annuloplasty systems play a key role in restoring valve function and enhancing patient outcomes. The increasing prevalence of heart disease is driving the market for innovative annuloplasty solutions to address this expanding healthcare challenge.

In developed countries, heart valve diseases are frequently diagnosed in the elderly due to the natural aging process, where the heart's valves become less effective at regulating blood flow. Heart valve diseases can be caused by degenerative diseases, infections (such as endocarditis), and congenital defects, all of which contribute to the market's growth. The global population is aging rapidly, with estimates suggesting that by 2050, more than 2 billion people will be over the age of 60. As a result, heart valve disease diagnosis and treatment are becoming more common, leading to increased demand for effective therapies, including annuloplasty systems. This increasing patient pool represents a significant opportunity for market growth, as these devices are essential for repairing or replacing damaged heart valves, helping to restore proper heart function and improve patient outcomes.

Advancements in Medical Technology

The rapid advancement of medical technology plays a crucial role in driving the annuloplasty system market. Innovations in heart valve surgery and medical devices have led to the development of more effective, minimally invasive solutions for valve repair. Traditional heart valve surgery required open-heart surgery, which was invasive, carried a high risk of complications, and involved long recovery times. However, with the advent of minimally invasive procedures such as transcatheter annuloplasty, surgeons can now repair heart valves through small incisions, significantly reducing trauma to the body. This has improved the safety profile of the procedures, made surgeries less risky for patients, and accelerated recovery times. Advancements in the materials used for annuloplasty rings and sutures have also improved the durability and functionality of these devices. Modern annuloplasty systems are made with materials that offer better

biocompatibility, reducing the likelihood of infection or rejection by the body. Real-time imaging and robotic-assisted surgeries have made these procedures more accurate, enabling better surgical outcomes. These innovations have expanded the pool of patients eligible for surgery, particularly those who are elderly or have comorbidities, as minimally invasive procedures are much safer and more manageable for high-risk individuals. As medical technology continues to evolve, it is expected that annuloplasty systems will become even more effective, patient-friendly, and widely used, contributing to market expansion.

Expanding Patient Pool in Emerging Markets

The growing patient pool in emerging markets is another key factor driving the annuloplasty system market. With rising disposable incomes, improving healthcare infrastructure, and better access to medical care, patients in developing regions are increasingly seeking treatment for heart valve diseases. While heart valve diseases have historically been more common in developed countries due to an aging population, the burden of cardiovascular diseases is rapidly increasing in emerging economies due to lifestyle factors, such as poor diet, physical inactivity, and smoking. As the middle class grows and people in developing countries gain access to better healthcare, the demand for cardiovascular treatments, including annuloplasty systems, is expected to grow significantly. Healthcare providers in emerging markets are adopting advanced medical technologies to address this rising need, and global medical device manufacturers are increasingly focusing on expanding their presence in these regions. By offering cost-effective and accessible annuloplasty devices, companies are capitalizing on the opportunities presented by these rapidly expanding patient populations. As a result, the annuloplasty system market is experiencing significant growth in emerging markets, which is expected to continue as healthcare access improves.

Regulatory Approvals and Enhanced Reimbursement Policies

The availability of favorable regulatory frameworks and reimbursement policies in various countries is another driver of the annuloplasty system market. In many regions, government agencies and healthcare organizations have made significant strides in streamlining the approval processes for medical devices, including annuloplasty systems. Regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have implemented faster approval pathways for innovative medical devices, allowing for quicker market access. The approval of new annuloplasty devices and treatments is often supported by comprehensive clinical trials,

which help to ensure their safety and efficacy. Alongside regulatory approvals, the expansion of reimbursement policies for heart valve treatments in many countries has made it easier for patients to access these therapies. As reimbursement schemes become more inclusive and comprehensive, the financial burden of undergoing heart valve surgery or receiving annuloplasty system treatments is alleviated for patients, driving demand for these procedures. With better access to reimbursement and regulatory support, the annuloplasty system market is expected to experience accelerated growth.

Increasing Demand for Minimally Invasive and Patient-Centric Treatment Options

There is a growing preference for minimally invasive, patient-centric treatments, and this trend has significantly impacted the annuloplasty system market. An article by the American College of Cardiology Foundation, published in December 2023, emphasizes the growing global burden of cardiovascular disease (CVD), noting an increase in deaths from 12.4 million in 1990 to 19.8 million in 2022. This rise underscores the escalating need for effective cardiac interventions.

As patients and healthcare providers increasingly seek treatments that reduce the need for extensive surgical procedures, devices that allow for minimally invasive approaches to heart valve repair have become highly desirable. Minimally invasive annuloplasty procedures, such as transcatheter annuloplasty, offer a range of benefits, including smaller incisions, shorter recovery times, reduced risk of complications, and less trauma to the patient. These procedures are especially beneficial for elderly or high-risk patients who may not be suited for traditional open-heart surgery. These patient-centric solutions align with the broader healthcare trend of reducing hospital stays, improving post-operative outcomes, and enhancing overall patient satisfaction. As patients increasingly demand less invasive procedures with quicker recovery times and fewer side effects, the market for minimally invasive annuloplasty devices continues to expand, contributing to overall market growth.

Increased Focus on Personalized Medicine and Device Customization

The growing emphasis on personalized medicine is also shaping the annuloplasty system market. Personalized medicine involves tailoring treatments to individual patients based on their specific conditions, genetics, and preferences. In the context of annuloplasty, this could mean creating customized annuloplasty devices that are designed to meet the unique needs of each patient. Advances in 3D imaging and printing technologies have made it possible to create highly customized annuloplasty

rings and devices that can precisely match the size and shape of a patient's heart valves. This personalization ensures better outcomes and reduced risk of complications. As more healthcare providers adopt personalized medicine approaches, the demand for customizable annuloplasty systems is likely to increase. Personalized treatment plans are expected to enhance patient outcomes, leading to greater adoption of these systems and supporting the overall market growth. By offering tailored solutions that meet the specific needs of patients, the annuloplasty system market is poised for continued expansion.

Key Market Challenges

High Cost of Annuloplasty Systems

One of the major challenges facing the annuloplasty system market is the high cost of these devices, which can be a barrier to widespread adoption, especially in low- and middle-income countries. The materials used in annuloplasty devices, such as advanced polymers, titanium, and other high-grade materials, as well as the intricate design required for effective valve repair, contribute to the overall cost. In addition, the procedures themselves often involve significant surgical expertise and hospital resources, further increasing the price for patients. While advancements in technology have made these systems more effective, the financial burden associated with them remains substantial. For many patients, particularly in emerging markets, the cost of treatment may be prohibitive, limiting access to potentially life-saving procedures. Even in developed countries, high out-of-pocket costs, insurance coverage limitations, and lack of reimbursement for certain types of treatments can make it difficult for patients to afford annuloplasty systems. To overcome this challenge, manufacturers and healthcare providers need to find ways to lower costs while maintaining the effectiveness and safety of the devices. This could involve the development of more affordable alternatives or seeking new ways to improve reimbursement policies.

Regulatory Hurdles and Approval Delays

While regulatory bodies like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have streamlined the approval process for medical devices in recent years, regulatory hurdles remain a significant challenge in the annuloplasty system market. Regulatory approvals for new devices can take several years, and any delays in this process can hinder the market's growth. For example, if a company faces issues with safety data, clinical trials, or compliance with specific regulatory guidelines, the approval process can be delayed, which affects time-to-

market and revenue generation. Regulatory requirements can differ significantly between regions, requiring manufacturers to navigate multiple regulatory landscapes. In countries where regulatory processes are not as well-established, the process can be even more time-consuming and complicated. The lengthy approval timelines and the potential for regulatory setbacks can delay the introduction of innovative annuloplasty systems, affecting both the growth prospects of the market and the ability of healthcare providers to offer the latest treatments to patients.

Limited Awareness and Diagnosis in Underserved Regions

While awareness about heart valve diseases is growing, there are still many regions where knowledge of these conditions is limited, particularly in rural or underserved areas of low- and middle-income countries. Many patients in these regions may not have access to appropriate diagnostic tools or healthcare professionals who are trained to recognize heart valve issues. As a result, heart valve diseases may go undiagnosed until they reach more severe stages, making treatment less effective and complicating the patient's prognosis. The lack of infrastructure in some areas to support advanced diagnostic technologies, such as echocardiography, exacerbates this issue. Without proper screening and diagnosis, the demand for annuloplasty systems remains lower, limiting market growth. Even when patients are diagnosed, the financial barriers to treatment or lack of access to advanced medical devices in these regions can prevent timely intervention. Increased education, better diagnostic access, and efforts to strengthen healthcare infrastructure are needed to address this challenge.

Key Market Trends

Increasing Awareness and Early Diagnosis of Heart Valve Diseases

Increased awareness about heart valve diseases, driven by education initiatives from healthcare organizations, patient advocacy groups, and medical professionals, has contributed to earlier detection and diagnosis of these conditions. As patients become more informed about the symptoms of valve dysfunction, they are more likely to seek medical advice and undergo diagnostic tests, leading to earlier identification of heart valve problems. Early diagnosis is crucial for successful treatment, as it allows for timely interventions before the condition progresses to more severe stages. Advances in diagnostic technologies, such as echocardiography and MRI, have further facilitated early detection of heart valve diseases. These diagnostic tools allow healthcare professionals to identify even subtle valve abnormalities, ensuring that patients receive prompt and appropriate care. The availability of effective diagnostic methods and the

growing awareness of cardiovascular health have made it easier to identify patients who could benefit from annuloplasty system treatment. As more people are diagnosed with heart valve issues early in the disease process, the demand for treatment options like annuloplasty devices will continue to grow, contributing to market expansion.

Growth in Healthcare Spending and Access to Advanced Medical Treatments

A key driver of the global annuloplasty system market is the increasing healthcare spending across both developed and emerging economies. Rising incomes, expanding healthcare infrastructure, and government investments in public health are enhancing access to advanced medical treatments, including those for heart valve diseases. In many countries, there has been a concerted effort to provide better healthcare access to underserved populations, improving diagnosis and treatment for heart conditions. In January 2021, Valcare Medical Ltd., a developer of transcatheter mitral and tricuspid valve repair and replacement solutions, announced the successful completion of its first-in-human transseptal delivery of the AMEND™ annuloplasty ring. The procedure was carried out at the Schulich Heart Centre at Sunnybrook Health Sciences Centre in Toronto, under the Health Canada Special Access Program. Valcare's AMEND mitral valve repair device is an innovative, clinically proven D-shaped, semi-rigid closed ring with unique anchoring features. AMEND is designed to deliver the clinical standard-of-care surgical treatment through safer and more efficient catheter-based procedures. Additionally, the AMEND platform serves as a foundation for Valcare's mitral replacement system and tricuspid repair solution.

The growing affordability of healthcare services, coupled with a focus on improving healthcare outcomes, has spurred the demand for advanced medical devices such as annuloplasty systems. In developed nations, where healthcare systems are well-established, increased spending on medical research, surgical procedures, and cardiovascular care has driven the adoption of high-quality, cutting-edge treatments. Simultaneously, emerging economies have witnessed significant healthcare improvements, leading to greater access to advanced medical technologies and interventions. As more patients gain access to healthcare services, the demand for heart valve disease treatments, including annuloplasty systems, will continue to rise. This expanding market is driven by both private and public healthcare expenditure and the widespread availability of treatment options.

Segmental Insights

Application Insights

Based on the Application, Mitral Valve Repair is currently the dominant procedure in the global annuloplasty system market. The mitral valve, located between the left atrium and left ventricle of the heart, is the most commonly affected valve in heart disease, particularly in conditions such as mitral regurgitation, where the valve fails to close properly, causing blood to leak backward into the left atrium. This condition is more prevalent than aortic or tricuspid valve diseases, contributing to the prominence of mitral valve repair procedures.

Several factors contribute to the dominance of mitral valve repair in the annuloplasty system market. The frequency of mitral valve pathologies, especially mitral regurgitation, is significantly higher compared to conditions affecting the tricuspid or aortic valves. Mitral regurgitation is often associated with aging, degenerative changes, or underlying cardiovascular conditions such as hypertension, which have become more common globally. As the global population ages and cardiovascular disease prevalence increases, the demand for mitral valve repair procedures naturally rises, fueling the growth of the annuloplasty system market.

Advancements in surgical techniques and medical devices have made mitral valve repair a highly successful and desirable treatment option. Minimally invasive surgery for mitral valve repair has gained significant traction, with procedures such as robotic-assisted surgery and transcatheter techniques enabling better outcomes and faster recovery times compared to traditional open-heart surgery. This trend toward less invasive procedures has increased the adoption of mitral valve repair systems, further bolstering their market share. Unlike aortic or tricuspid valve repair, which often require more extensive surgeries, mitral valve repairs can be performed with fewer complications, especially when using annuloplasty rings, which are designed to restore the proper shape and function of the valve. The popularity of minimally invasive mitral valve surgeries, paired with the effectiveness of annuloplasty devices, has made this type of valve repair the procedure of choice for many patients and healthcare providers.

End Use Insights

Based on the end use segment, hospitals continue to dominate the landscape, surpassing ambulatory surgical centers (ASCs) in terms of procedure volume and market share. This dominance is largely due to the complex, high-risk nature of heart valve repair surgeries, including annuloplasty procedures, which require highly specialized medical expertise, sophisticated equipment, and advanced post-operative care, all of which are more readily available in hospital settings.

Hospitals offer a broad spectrum of services, including intensive care units (ICUs), specialized heart surgery units, and multidisciplinary teams of cardiologists, cardiac surgeons, and anesthesiologists, which makes them the ideal setting for annuloplasty procedures. Heart valve surgeries often involve intricate, high-stakes interventions that demand advanced monitoring, complex surgical instruments, and, in some cases, prolonged recovery periods, all of which hospitals are better equipped to handle. These procedures can carry risks such as infections, bleeding, arrhythmias, or complications requiring extended monitoring, which necessitates the robust infrastructure and emergency capabilities that hospitals provide. Therefore, patients undergoing annuloplasty are more likely to receive these treatments in a hospital setting where they can be closely monitored before, during, and after the surgery.

Hospitals generally possess the cutting-edge technology and medical devices needed for advanced surgical techniques. Many annuloplasty procedures are performed using minimally invasive techniques, such as robotic-assisted surgery or transcatheter valve repair, which require highly specialized equipment and technology. Hospitals are more likely to invest in these technologies, as they serve a wide range of patients and have the resources to maintain and operate such equipment. Large hospitals are typically more prepared for emergencies and complications that may arise during surgery, offering a level of security and expertise that smaller facilities, like ambulatory surgical centers, may not be able to match.

Regional Insights

North America dominated the global annuloplasty system market, with the United States being the key driver of this regional leadership. The dominance of North America in the annuloplasty market can be attributed to several critical factors, including the region's advanced healthcare infrastructure, high levels of healthcare spending, early adoption of innovative medical technologies, and a well-established healthcare system that supports both diagnosis and treatment of heart valve diseases.

One of the key reasons for North America's market leadership is its sophisticated healthcare infrastructure. Hospitals in the U.S. and Canada are equipped with state-of-the-art technology, including advanced imaging systems, robotic surgery tools, and specialized cardiac units that are essential for performing complex annuloplasty procedures. The healthcare providers in these regions are also equipped with the expertise required to conduct high-risk heart surgeries, ensuring the success of procedures like mitral, tricuspid, and aortic valve repairs. This infrastructure supports

the widespread use of annuloplasty systems, enabling early intervention and high-quality patient care, which drives the demand for these devices.

North America benefits from substantial healthcare spending, which is among the highest in the world. The U.S. healthcare system, in particular, sees significant investment in cutting-edge medical treatments and technologies. The country's spending on cardiovascular disease treatments is notably high, as heart disease remains one of the leading causes of death in the United States. This large financial commitment to cardiovascular healthcare has facilitated the widespread adoption of advanced medical devices, including annuloplasty systems, which are used in heart valve repair surgeries. Insurance coverage for heart surgeries is also widely available, which reduces financial barriers for patients and encourages more individuals to seek treatment for heart valve diseases, further fueling the demand for annuloplasty systems.

Key Market Players

Medtronic Plc

Abbott Laboratories, Inc.

Edwards Lifesciences Corporation

Corcym Group

Labcor Laboratórios Ltda

Affluent Medical SA

Valcare Medical

Braile Biomédica

LivaNova PLC

Micro Interventional Devices, Incorporated

Report Scope:

In this report, the Global Annuloplasty System Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Annuloplasty System Market, By Application:

Mitral Valve Repair

Tricuspid Valve Repair

Aortic Valve Repair

Annuloplasty System Market, By End Use:

Hospitals

Ambulatory Surgical Centers

Others

Annuloplasty System Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Annuloplasty System Market.

Available Customizations:

Global Annuloplasty System market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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