U.S. Artificial Heart Valve Markets

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Executive Summary

Executive Summary

The following executive summary presentation contains an overview of the U.S. Artificial Heart Valve Markets.

2

U.S. Artificial Heart Valves Market

Market Overview

Overview

The cardiovascular system is one of the most complicated systems in the human body. It requires the coordination of a number of muscles, valves, and nerves to ensure consistent and constant blood flow. Any disruption or malfunction in the process, could lead to death within minutes.

A key mechanism in that process is the functionality of the small tissue valves located in each of the four chambers of the heart. These small tissue flaps serve as one way gates to control flow of blood, and ensure no reverse leakage. When these tissue flaps become diseased, they can create major problems for cardiovascular function. If the diseased valve is weakened, creating a gap, there is a regurgitation of flow. On the opposite end of the spectrum, if the valve undergoes stenosis, the narrowed valve opening forces the heart to exert more force, and thereby stress to maintain blood flow. Most of these conditions develop over time, and when diagnosed require immediate attention. Due to a lack of significant pharmaceutical therapies that can reverse valvular disease, primary intervention is the gold standard for care.

When a defect is detected, a specialist must make the decision if the valve can be repaired, or it needs to be replaced. Heart valve repair with annuloplasty involves the stitching of a ring at the base of the valve in order to help it maintain a level of tightness. If repair is too risky or the valve is beyond repair, the valve is replaced outright with an artificial valve.

Artificial heart replacement valves have been in existence since the 1950's. While there have been significant upgrades in the materials used and methodology of implantation for these devices, currently used devices are essentially analogous to the first generation of devices developed fifty years ago. Surgeons must weigh the options between selecting a mechanical tissue valve, or one made of animal tissue. The issues of selecting one over the other are the same trade off that have existed since their inception. Mechanical valves are more durable, while tissue valves are more biocompatible.

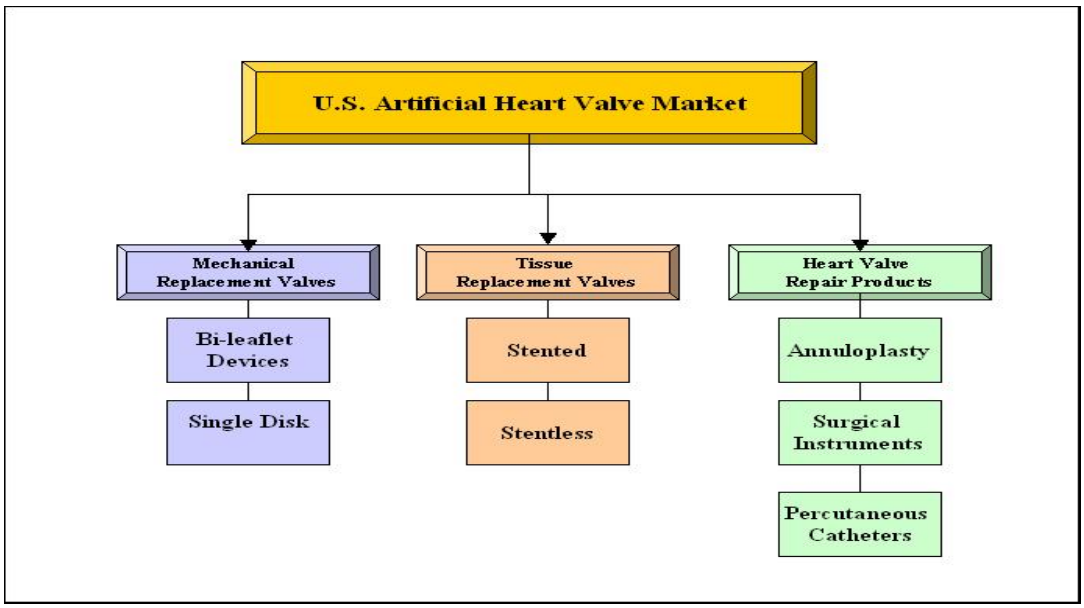
As the societal demographic shifts towards an older and more obese population, there is a heightened demand for advanced heart valve therapy products.

Scope and Segmentation

Chart 2.1 illustrates the market segmentation for the U.S. Artificial Heart Valve Market.

Chart 2.1

Artificial Heart Valve Market: Market Segmentation (U.S.), 2005



Source: Frost & Sullivan

This research service examines the U.S. market for heart valve replacement and repair products. This study examines commercially available mechanical prosthetics, bioprosthetics, and annuloplasty repair products. This study does not cover non-commercially available heart valve replacements such as those with cadaver harvested valves, or those done with autograft tissue.

The impetus for this study is to examine the U.S. artificial heart valve market and analyze in-depth market dynamics, competitors, products, and provide future market forecasts.

Segmentation

The bioprosthetic valve segment of the market analyzes tissue-based replacement valves. Tissue valves include those from porcine and bovine tissue. The harvested tissue is usually mounted on a stent or stentless fixture.

The mechanical valve segment of the market analyzes man made material based prosthetics. Devices are usually of a bi-leaflet design, and are made from a combination of aluminum, titanium, tungsten, and plastics.

The heart valve repair segment of the market analyzes devices used to correct defects in heart valves causing regurgitation or calcification. Devices include percutaneous tools to access heart valves minimally invasively, annuloplasty rings to tighten and structure valves, and other tissue modeling instruments.

Market Trends

Market Drivers

Figure 2-1 shows the market drivers ranked in order of impact for the U.S. artificial heart valve market 2006-2012.

Figure 2-1

Artificial Heart Valve Market: Market Drivers Ranked in Order of Impact (U.S.), 2006-2012

Rank	Driver	1-2 Years	3-4 Years	5-7 Years
1	Increased device durability spurs confidence in device usage	High	High	High
2	Lack of effective pharmaceutical or other non-invasive treatment for heart valve disease heightens demand for interventional devices	High	Medium	Medium
3	Advances in polymer technology augment biomimetic device performance	Medium	Medium	High
4	Increased screening and diagnosis expand patient population	Medium	Medium	Medium

Source: Frost & Sullivan

Increased Device Durability Spurs Confidence in Device Usage

Increased performance durability data from stents, particularly tissue-based devices is spurring usage. Most recent device iterations from manufacturers have shown consistent performance 20 years out. Mechanical tissue valves have an inherent disadvantage, in that they require patients to be on continuous anti-coagulant therapy, such as Warfarin. Moreover, they need to be continuously monitored. Patients on those blood thinning and immunosuppressant drugs are at a high risk of having a serious condition develop in the case of injury or infection. Therefore, the preferred device has always been tissue-based heart valves, usually made of bovine or porcine parts. While in the past these devices have had limited durability, improved manufacturing techniques and materials are allowing for devices that have proven functionality out to 20 years, much longer than the remaining average expected lifespan of an individual who undergoes heart valve replacement surgery. This driver will likely have a high impact through out the market forecast period, as manufacturers are constantly making advancements in materials design.

Lack of Effective Pharmaceutical or other Non-invasive Treatment for Heart Valve Disease Heightens Demand for Interventional Devices

The lack of effective pharmaceutical or other treatment options, means that interventional heart valve repair or replacement is the gold standard for treatment. For other cardiovascular diseases such as arrhythmia or atherosclerosis, physicians often prescribe drugs as a primary form of treatment, hoping that it slows down disease progression. However, there is no wonder drug that can cure stenosis or weakening of the heart valves. Currently the only medications prescribed after a diagnosis of heart valve disease are diuretics to help the body excrete excessive salts and fluid accumulation, ACE inhibitors or ARA's to augment heart function, and Warfarin or other nitrates to thin the blood and prevent clot formation. None of those medications, however, can reverse a stenosed or a regurgitative valve. This driver will likely have a high impact in the short term future of the market, and medium impact through the rest of the forecast period as there are greater opportunities to develop pharmaceuticals that can reverse heart valve stenosis.

Advances in Polymer Technology Augment Biomimetic Device Performance

Advances in the development of biomimetic polymers that can mask devices from triggering the immune cascade are increasing device adoption. Polymers that serve as a coat to the newer poly-carbon heart valves are reducing the risk of blood clots forming around devices. In the past manufacturers were limited by the available materials they could use for device design,; advances in polycarbons not only enhance durability, but long term biocompatiability as well. Given the advances in recent years of developing drug-hybrid technologies, such as drug eluting stents, it is likely similar hybrid technologies could be used for subsequent generations of heart valve technologies. This driver will likely have medium impact in the short and mid term market future, with a possible high impact as polymer and coating processes improve.

Increased Screening and Diagnosis Expand Patient Population

The failure to diagnose and identify heart valve disease in a timely manner could delineate into a fatal circumstance, therefore private and governmental insurance agencies are trying to increase the frequency and thoroughness of cardiovascular screening. Typically, heart valve disease can be diagnosed with an instrument as simple as a stethoscope, where the physician can listen for atypical sounds or murmurs. More advanced imaging techniques, as such optical coherence tomography and ultrasound, provide doctors a detailed understanding of the anatomical status of the valves. An echocardiogram can provide confirmation of a leaky or stenosed heart valve, based on flow tracking. Cardiac catheterization using the analysis of flow with injectable dyes can provide information on pulmonary and aortic pressure. Studies done with fiber optic based optical coherence tomography are able to give detailed visual images of the heart valves themselves. Given the increased frequency of screening and advances in imaging, we should be able to diagnose heart valve disease with greater proficiency. This driver will likely have a moderate impact throughout the forecast period.

Market Restraints

Figure 2-2 shows the market restrains ranked in order of impact for the U.S. artificial heart valves market during 2006-2012.

Figure 2-2

Artificial Heart Valve Market: Market Restraints Ranked in Order of Impact (U.S.), 2006-2012

Rank	Restraint	1-2 Years	3-4 Years	5-7 Years
1	Saturated patient population limits market potential for growth	High	High	Medium
2	Price stagnation inhibits market	Medium	Medium	Medium

Source: Frost & Sullivan

Saturated Patient Population Limits Market Potential for Growth

The saturated patient population for heart valve replacement and repair is a major limitation to total market growth. The overall market is limited in that, while there might be potential growth opportunities for individual segments of the market, usage of those devices would be at the expense of another form of therapy. Heart valve replacement technology, with respect to other medical devices, is a fairly mature technology. Moreover, since there is no competing pharmaceutical therapy that can reverse calcification or weakening heart vales, the market has witnessed higher adoption rates than other medical implant technologies. This restraint will likely have a high impact in the near and mid term market futures, and could lessen as the patient population expands.

Price Stagnation Inhibits Market

Price stagnation and erosion has restricted the market from being able to procure double digit market growth rates. Price gains in the declining mechanical heart valve market are not significant enough to cause a major impact in the market, and neither are price gains helping to accelerate growth of the tissue valve replacement and heart valve repair market segments. Reducing pricing would have only a marginal effect on incentivizing usage of one form of valve over another. Moreover, reimbursement agencies have not shown any signs that there will be significant increases in spending limits for heart valve therapies in the near future. The main contributing factors to price stagnation in the market are limitations in technological development and lack of competitive differentiation from participants. There have been no market altering technologies to significantly change perception of heart valve products. In the future, autologous stem cell valves could fill that void, but by most estimates this technology is still more than a decade away from being commercially ready. Among current products on the market, there is very little distinction to allow competitors to warrant higher pricing. This restraint will likely have a moderate impact throughout the forecast period.

Industry Challenges

Figure 2-3 shows the industry challenges and strategic recommendations for the U.S. artificial heart valves market in 2006.

Figure 2-3

Artificial Heart Valve Market: Challenges and Corresponding Strategic Recommendations (U.S.), 2006-2012

Challenge	1	2	3	4
Instigating Growth in Mature Market	■	■	■	■

Strategies Key: 1. Compiling Early Stage and Post Market Launch Clinical Data to Help Clinicians in Device Selection
2. Dedicating Focus to Design of Percutaneous Products
3. Diversification of Product Line
4. Maximizing Sales and Distribution Channels

Source: Frost & Sullivan

Expanding Growth in a Mature Market

One of the biggest challenges to growing in a mature market is executing strategies with enough of a magnitude to instigate a significant shift in the market. In nascent or developing medical device fields, a new product with advanced features or improved procedural efficiency in most cases witnesses rapid market adoption. In mature markets such as that faced by the competitors in the heart valve market, the ability to shift market perception about brand name or a specific technology is quite limited.

In cardiac rhythm management, technological advances such as bi-ventricular pacing, and remote home monitoring help to both increase the addressable patient population size, and warrant increases in product pricing. Simlarly in the interventional vascular markets, drug eluting technologies have led to dramatic growth for vascular stent manufacturers. On the contrary, in the artifical heart valve markets there have been no such significant paradigm shifting technologies that have helped expand the market.

One issue is that in certain markets a technology hits a ceiling of addressable patients. For instance, if one were to look at the mechanical and hydrodynamic thrombectomy markets, the market appears to be mature with tempered growth. However, that technology has the potential to expand its addressable market if it develops greater efficacy in coronary and peripheral treatments. Once market participants cross that hurdle, their possibilities for expansion are immense. However, for heart valve replacement and repair technology, there is no other potential application of technology.

Another common barrier for growth is the regulatory and reimbursement requirements for defining qualified patients for a given therapy. By improving device performances and reducing procedural risks, they can ease the requirements for a patient qualified for treatment. However, with respect to heart valve disease there is no medication that can directly address disease progression. Additionally, there is no expectation that the conditions can be improved with conditioning, or reversed through natural biological processes. Therefore, heart valve repair or replacement is already the current gold standard of treatment. Consequently, the market is nearly fully saturated.

These significant challenges pose seemingly immovable obstacles to generate significant market growth.

Strategies

Compiling Early Stage and Post Market Launch Clinical Data to Help Clinicians in Device Selection

Given the importance placed on evidence-based medicine, it is important that market participants be able to profile their devices with early stage and post market launch clinical data. Market participants often request to extract devices from patients that have passed, in order to be able to evaluate device quality. Device thrombosis and durability are the biggest factors that affect device selection for clinicians. Being able to show low rates of complications requiring follow up procedures to clean or replace the device are critical to persuading device adoption. For newly launched products, clinicans are aware of the gimmicks sometimes employed by health care companies to make the clinical trial data display favorable results for their new technologies. Clinicians scrutinize and formulate their own opinions on the validity of certain clinical trials, and only trials that produce sound data are used in the decision making process. In established markets such as those for heart valves, where there are no external threats, head-to-head trials versus market competitors' devices can be powerful in shifting market share within a short time period.

Dedicating Focus to Design of Percutaneous Products

Endovascular surgeries are becoming the preferred approach for treating cardiovascular diseases. Being able to insert a catheter in a peripheral blood vessel, and perform a surgery anywhere in the body has immense appeal to surgeons. They have become well versed in the techniques and tools involved for minimally invasive procedures, and see an immense benefit over open cavity approaches. Therefore, with respect to replacement heart valve implantation and heart valve repair, clinicians are looking to manufacturers that can provide them the most advanced minimally invasive solutions. Since each device has its own specifics for operation, once a provider trains himself on a certain product it becomes increasingly more difficult to convert them to a competitor's device. Therefore, it is important that manufacturers keep pace with competitors and introduce the latest in percutaneous products, or else sacrifice future sales as a late arriver.

Diversification of Product Line

It is important that manufacturers not be pigeon holed as the nice supplier of a certain product. In the heart valve market, the current buying trends are towards the usage of bioprosthetic implants. Accordingly, mechanical heart valve manufacturers are facing decreasing sales, and a depressed market outlook. In order to expand their opportunities for success, traditional mechanical heart valve manufacturers are looking to expand into tissue heart valve markets. St.Jude Medical recently launched their Biocor tissue heart valve implant, ATS Medical recently acquired 3 F Therapeutics and their beating heart tissue replacement valve technology. In doing so these manufacturers have expanded their ability to be a total solutions provider. That's not to say in the future there could not be a renewed focus on mechanical valves. Were there to be development of a polymer that completely masks devices from thrombosis, mechanical valves with their durability would be the market gold standard. At that time, companies solely with tissue valve products would be struggling in the market. Being able to anticipate market and technology trends, and being able to quickly act on those findings is critical to maintaining future market success.

Maximizing Sales and Distribution Channels

In addition to general clinicians and surgeons, hospital administrators and their business advisors, have been increasingly more influential in specific device usage. Given the rising emphasis on cost containment for health care spending, the business aspects of running a hospital have gained more power in the decision making process. Sales and distribution teams must learn how to appeal to those administrators, in addition to their traditional focus on clinicians. Proving device efficiency will no longer suffice, market participants must also prove the cost effectiveness of their approach.

A third, and growing arm of the sales and marketing of medical devices is focused on direct-to-consumer advertising. While the individual has little say on the devices used in their care, being able to inform patients about the latest in care could help spur adoption of new technology. Patients and patients groups can be used to pressure hospitals and reimbursement agencies to increase spending for next generation products.

Market Engineering Measurements

Chart 2.2 shows the Market Engineering measurements for the U.S. artificial heart valves market for 2005.

Chart 2.2

Artificial Heart Valve Market: Market Engineering Measurements (U.S.), 2005

Market Engineering Drives Market Strategy and Planning

Measurement Name	Measurement	Trend
Market age	Mature	Increasing
Revenues	$519.0 million	Increasing
Potential revenues (maximum future market size)	$867.0 million	---
Base year market growth rate	13.3%	Increasing
Compound annual growth rate (2006-2012)	7.8%	---
Number of competitors	4	Increasing
Average price	$4,500	Stable
Market saturation	80%	Increasing
Price sensitivity	Low	---
FDA classification	Class III	---

Note: All figures are rounded. Source: Frost & Sullivan

Total Revenue Forecasts

Figure 2-4 and Chart 2.3 show the revenue forecasts for the U.S. artificial heart valves market from 2002 to 2012.

Figure 2-4

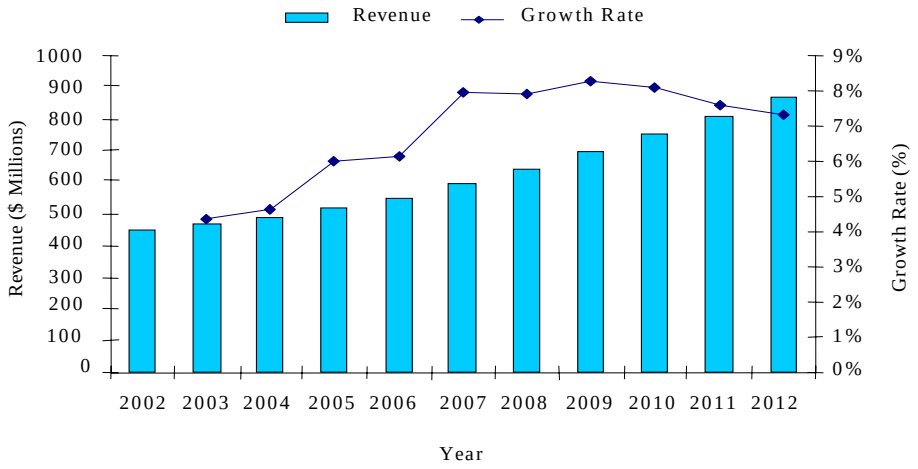
Artificial Heart Valve Market: Revenue Forecasts (U.S.), 2002-2012

Year	Revenues ($ Million)	Revenue Growth Rate (%)
2002	448.5	---
2003	468.1	4.4
2004	489.7	4.6
2005	519.0	6.0
2006	550.9	6.1
2007	594.6	7.9
2008	641.5	7.9
2009	694.7	8.3
2010	750.9	8.1
2011	808.0	7.6
2012	867.0	7.3
Compound Annual Growth Rate (2005-2012): 7.8%		

Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Chart 2.3

Artificial Heart Valve Market: Revenue Forecasts (U.S.), 2002-2012



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

For the base year 2005, the total revenue for the U.S. artificial heart valves market was $519 million, with an estimated market potential of $867 million in 2012. A compound annual growth rate (CAGR) of 7.8 percent is expected for the period 2006 to 2012.

Growth in the market is expected to be primarily driven by sales of tissue-based heart valves, and heart valve repair products. The newer technologies being launched in those two segments of the market are expected to compensate for declining mechanical replacement valve sales. New product launches, increased screening, and rising patient populations all factor into steady increases in growth rates. Due to market maturity, and that there is no foreseeable major industry breakthrough, the average selling price for devices is expected to remain fairly constant. Pricing is expected to slightly decline for mechanical valves, and slightly increase for tissue based valves with the introduction of newer stent based products. There is not expected to be any significant merger and acquisition activity, nor any new market entrants launching fully approved products in the near future. While the market could accelerate in the near term, over the long term market outlook growth rates are expected to dampened slightly due to ceilings on reimbursement spending.

As in most medical device fields, revenues could be negatively affected by a change in regulatory or reimbursement policy.

Total Heart Valve Replacement Procedures

Figure 2-5 and Chart 2.4 show the procedure forecasts for the U.S. artificial heart valves market from 2002 to 2012.

Figure 2-5

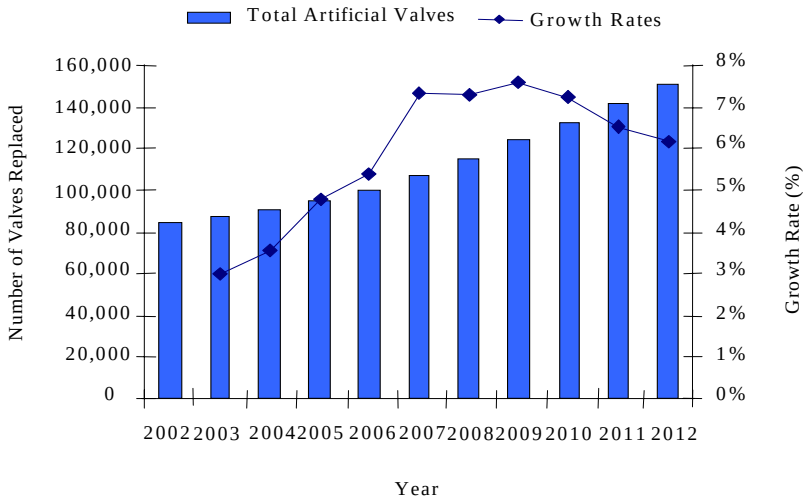
Artificial Heart Valve Market: Procedure Forecasts (U.S.), 2002-2012

Year	Number of Valves Replaced	Growth Rate (%)
2002	84,905	---
2003	87,470	3.0
2004	90,610	3.6
2005	94,948	4.8
2006	100,065	5.4
2007	107,420	7.4
2008	115,268	7.3
2009	124,011	7.6
2010	132,977	7.2
2011	141,682	6.5
2012	150,389	6.1

Note: The base year is 2005. Source: Frost & Sullivan

Chart 2.4

Artificial Heart Valve Market: Procedure Forecasts (U.S.), 2002-2012



Note: The base year is 2005. Source: Frost & Sullivan

For the base year 2005 the total number heart valve replacement procedures performed were 94,948, with an estimated potential of 150,389 replacements in 2012. The compound annual growth rate for procedures for the forecast period from 2006 to 2012 is expected to be 7.0 percent.

Of the total valve replacement procedures performed, 23.0 percent were mechanical valves, and resultantly 77.0 percent bioprosthetic tissue valves. Due to growth in the larger tissue valve segment of the market, and a slight decline in mechanical valve sales over the forecast period, the overall number of procedures performed is expected to have a stable growth rate. The growth in number of procedures performed is expected to be predominantly attributed to the rising prevalence of heart valve disease. If newer heart valve repair therapies enjoy higher than anticipated market adoption rates, the number of replacement procedures could be negatively affected. The growth rate is expected to be dampened slightly over the forecast period due to ceilings on reimbursement spending. Additional threats to procedure rates include device recalls, changes in reimbursement spending, and stunted FDA approval of next generation products.

Important factors that go into consideration for devices include the age of the patient, their tolerance to anti-coagulation therapy, clinical history, and the overall risk of performing a subsequent replacement procedure 10 to 15 years down the line.

Procedural Volume by Valve Type

Figure 2-6 and Chart 2.5 show the procedure volume of replacement valves by anatomical location from 2004 to 2006.

Figure 2-6

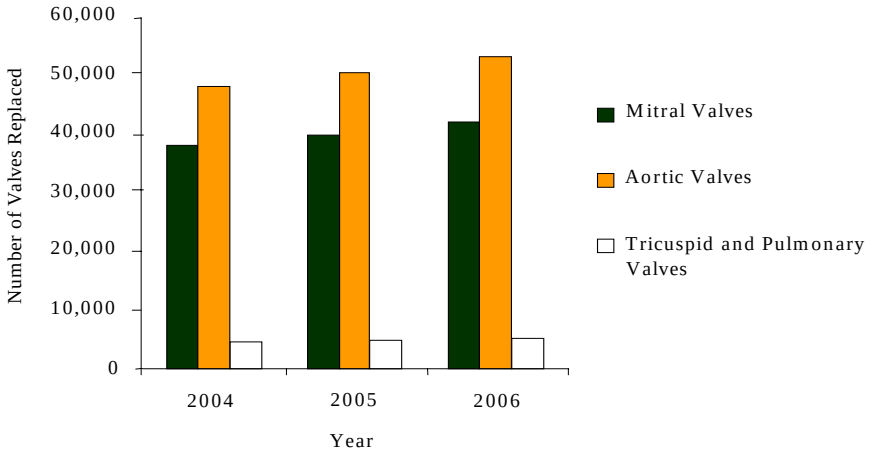
Artificial Heart Valve Market: Replacement Forecasts by Anatomical Location (U.S.), 2004-2006

Year	Total Mitral Valves Replaced	Total Aortic Valves Replaced	Total Tricuspid & Pulmonary Valves Replaced
2004	38,095	47,984	4,531
2005	39,885	50,316	4,747
2006	42,034	53,028	5,003

Note: The base year is 2005. Source: Frost & Sullivan

Chart 2.5

Artificial Heart Valve Market: Replacement Forecasts by Valve Type (U.S.), 2004-2006



Note: The base year is 2005. Source: Frost & Sullivan

For the base year 2005 there were an estimated 39,885 mitral valves replaced, 50,316 aortic valves replaced, and 4,747 tricuspid and pulmonary valves replaced. Aortic and mitral valve replacement procedures make up 95.0 percent of artificial valve implantations.

Mitral valves undergo the most pressure and therefore have been historically addressed with the more durable mechanical valves. Typical clinical benchmarks for valve selection have been usage of mechanical prosthetics for aortic valve replacement in patients younger than 65 years old, and younger than 70 years old for mitral valve replacement. However, recent trends and improved durability of biprosthetic valves are shifting those age ranges downward by approximately 5 years.

All three types of valves have stable forecasted growth rates expected. Advanced development of stent mounted tissue valves in the narrow tricuspid and pulmonary valves could spur higher than expected growth in those procedures.

Competitive Analysis

Competitive Structure

Figure 2-7 shows the competitive structure for the U.S. market in 2005. Figure 2-8 show market participants segmented by the type of valve produced.

Figure 2-7

Artificial Heart Valve Market: Competitive Structure (U.S.), 2005

Number of Companies in the Market	20
Types of Competitors	Large medical device manufacturers Midlevel cardiovascular disease focused companies Niche start-up manufacturers with one core technology
Distribution Structure	Direct sales to hospitals
Tiers of Competition	Tier 1: Edwards Life Sciences, St.Jude Medical Tier 2: Carbomedics, ATS Medical Tier 3: Myocor
Notable Acquisitions, Mergers	ATS Medical Acquisition of 3F Therapeutics
Key End-user Groups	Congestive heart failure Cardiovascular disease Obese Elderly
Providers	Cardiac surgeons
Competitive Factors	Clinical trials data Ease of operation Procedure time Device versatility

Source: Frost & Sullivan

There are three distinctive tiers of competition in the heart valve therapies market. The top tier of competitors is comprised of large medical device manufacturers that have been developing heart valve technologies for over twenty years, including Edwards Lifesciences, Medtronic, and St.Jude Medical. Each of theses companies are publicly traded, and across all of their business units generate close one billion dollars annually.

As a publicly traded company, not only do these companies have an obligation to their patients and doctors, but they are responsible to their stockholders as well. As such, these companies and their business units, in addition to merely being profitable, need to be able to generate growth. When dealing with companies as large as the three companies at the top of the market, it takes a significant amount of new revenue generation to create noticeable growth. With this upward movement focus, companies must rely on new product launches, technical advances, and efforts to expand their customer base in order to even maintain their present status.

Typically, in the medical device industry once a market leader becomes established, they become hard to displace. Edwards Lifesciences currently dominates the tissue valve replacement market, while St.Jude Medical dominates the mechanical valve market. Since the mechanical valve market has been declining in recent years, St.Jude Medical must depend on both a resurgence of mechanical heart valve sales, and diversification into the tissue replacement valve market to expand their business. Edwards Lifesciences on the other hand must focus on defending their market share, and expand naturally as that segment of the market expands. Additionally, since Edwards Lifesciences is not interested in bolstering its mechanical valve products, it can focus its efforts on the growing percutaneous heart valve repair market. Though the third largest company in the heart valve market, Medtronic generates more overall revenue in the medical device industry than any of the other competitors. Their size allows them the resources to execute the best strategy of success, whether that be through internal product development, deployment of sales forces, or even expansion through mergers and acquisition. Smaller competitors might not necessarily have the available capital, or man power to execute their vision.

The second tier of competition in the industry is comprised of the only other two manufacturers with products commercially available in the United States. Carbomedics, whose parent company is the Sorin Group based out of Europe, and ATS Medical. Being a mid sized company with limited market share, these manufacturers must identify a marked added benefit over competitors to even tempt clinicians to consider migrating away from the more established products. Publicly traded companies like ATS Medical, like the Tier 1 manufacturers, must initiate strategies that will allow the company to expand in the market. Given that previously ATS Medical was a niche mechanical valve manufacturer, their acquisition of third tier tissue valve manufacturer 3 F Therapeutics allows them entry into that market segment. Now ATS Medical can point to the mechanical and tissue valve market segments as opportunities for expansion.

Given the relative market maturity of replacement valves, the majority of start up activity among third tier market players has been focused on the development of tissue valve repair products. Minimally invasive surgical procedures to repair heart valve leakage are on the rise, given the recent advances in catheter technology. Previously, in open heart procedures, total replacement of the heart valve involved no less complex a technique than trying to repair the existing valve. However, with minimally invasive beating heart products being introduced, heart repair is seen as a more feasible option. Catheter advancements, and the rising prevalence of congestive heart failure and valve regurgitation has spurred the rise of a number of entrepreneurial annuloplasty designers.

Understandably there has been limited venture capital funding on the mechanical valve market segment, there is however some interest in next generation tissue valves. Niche designers are developing foldable tissue valves that are mounted on a stent, that can be compressed with a low profile and implanted with out requiring an open heart procedures. On the investigational side, academics are currently exploring the design of autologous stem cell valves.

Competitive Factors

Ability to Design a Device with Ease of Implantation

The ability to design a device with simple ease of implantation is critical to increasing adoption rates of new devices. This involves advancements of both device design and catheter operation. A couple of features can significantly bolster the ease of implantation of a device. One of those is device profile during insertion. The other is the amount of post implantation assembly required. Certain devices—predominantly tissue-based devices—can be folded to reduce its profile during insertion. Mechanical devices are designed with attention to protrusions that could cause damage during insertion. Similar considerations are also given for heart valve repair products and rings. The importance of minimally invasive catheter design is even more critical when trying to address the difficult to access pulmonary valves. Additionally, devices used on pediatric patients have a higher consideration placed on ease of implantation than other competitive factors.

Device Materials and Construction

Devices, particularly mechanical heart valves, are highly dependant on design and anti thrombolytic medications to prevent device encrustation. Device encrustation, in addition to inhibiting device function, can also risk heart damage due to distal embolization. The main approaches to minimize thombolytic buildup are materials selection and component construction. Devices with coatings that are biomimetic or more resistant to thrombolytic aggregation can function for longer periods of time, and lessen the burden of blood thinning therapeutics to maintain flow. Device construction is important because if a joint or pivot between device components were to become encrusted, it could hinder the ability of the valves to close or open properly. Device design that can be proven in clinical trial, and historical use data with the least likelihood to encounter major thromboembolic complications gain a significant competitive advantage over others.

Performance Evaluation and in-situ Visualization

An important competitive feature in device design is the ability to non-invasively visualize implanted devices, and accurately evaluate performance. Through echocardiography, specialists have the capability to evaluate the rate of blood flow and if there are developing complications. Tissue-based valves have limited durability and therefore must be monitored for developing stenosis or regurgitations. Mechanical valves, while durable, must be monitored because encrustation could also prevent valves from closing or opening properly. Devices often are imbedded with materials that help improve contrast imaging when using visualization techniques such as CT or X-ray. The more accurate the feedback specialists can receive on in-situ device performance, the more confident they feel with a given device.

General Patient Compliance

An often overlooked component to device competition is overall patient compliance. How accepting is the patient of a certain device? Do they trust the brand name and manufacturer? Is there public information that would cause them to worry about device performance? Are they ready to accept the responsibility of maintaining daily medication, and accepting of the associated risks? Does the device make noises that could affect patient general state of mind? Each are important questions and considerations a specialists must go over with their patient before a certain device is chosen for them. These obligations also play a role in the competitive advantages one device or brand can have over another.

Distribution Structure

Distribution Structure

Heart valve replacement and repair products are special-use devices that are not sold in bulk. Devices can cost up to $5,000. Due to the high cost of devices, most implants are sold through direct sales interactions. Most manufacturers' sales teams will include a number of sales representatives, a regional sales manager, and many dedicated clinical specialists. These clinical specialists assist in device training of surgical and nursing staffs, and provide insight into ideal candidates for a particular type of device use. Direct sales structures allow market participants greater freedom in offering incentives, or regional pricing, and are not encumbered by the issues of an indirect sales model encumbered by short contracts, discounts, and distribution alliances.

Key End-user Group

The primary societal demographic for heart valve disease are individuals over the age of 65, and with a body mass index that would classify them as clinically obese. Obesity causes the heart to exert more work to perform its duties than otherwise would be necessary, and over time that stress causes the heart itself to deform, leading to abberations in heart valve shape. There are also a number of genetic defects, that could cause heart valve defects to manifest themselves in younger patients.

If possible, heart valve repair is the first option over heart valve replacement, however in most cases the valve needs to be replaced. Patients are recommended for mechanical valve repair typically if they have an expected remaining lifespan of over 15 years (ages 65 and below), if they already have a mechanical valve in another location than the currently problematic valve, have kidney failure and are therefore on hemodialysis, are already taking blood thinners, or have had a negative result to a previously implanted bioprosthetic valve.

Bioprosthetic valves are recommended for patients who are unable to take blood thinners, who are taking other medications that are contra indicative to blood thinners, who are over the age of 70, are replacing a blocked mechanical valve, or for pediatric patients who are still growing.

Market Share Analysis

Figure 2-8 shows the market participants by area for the U.S. artificial heart valves market in 2005.

Figure 2-8

Artificial Heart Valve Market: Market Participant by Area (U.S.), 2005

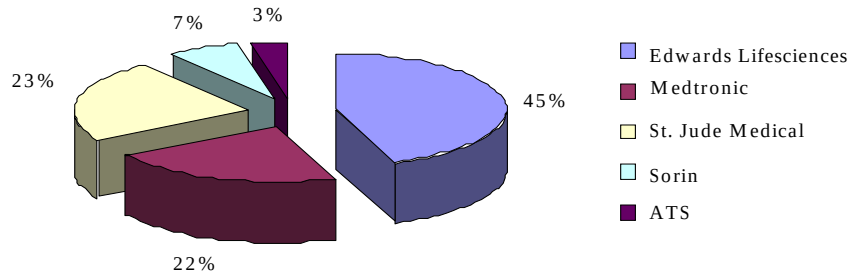
Company	Mechanical Heart Valve	Tissue Based Heart Valve	Heart Valve Repair
3F Therapeutics (ATS Medical)			■
ATS Medical	■	■	■
CarboMedics (Sorin)	■	■	■
Cardiac Dimensions			■
Corazon			■
CoreValve		■	■
Direct Flow Medical		■	
Edwards LifeSciences	■	■	■
Evalve		■	
Heart Leaflet Technologies			■
Medtronic	■	■	■
Mitralign			■
Mitralsolutions			■
Myocor			■
Palmaz/Baley's			
Quantum Cor			■
Sadra Medical		■	
Shelhigh		■	
Valve Xchange			
Viacor			■

Source: Frost & Sullivan

Chart 2.6 shows the company market share by revenues for the U.S. artificial heart valves market in 2005.

Chart 2.6

Artificial Heart Valve Market: Market Share of Major Market Participants (U.S.), 2005



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

The overall market share leader for the Heart valve replacement and repair markets is Edwards Lifesciences with 44.6 percent of the overall market. Their strong position in the market can be directly attributed to their dominance of the artificial tissue heart valve market. New product introductions such as their Perimount Magna valves, allow them to defend their market share. The overall market shift to tissue valves should allow them to strengthen their future revenue stream and overall growth, but could be a threat to their overall market share. Companies such as St.Jude Medical and ATS Medical, traditional mechanical valve manufacturers, have made significant efforts to bolster their presence in the tissue heart valve market.

St.Jude Medical slightly owns the second highest market share with 23.3 percent, edging out Medtronic with 22.0 percent. St. Jude Medical was initially founded as a heart valve company, and have established their dominance in the mechanical heart valves segment. Despite that market declining overall, there are still definite circumstances where a clinician would prefer a mechanical valve over a tissue valve. Due to declining sales in that segment of the market, there has been a lack of new competitors seeking to gain entry into the market, and there has been a lack of significant activity from existing players attacking St.Jude to capture their market share. Therefore St.Jude has the potential to gain market share by further increasing their dominance of the mechanical heart valves market, and broadening their product offerings on the tissue valve side.

Medtronic is constantly developing new products, and is seeking to leverage their experience in the stent industry to develop advanced stented tissue valves, that can be implanted with percutaneous methods. Speaking to Medtronic's over all size in the medical device industry, despite a 22.0 percent market share of the heart valve markets, it accounts for less than 7 percent of their overall business.

Carbomedics, whose parent company is European based Sorin Group, and ATS Medical are the only other major market participants. There are a few competitors such as Cook who develop exclusively heart valve repair products, but do not register a significant market share. Carbomedics and ATS Medical both built their business on the development of advanced mechanical heart valves. Since the market is declining, both have sought to expand their portfolio in the tissue valve segment of the market. ATS Medical, which previously had no tissue valve products, recently acquired 3F Therapeutics and is expected to have products ready for market launch in the near future.

Technology and Market Trends

Emerging Technologies

Autologous Tissue Replacement Heart Valves

Due to the biocompatibity issues of mechanical replacement heart valves, and the limited durability of animal tissue based replacement valves; researcher have been striving for a methodology to develop valves designed from autologous stem cells. Current tissue engineering techniques involve a combination of bio-erodible scaffolds seeded with mesynchamal stem cells. The main challenges are building devices that can are structurally strong enough to endure the high pressure gradients in the heart. The biodegradable scaffolds are typically designed with a PLGA and PLA, that not only have consistant degredation profiles, but whose individual components are inert. The scaffold serves as the framework for the mesynchymal stem cells, and as the cells grew the synthetic scaffold would dissolve away. It is assumed during creation the stress placed on the cells in a bioreactor would force the cells to become stronger through the natural remodeling process.

Minimally Invasive Trans-catheter Implantable Devices

Stent based tissue devices can be implanted with minimally invasive catheter technologies. By avoiding open heart procedures, these low profile implantations have a reduced risk of infection or other complications. The stent-based devices use shape memory alloy, Nitinol, and therefore can maintain a low profile until it is positioned at the target site. Self-expanding stents create the best level of contact along the vessel wall without having to be manually stitched into place.

Mergers and Acquisitions

ATS Medical Acquisition of 3F Therapeutics

The most significant recent activity on the mergers and acquisition front for the heart valve industry, has been ATS medical's acquisition of 3F Therapeutics. ATS Medical is a publicly traded company that has up until now been a niche player in the mechanical heart valve market. With their acquisition of privetly held 3F Therapeutics, ATS Medical broadens their portfolio of heart valve therapy products. 3F Therapeutics, based out of California, is in development of advanced beating heart tissue based valve implants. Given the declining mechanical heart valve market, the acquisition of 3F Therapeutic's technology allows ATS Medical to be able to compete with the other larger market participants that have both mechanical and tissue-based product offerings. The deal was announced in January of 2006 and was finalized and agreed upon in October of 2006.

Start-up Market Activity

Figure 2-9 shows the various venture companies that are developing treatment devices in the artifical heart valve market.

Figure 2-9

Artificial Heart Valve Market: Venture Landscape (U.S.), 2005

Company	Approach
3F Therapeutics	A private company developing beating heart implanted replacement tissue valves, that was recently purchased by ATS Medical.
Cardiac Dimensions	Is a developmental stage company who is working on catheter based technologies for treating mitral valve leakages that lead to congestive heart failure. [The CARILLON Mitral Contour System combines a proprietary implantable device and delivery system. The implant consists of a shaping ribbon between distal and proximal anchors. The device is delivered percutaneously via jugular access under fluoroscopic guidance. The implant is designed to be positioned, adjusted, and gently anchored in the coronary sinus/great cardiac vein (GCV) to reshape the annulus around the mitral valve to reduce mitral regurgitation. Preclinical data has demonstrated both a reduction in MR and an improvement in Cardiac Output.]
Corazon	Corazon Technologies Inc develops beating heart devices to remove calcification from heart valves.
CoreValve	Is an early stage company seeking to develop trasvascular devices for treatment and replacement of diseased heart valves.
Direct Flow Medical	Direct Flow Medical is a early stege medical device technology developing percutaneous tissue based artifical heart valves.
Evalve	Evalve is an entrepreneurial medical device company that is developing a percutaneous methodology for suturing the free edge of the anterior leaflet of the mitral valve to a corresponding portion on the posterior leaflet, in the treatment of mitral valve regurgitation.
Heart Leaflet Technologies	Is an early stage company developing treatment devices for addressing damaged heart valves.
Mitralign	Is a start-up medical device company seeking to develop minimally invasive catheter products that can perform tasks analagous to opean heart valve repair techniques.
Mitralsolutions	Is a venture capital funded entrepreneurial company in the heart valve space focused on designing implantable annuloplasty devices to treat heart valve abnormalities. Founded in 2004 they are exclusively focused on repair solutions instead of replacement valves. Their products are expected to be implanted by percutaneous beating heart methods, and is designed to be able to be adjusted in-situ.
Myocor	Is a start-up medical device company developing minimally invasive methodologies to treat mitral heart valve regurgitation, their products are still under clinical investigation.
Quantum Cor	Is a early stage medical device company dedicated to developing minimally invasive methodologies to treat mitral and triscupid valve regurgitation.
Shelhigh	A private stentless tissue valve manufacturer, that has developed a propietary No-React methodology for detoxifying glutaraldehyde, eliminating many of the concens with gluteraldehyde usage.
Viacor	Is a developmental stage company working on percutaneous mitral valve repair products. They currently have Investigational Device Exemption for their Viacor PTMA system in the United States.

Source: Frost & Sullivan

Reimbursement Trends

Given the maturity of heart valve technology, there have been limited changes in reimbursement pricing. Third party payers do not typically make distinctions as to which device to use on patients, but they do set price ceilings, which could exclude certain advanced technologies.

Manufacturers launching a new product that has pricing that exceeds the base reimbursement spending limits must conclusively prove their technologies provide a significant patient benefit. In addition to clinical data, cost analysis that shows how the newer device lower long term costs are effective in altering payment schemes..

Regulatory Trends

The regulatory environment currently faces no more stringent monitoring than other medical device products. There have been no major device recalls, or product malfunctions that have warranted special attention be paid to heart valve replacement or repair products. The market overall is poised to witness new levels of post market launch device monitoring. The FDA is hoping to install new channels for device evaluation and public disclosure. Additional measures include more frequent inspection of manufacturing sites.

By its essential set up the regulatory environment, delays the launch of threatening technologies, allowing adequate time for market participants to position their devices accordingly. Most of the start-up activity in the heart valve market pertains to individuals seeking to develop biodegradable mesh devices that serve as a scaffold for seeding autologus stem cells. By the time these devices are ready for market launch, the major competitors can make their decision whether the devices are no significant threat, they need to develop that technology in house, or they can acquire a firm developing those technologies.

3

Tissue Valve Replacement Market

Market Forecast and Analysis

Market Overview

Bioprosthetic valves are harvested tissue valves from either human or animal donors. Human bioprosthetic valves are either obtained from cadavers (allograft), or from one's own body (autograft).

Allograft valves obtained from deceased family members or anonymous donors are cryopreserved at the time of death and thawed before usage. Autograft valves are obtained through the complicated Ross procedures, whereby part of the pulmonary valve is harvested and grafted into the aortic position. Human donor valves involve complicated extraction and insertion procedures, are of limited supply, and typically do not demonstrate significantly higher performance rates than the commercially available xenograft valves.

The vast majority of commercially available bioprosthetic tissue valves are derived from porcine or bovine donors. Before the animals are slaughtered for consumption, the valves are removed from the animal. The harvested valves are then inspected, and only those that meet a certain quality standard are used by manufacturers. In some cases the pericardium tissue can be utilized.

The devices are constructed by sewing the animal valve into a plastic ring or stent. Before being implanted the tissue undergoes multiple chemical treatments to detoxify the tissue, and make it more biocompatible. Advances in polymer coatings have made bioprosthetic valves more durable than ever. In 2006, multiple publications, including a leading cardiovascular journal, expanded recommending tissue prosthesis valves for patients between the ages of 65 and 70. In the past, given durability concerns, those patients would have typically received a mechanical replacement valve. While mechanical valves require life long anti-coagulation therapy, tissue valves typically only require them for around 3 months after implantation. Current tissue valve technology has shown consistant performance in durability trials out to 15 years, at which point degredation leads to regurgitation or tissue calcification. If either is noticed in screening, the valve must be replaced again.

The next major advantage of tissue valve devices is newer stented tissue valves that can be implanted percutaneously. Typically in open heart procedures, the heart is stopped and sustained by a perfusion device, while blood flow is maintained by a heart lung machine. In these minimally invasive procedures, the implant can be performed on a beating heart. Beating heart procedures drastically simplify surgeries, and have a diminished risk for infection. Mechanical valves can not be compressed in a manner to be inserted via a catheter.

Market Engineering Measurements

Chart 3.1 shows the Market Engineering measurements for the U.S. artificial heart valves market for 2005.

Chart 3.1

Tissue Valve Replacement Market: Market Engineering Measurements (U.S.), 2005

Market Engineering Drives Market Strategy and Planning

Measurement Name	Measurement	Trend
Market age	Maturing	Increasing
Revenues	$360.0 million	Increasing
Potential revenues (maximum future market size)	$645.0 million	---
Base year market growth rate	7.5 %	Increasing
Compound annual growth rate (2005-2012)	8.7 %	---
Number of competitors	4	Increasing
Average price	$4,929	Increasing
Market saturation	85%	Increasing
Market concentration (percent of base year market controlled by top three competitors)	97.4%	Decreasing
Price sensitivity	Low	Stable
FDA classification	Class III	---

Note: All figures are rounded. Source: Frost & Sullivan

Revenue Forecasts

Figure 3-1 and Chart 3.2 show the revenue forecasts for the U.S. artificial tissue heart valves market during 2002-2012.

Figure 3-1

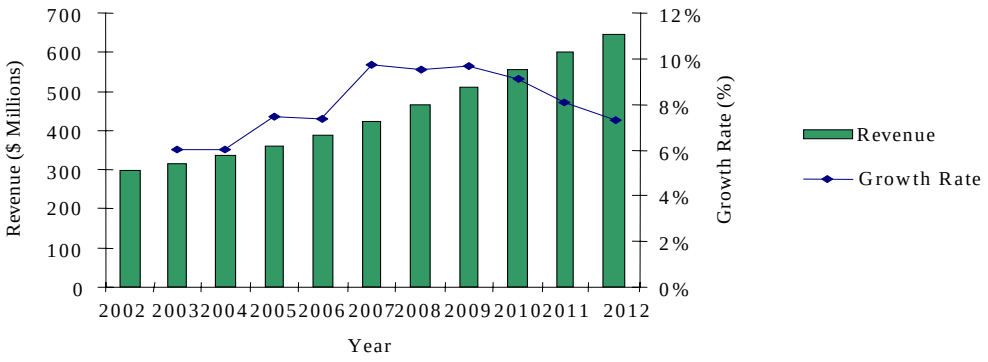
Tissue Valve Replacement Market: Revenue Forecasts (U.S.), 2002-2012

Year	Revenues ($ Million)	Revenue Growth Rate (%)
2002	298.1	---
2003	316.0	6.0
2004	335.0	6.0
2005	360.0	7.5
2006	386.5	7.3
2007	424.1	9.7
2008	464.6	9.5
2009	509.6	9.7
2010	556.0	9.1
2011	601.0	8.1
2012	645.0	7.3
Compound Annual Growth Rate (2005-2012): 8.9%		

Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Chart 3.2

Tissue Valve Replacement Market: Revenue Forecasts (U.S.), 2002-2012



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

For the base year 2005, the revenue for the U.S. tissue heart valve replacement market was $ 360.0 million, with an estimated market potential of $ 645.0 million in 2012. A compound annual growth rate (CAGR) of 8.9 percent is expected for the period 2006 to 2012.

The market is expected to continue sustained growth throughout the forecast period due to the launch of new minimally invasive implanted stent based devices, and the rising overall patient demand. Additional growth should be bolstered by clinicians continuing their shift away from mechanical based valves. The market could achieve larger than forecasted growth, should a manufacturer develop a proficient manner for synthesizing autologous tissue heart valves.

Market growth could be negatively affected if the durability concern for tissue valves, is proven to be a larger concern than previously thought

Procedure Forecasts

Figure 3-2 and Chart 3.3 show the procedure forecasts for the U.S. tissue heart valve replacement market for 2002-2012.

Figure 3-2

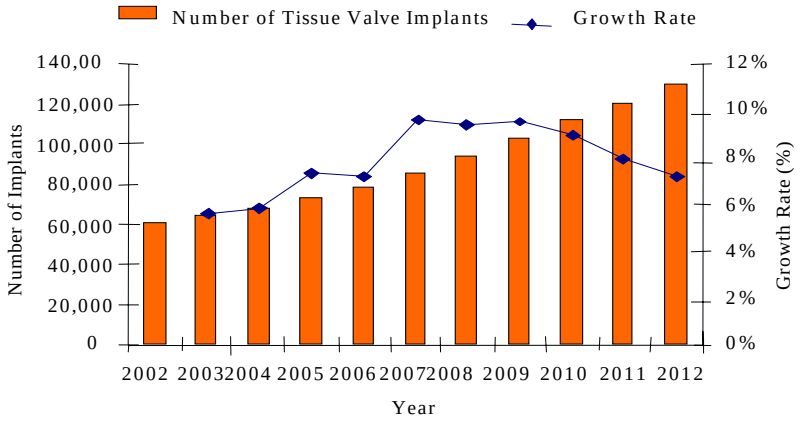
Tissue Valve Replacement Market: Procedure Forecasts (U.S.), 2002-2012

Year	Number of Valves Replaced	Growth Rate (%)
2002	60,946	---
2003	64,340	5.6
2004	68,062	5.8
2005	73,037	7.3
2006	78,294	7.2
2007	85,794	9.6
2008	93,848	9.4
2009	102,800	9.5
2010	112,006	9.0
2011	120,901	7.9
2012	129,570	7.2

Note: The base year is 2005. Source: Frost & Sullivan

Chart 3.3

Tissue Valve Replacement Market: Procedure Forecasts (U.S.), 2002-2012



Note: The base year is 2005. Source: Frost & Sullivan

Figure 3-3 shows the average selling price forecast for the tissue valve replacement market.

Figure 3-3

Tissue Valve Replacement Market: Average Selling Price Forecast (U.S.), 2002-2012

Year	Average Selling Price ($)
2002	4,892
2003	4,912
2004	4,922
2005	4,929
2006	4,936
2007	4,943
2008	4,950
2009	4,957
2010	4,964
2011	4,971
2012	4,978

Note: The base year is 2005. Source: Frost & Sullivan

For the base year 2005, the total number of tissue valve replacements in the U.S. was 73,037 with an estimated market potential of 129,570 valves replaced in 2012. A compound annual growth rate of 8.7 percent is expected for the forecast period from 2006 to 2012.

Clinical trial data showing improved tissue valve durability, and recommendation that the age limits be reduced for mitral valve replacement with a bioprosthetic are spurring usage. Newer devices that can be implanted percutaneously during beating heart procedures will further fuel growth in the future. Overall total growth is expected to be a combination of new product introductions, and migration away from mechanical heart valve implants.

Market leader Edwards Llifesciences uses bovine tissue for their Perimount device, while most other manufacturers use porcine tissue. There is some clinical data that would indicate bovine tissue has better durability than porcine tissue.

The average selling price (ASP) for a bioprosthetic tissue valve was $4,929.00 USD in 2005. The ASP is expected to remain fairly stable with a slight upward trend.

Competitive Analysis

Market Share Analysis

Figure 3-4 displays the market share trends of major market participants in the U.S. tissue valve market in 2005.

Figure 3-4

Tissue Valve Replacement Market: Market Share Trends of Major Market Participants (U.S.), 2005

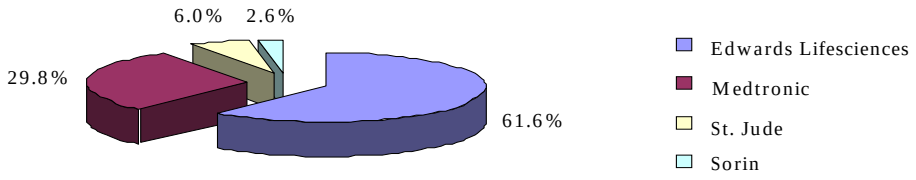
Company	2005 (%)	04/05 Trend
Edwards LifeSciences	61.6	Decreasing
Medtronic	29.8	Stable
St.Jude Medical	6.0	Increasing
CarboMedics (Sorin)	2.6	Stable
TOTAL	100.0	

Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Chart 3.4 shows the company market share by revenues for the U.S. tissue valve market in 2005.

Chart 3.4

Tissue Valve Replacement Market: Market Share of Major Market Participants (U.S.), 2005



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

The tissue valve market is dominated by Edwards Lifesciences which controls 61.6 percent of the market. The growing market preference for tissue valves has increased the demand for Edwards Lifesciences products. Additional measures to increase growth include the upcoming launch of their Perimount Magna Mitral Valve, and are expected to help further increase their market share. Since the mitral valve faces so much pressure, clinicians have traditionally preferred using mechanical heart valves despite the accompanying dependence on blood thinning drugs. However, the launch of newer more durable tissue valves for mitral use could further spur growth for companies such as Edwards Lifesciences.

While Edwards Lifesciences primarily uses bovine tissue for their valves, St.Jude and Medtronic use porcine tissue. Medtronic has a 29.8 percent share of the market, and is the main competitor to Edwards Lifesciences. They have introduced a number of new products that could bolster their presence in the market, such as their new transcatheter products.

St.Jude Medical, CarboMedics, and even ATS medical are companies that established their identity in the mechanical valves segment in the market. Realizing the market preference for tissue products, each has made significant strides to expand their presence in the tissue valve market. St Jude Medical has been conducting durability trials on their new tissue valve products, CarboMedics has been working on design of newer products, and ATS Medical, which currently has no product offerings, recently acquired tissue valve developer 3F Therapeutics.

Product Chart

Figure 3-5 provides a product profile of each competitor's main products in the tissue valve replacement market.

Figure 3-5

Tissue Valve Replacement Market: Product Profile (U.S.), 2005

Company	Product	Tissue Type	Product Profile	Approval Status
Edwards LifeSciences	Carpentier	Bovine	Stented	US FDA
	Perimount Magna	Bovine	Stented	US FDA
Sorin (CarboMed)	Pericarbon	Bovine	---	---
Medtronic	Mosaic Ultra	Porcine	Stented	---
	Hancock	Porcine	Stented	US FDA
St.Jude Medical	Biocor	Porcine	Stented	US FDA
	Toronto SPV	---	Stentless	US FDA
	Epic	Porcine	---	---

Source: Frost & Sullivan

4

Mechanical Valve Replacement Market

Market Forecast and Analysis

Market Overview

While its functionality might seem relatively simple, the designs of mechanical replacement heart valves have undergone countless iterations since their inception over fifty years ago. Devices are made from materials such as stainless steel, silicone, teflon, and polycarbons. Given their durability, mechanical valves are primarily used for young patients, and to replace the mitral valve, due its high pressure gradient. Unlike tissue valves, once implanted they never wear down, and rarely ever have to be replaced.

One of the first generation of device designs for mechanical heart valves included a caged ball construct. The device functioned much like a ball point pen, serving as a one way flow point for blood between the chambers of the heart. However, the design was not ideal in that the heart had to work harder to maintain flow through this ball mechanism, as opposed to the standard open and close central flow heart valve. Furthermore, as blood was passing through the valve, the ball mechanism was known to crush and destroy red blood cells.

Subsequent generations of device design focused on an open and close valve, that allowed for central blood flow. The two approaches are the tilting disk model, and the bi-leaflet model. In the tilting disk design, a disk sits on two struts in such a manner that it closes completely when blood is flowing backward, and open when blood is flowing forward. This design however does not provide ideal central flow, as the valve opens at a 60 degree angle. The most popular current device design is the bileaflet design that uses two half moon shaped carbon flaps that open and close parallel to the flow of blood. The devices allow for maximum flow, and pose the least risk to mechanical laceration of red blood cells.

Mechanical heart valve manufacturers have been facing several major problems to future growth. Their most significant issue is that of thrombosis and clot formation. Despite improvements in device design to be more biomimetic, and less prone to cellular aggregation, patients still require lifelong anti-coagulant mediation. Secondly, they are now being threatened by bioprosthetic tissue valves that are more durable, and can be compacted and implanted percutaneously. Given the risks associated with open heart procedures, percutaneous implants are more favorable in the minds of clinicians.

Given the circumstances of the type of valve that needs replaced and the age of the patient, there will always be a demand for mechanical heart valves. However, in order to expand adoption, it is up to manufacturers to design advanced next generation devices that engender confidence in device safety.

Market Engineering Measurements

Chart 4.1 shows the Market Engineering measurements for the U.S. mechanical replacement heart valves market for 2005.

Chart 4.1

Mechanical Valve Replacement Market: Market Engineering Measurements (U.S.), 2005

Market Engineering Drives Market Strategy and Planning

Measurement Name	Measurement	Trend
Market age	Mature	Increasing
Revenues	$97.0 million	Declining
Potential revenues (maximum future market size)	$91.0	---
Base year market growth rate	(3.0)%	Increasing
Compound annual growth rate (2005-2012)	0.9%	---
Number of competitors	5	Decreasing
Average price	$4,427	Increasing
Market saturation	95%	Increasing
Market concentration (percent of base year market controlled by top three competitors)	84.5%	Decreasing
Price sensitivity	Low	Stable
FDA classification	Class III	---

Note: All figures are rounded. Source: Frost & Sullivan

Revenue Forecasts

Figure 4-1 and Chart 4.2 show the revenue forecasts for the U.S. mechanical heart valve market for 2002 to 2012.

Figure 4-1

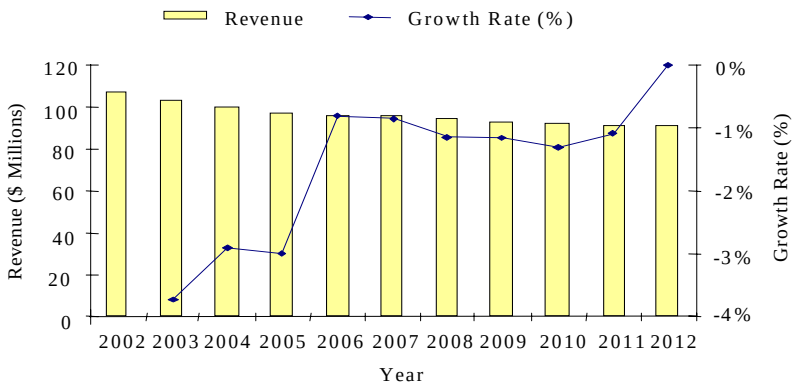
Mechanical Valve Replacement Market: Revenue Forecasts (U.S.), 2002-2012

Year	Revenues ($ Million)	Revenue Growth Rate (%)
2002	107.0	---
2003	103.0	(3.7)
2004	100.0	(2.9)
2005	97.0	(3.0)
2006	96.2	(0.8)
2007	95.4	(0.8)
2008	94.3	(1.1)
2009	93.2	(1.1)
2010	92.0	(1.3)
2011	91.0	(1.1)
2012	91.0	0.0
Compound Annual Growth Rate (2005-2012): (0.9)%		

Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Chart 4.2

Mechanical Valve Replacement Market: Revenue Forecasts (U.S.), 2002-2012



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

For the base year 2005, the revenue for the U.S. mechanical heart valve replacement market was $ 97.0 million, with an estimated market potential of $ 91.0 million in 2012. A compound annual growth rate (CAGR) of (-0.9) percent is expected for the period 2006 to 2012.

The market is expected to continue its decline due to saturated patient demand and declining prices. New products and overall increases in patient population should help bring the market closer to zero growth by the end of the forecast period. The superiority of tissue valves in most circumstances has been firmly entrenched in the minds of clinicians, therefore without any groundbreaking product developments current trends can not be reversed. Due to the declining market, there has been little activity with respect to new market entrants exploring the market, or start-ups developing next generation solutions.

Currently the only achievement that could significantly alter market forecasts, would be the development of a highly biocompatiable polymer or carbon material that could allow mechanical devices to approach the performance of tissue based valves.

Procedure Forecasts

Figure 4-2 and Chart 4.3 show the procedure forecasts for the U.S. mechanical heart valve replacement market for 2002-2012.

Figure 4-2

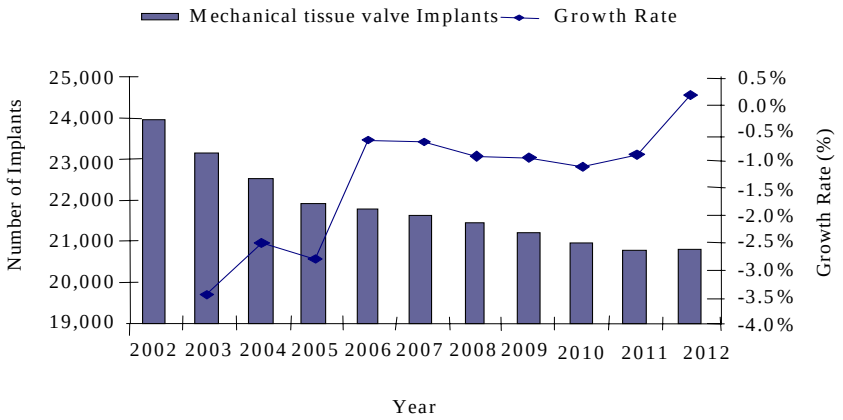
Mechanical Valve Replacement Market: Procedure Forecasts (U.S.), 2002-2012

Year	Number of Valves Replaced	Growth Rate (%)
2002	23,959	---
2003	23,130	(3.5)
2004	22,548	(2.5)
2005	21,911	(2.8)
2006	21,771	(0.6)
2007	21,626	(0.7)
2008	21,419	(1.0)
2009	21,211	(1.0)
2010	20,971	(1.1)
2011	20,781	(0.9)
2012	20,819	0.2

Note: The base year is 2005. Source: Frost & Sullivan

Chart 4.3

Mechanical Valve Replacement Market: Procedure Forecasts (U.S.), 2002-2012



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Figure 4-3 shows the average selling price forecast for the mechanical valve replacement market.

Figure 4-3

Mechanical Valve Replacement Market: Average Selling Price Forecast (U.S.), 2002-2012

Year	Average Selling Price ($)
2002	4,466
2003	4,453
2004	4,435
2005	4,427
2006	4,419
2007	4,411
2008	4,403
2009	4,395
2010	4,387
2011	4,379
2012	4,371

Note: The base year is 2005. Source: Frost & Sullivan

For the base year 2005, the total number of mechanical valve replacements in the U.S. was 21,911, with an estimated market potential of 20,819 valves replaced in 2012. A compound annual growth rate of (-0.7) percent is expected for the forecast period from 2006 to 2012.

The average selling price (ASP) for a mechanical replacement valve in 2005 was approximately $4,427.00 USD. The ASP is expected to remain fairly stable over the forecast period with a slight downward trend.

Improved durability and launch of percutaneous tissue valve replacements have threatened the future usage of mechanical prosthetics. Even for mitral valve replacements, a traditionally strong sector for usage mechanical prosthetics is shifting towards newer bioprosthetic valve replacements.

Market decline could be reversed were there to be reported major adverse effects or limited durability of newer tissue stented valves. Additionally, further development with respect to anti-coagulation coatings on device surfaces could spur usage.

Competitive Analysis

Market Share Analysis

Figure 4-4 shows the market share breakdown of the major market participants for the U.S. mechanical heart valve market in 2005.

Figure 4-4

Mechanical Valve Replacement Market: Market Share Trends of Major Market Participants (U.S.), 2005

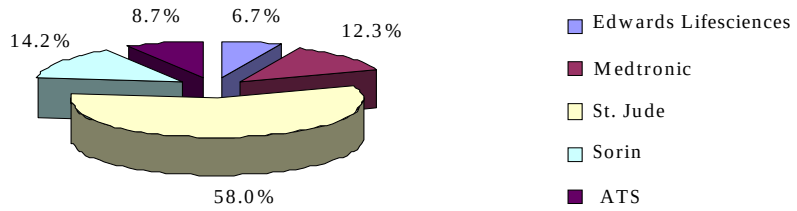
Company	2005 (%)	04/05 Trend
St.Jude Medical	58.0	Increasing
Medtronic	12.3	Decreasing
CarboMedics (Sorin)	14.2	Stable
ATS Medical	8.7	Increasing
Edwards Lifesciences	6.7	Decreasing
TOTAL	100.0	

Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Chart 4.4 shows the company market share by revenues for the U.S. mechanical heart valve market in 2005.

Chart 4.4

Mechanical Valve Replacement Market: Market Share of Major Market Participants (U.S.), 2005



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

The mechanical heart valve market is dominated by St.Jude Medical with a 58.0 percent overall share of the market. The product portfolio for ATS Medical and CarboMedics (Sorin), consist predominantly of mechanical heart valves. Mechanical valves are still primarily used for mitral valve repair, and for younger patients with a life expectancy longer than 20 years. The options for those patients are either to stay on lifelong anti-thrombolytic medications, or use a tissue lab and possibly require another heart valve replacement in 15 to 20 years.

Clinicians currently shifting to the newer tissue heart valves are doing so under the assumption that the durability trials showing tissue valves lasting 15 to 20 years is valid. Should there arise a point where in actual general patient settings that proves to be not true, the market could witness a swing back towards mechanical valves.

Product Chart

Figure 4-5 provides a product profile of each competitor's main products in the mechanical valve replacement market.

Figure 4-5

Mechanical Valve Replacement Market: Product Profile (U.S.), 2005

Company	Product	Valve Type
St. Jude Medical	Reagent Valve	Bi-leaflet
	Masters Series Hemodynamic Valve	Bi-leaflet
	Mechanical Heart Valve	Bi-leaflet
Sorin (CarboMedics)	Orbis Universal Valve	Bi-leaflet
	Pediatric/Small Adult Valve	Bi-leaflet
	Top Hat Supra Annular Aortic Valve	Bi-leaflet
	Allcarbon Monodisc	Single disk
Medtronic	Hall Mechanical Valve	Single disk
ATS Medical	Open Pivot Heart Valve	Bi-leaflet

Source: Frost & Sullivan

5

Heart Valve Repair Products

Market Forecast and Analysis

Market Overview

The inability to definitively address the issues posed by replacement valves, such as durability or biocompatibility, have instigated market focus on heart valve repair products. Advances in technology such as intravascular imaging, catheter technology, and minimally invasive tools have enabled new avenues for heart valve repair. High growth sectors of a market can usually be qualitatively assessed by the level of venture and entrepreneurial activity being conducted. If so, than the level of start-up activity in the heart valve repair market might be indicative of its potential for growth.

The main types of heart valve repair procedures are commissurotomy, valvuloplasty, valve remodeling, decalcification techniques, chordae tendineae remodling, and defect closure. For commussurotomy if a valve has become thickened to the point that it is difficult for blood to flow through, the surgeon can surgically trim the leaflets. Valvulaplasty is where a plastic ring is attached to the annulus to allow the valve more support and tighten the tissue. Decalcification procedures can be performed to remove calcium build up on the leaflets that are affecting blood flow. Valve remodeling procedures involve cutting or sewing up the valve leaflets so that it can restore healthy blood flow. Shortening or replacing the chordae tendineae that attaches to the valves can aid in allowing normal valve function. Minor tears or holes in the heart valve can be sealed or sewn together to prevent regurgitation. Most commercial manufacturers are focused on the valvuloplasty market and are developing the plastic rings used in those procedures.

New approaches involving percutaneous beating heart procedures are being developed to address repair of diseased mitral and tricuspid valves. Valvular repair involves reshaping the annulus through the coronary sinus, the ventricle, or connecting the anterior and posterior leaflets.

As a relatively new approach, the market is limited by provider training and the lack of long term proven in-situ durability data. Given the rising prevalence of congestive heart failure, the demand for these products is entering a new era of importance.

Market Engineering Measurements

Chart 5.1 shows the Market Engineering measurements for the U.S. heart valve repair market for 2005.

Chart 5.1

Valve Repair Market: Market Engineering Measurements (U.S.), 2005

Market Engineering Drives Market Strategy and Planning

Measurement Name	Measurement	Trend
Market age	Growth	Increasing
Revenues	$62.0 million	Increasing
Potential revenues (maximum future market size)	$131.0	---
Base year market growth rate	13.3%	Increasing
Compound annual growth rate (2005-2012)	11.3%	---
Number of competitors	5	Increasing
Market saturation	95%	Increasing
Market concentration (percent of base year market controlled by top three competitors)	89.7%	Decreasing
Price sensitivity	Low	Stable
FDA classification	Class III	---

Note: All figures are rounded. Source: Frost & Sullivan

Revenue Forecasts

Figure 5-1 and Chart 5.2 show the revenue forecasts for the U.S. heart valve repair market during 2002-2012.

Figure 5-1

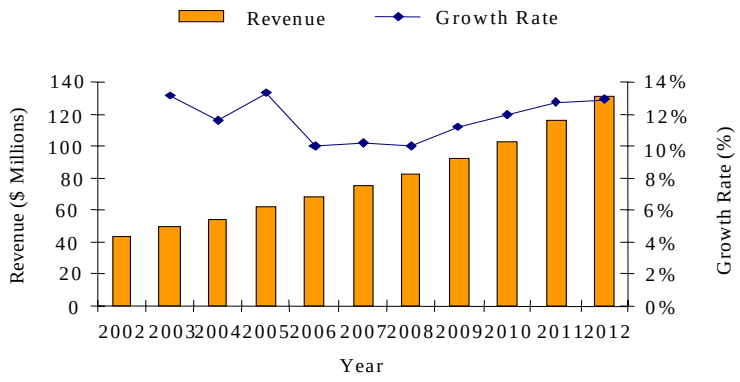
Valve Repair Market: Revenue Forecasts (U.S.), 2002-2012

Year	Revenues ($ Million)	Revenue Growth Rate (%)
2002	43.3	---
2003	49.0	13.2
2004	54.7	11.6
2005	62.0	13.3
2006	68.2	10.0
2007	75.1	10.2
2008	82.7	10.0
2009	91.9	11.2
2010	102.9	12.0
2011	116.0	12.7
2012	131.0	12.9
Compound Annual Growth Rate (2006-2011): 11.4%		

Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Chart 5.2

Valve Repair Market: Revenue Forecasts (U.S.), 2002-2012



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

For the base year 2005, the revenue for the U.S. heart valve repair market was $ 62.0 million, with an estimated market potential of $131.0 million in 2012. A compound annual growth rate (CAGR) of 11.5 percent is expected for the period 2006 to 2012.

Repair products have a higher growth potential than any other segment of the heart valve market. Given the issues of biocompatibility with mechanical valves, and durability with tissue based valves, certain clinicians are turning to usage of repair products over complete replacement. The market has more participants than the total artificial replacement segments, therefore there are more opportunities for growth and new product introduction.

Increased safety or proficency from replacement valves could negatively affect market projects.

Competitive Analysis

Market Share Analysis

Figure 5-2 shows the market share trends of major market participants for the U.S. heart valve repair market in 2005. Chart 5.3 shows the market share by revenues for major market participants.

Figure 5-2

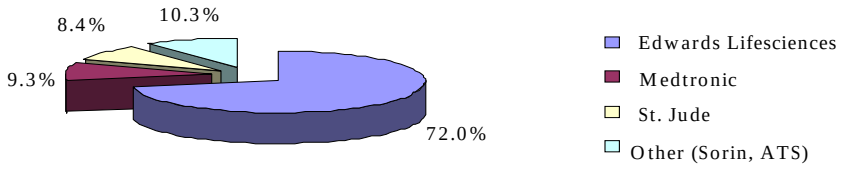
Valve Repair Market: Market Share Trends of Major Market Participants (U.S.), 2005

Company	2005 (%)	04/05 Trend
Edwards LifeSciences	72.0	Decreasing
Medtronic	9.3	Stable
St.Jude Medical	8.4	Increasing
Other (ATS, Sorin)	10.3	Increasing
TOTAL	100.0	

Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Chart 5.3

Valve Repair Market: Market Share of Major Market Participants (U.S.), 2005



Note: All figures are rounded; the base year is 2005. Source: Frost & Sullivan

Edwards LifeSciences is the clear market leader in the heart valve repair market with a 72.0 percent market share. Edwards Lifesciences has been able to leverage their expertise in the tissue valve market to accelerate market adoption of their products. Recent product introductions such as their Geoform devices should allow them to maintain their control as the market share leader.

Each of the other four main manufacturers in the market have recent product introductions. However, nearly all of the products have similar features, and the market has not shown a major preference for one over another.

Due to the high level of start-up activity being explored in the market, the competitive landscape could be dramatically altered over the next 10 years.

Product Chart

Figure 5-3 provides a product profile of each competitor's main products in the heart valve repair market.

Figure 5-3

Valve Repair Market: Product Profile (U.S.), 2005

Company	Product	Product Profile
Edwards LifeSciences	Geoform Carpentier Annuloplasty	Titanium
Sorin (CarboMed)	Sovering	Knitted polyester
Medtronic	Duran Annuloplasty	Knitted polyester
ATS Medical	Stimulus Annuloplasty	Knitted polyester
St.Jude Medical	Sequin Tailor Annuloplasty	Knitted polyester Knitted polyester

Source: Frost & Sullivan

6

Decision Support Databases

Decision Support Databases

Population 65 and above

Figure 6-1 provides the total population aged 65 and above from 1999 to 2006.

Figure 6-1

Decision Support Database: Total Population aged 65 Years & above in Millions (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
North America									
Canada	3.9	4.0	4.0	4.1	4.2	4.2	4.3	4.4	1.88
Mexico	4.2	4.3	4.5	4.7	4.8	5.0	5.2	5.4	3.88
United States	34.8	35.1	35.3	35.6	35.9	36.3	36.7	37.2	1.21
TOTAL	42.8	43.3	43.8	44.3	44.9	45.5	46.2	47.0	1.57
Latin America									
Argentina	3.8	3.8	3.9	4.0	4.0	4.1	4.2	4.2	1.64
Brazil	8.9	9.3	9.6	10.0	10.3	10.7	11.1	11.5	3.57
Chile	1.1	1.1	1.1	1.2	1.2	1.2	1.3	1.3	3.53
Peru	1.2	1.3	1.3	1.4	1.4	1.5	1.5	1.6	3.71
Venezuela	1.1	1.1	1.1	1.2	1.2	1.3	1.3	1.3	3.48
TOTAL	16.0	16.6	17.1	17.6	18.2	18.8	19.4	20.0	3.15

Figure 6-1 (Continued)

Decision Support Database: Total Population aged 65 Years & above in Millions (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Asia—Pacific									
Australia	2.3	2.4	2.4	2.5	2.5	2.5	2.6	2.6	1.91
China	84.7	87.4	90.2	92.8	95.4	97.6	99.9	102.3	2.37
Hong Kong	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.9	1.89
India	45.5	46.5	47.6	48.7	49.9	51.1	52.5	54.0	2.67
Indonesia	9.5	10.0	10.6	11.1	11.6	12.2	12.7	13.2	4.18
Japan	21.0	21.7	22.4	23.1	23.7	24.2	24.8	25.5	2.49
Malaysia	0.9	0.9	0.9	1.0	1.0	1.1	1.1	1.2	4.26
New Zealand	0.4	0.4	0.4	0.5	0.5	0.5	0.5	0.5	1.65
Philippines	2.9	3.0	3.1	3.2	3.3	3.4	3.5	3.6	3.51
Singapore	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.4	4.26
South Korea	3.1	3.3	3.5	3.6	3.8	4.0	4.2	4.3	4.49
Taiwan	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.3	2.52
Thailand	3.8	4.0	4.1	4.3	4.5	4.7	4.9	5.1	3.91
TOTAL	177.0	182.5	188.2	193.9	199.4	204.6	210.0	215.8	2.67
Western Europe									
Austria	1.2	1.3	1.3	1.3	1.3	1.3	1.3	1.4	2.89
Belgium	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	0.67
Denmark	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	1.07
Finland	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	1.52
France	9.4	9.5	9.6	9.7	9.8	9.9	10.0	10.0	0.66
Germany	13.2	13.5	13.9	14.2	14.6	15.1	15.6	16.0	3.04
Greece	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.0	1.49
Iceland	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.00
Ireland	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5	1.47
Italy	10.2	10.4	10.6	10.7	10.9	11.1	11.3	11.5	1.67
Luxembourg	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	1.54
Netherlands	2.1	2.2	2.2	2.2	2.2	2.3	2.3	2.4	1.61
Norway	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.25
Portugal	1.5	1.5	1.6	1.6	1.6	1.6	1.7	1.7	1.02
Spain	6.7	6.8	6.9	7.0	7.1	7.1	7.1	7.2	0.44

Figure 6-1 (Continued)

Decision Support Database: Total Population aged 65 Years & above in Millions (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Sweden	1.5	1.5	1.5	1.5	1.5	1.6	1.6	1.6	0.67
Switzerland	1.1	1.1	1.1	1.1	1.1	1.2	1.2	1.2	1.60
United Kingdom	9.3	9.3	9.3	9.4	9.4	9.5	9.5	9.6	0.47
TOTAL	62.6	63.4	64.4	65.3	66.2	67.2	68.2	69.1	1.46
Eastern Europe									
Czech Republic	1.4	1.4	1.4	1.4	1.4	1.5	1.5	1.5	1.15
Hungary	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	0.66
Poland	4.7	4.7	4.8	4.9	4.9	5.0	5.0	5.0	0.83
Russia	18.4	18.4	18.6	19.1	19.6	20.1	20.4	20.5	1.57
Turkey	3.8	3.9	4.1	4.2	4.4	4.5	4.7	4.8	3.12
TOTAL	29.7	30.0	30.4	31.1	31.9	32.5	33.1	33.4	1.61
Middle East									
Egypt	2.7	2.8	2.9	3.1	3.2	3.3	3.4	3.5	3.82
Israel	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.82
Saudi Arabia	0.5	0.6	0.6	0.7	0.7	0.7	0.8	0.9	6.87
TOTAL	3.8	4.0	4.1	4.3	4.5	4.6	4.8	5.0	3.92
Africa									
South Africa	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3	2.60
TOTAL	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3	2.60
WORLD TOTAL	333.9	341.8	350.2	358.6	367.2	375.5	384.0	392.7	2.26

Definition: The above figures represent total mid-year population aged 65 years and above

Note: All figures are rounded; the base year is 2003. Source: Frost & Sullivan

Obesity Rates

Figure 6-2 provides the prevalence of obese population over 15 years of age from 1999 to 2006.

Figure 6-2

Decision Support Database: Prevalence of obese population over 15 years of age in Million (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
North America									
Canada	3.5	3.7	3.8	4.0	4.2	4.3	4.5	4.6	3.65
Mexico	9.9	10.1	10.5	10.8	11.0	11.3	11.6	11.9	2.63
United States	40.6	43.0	45.8	48.3	50.6	53.2	55.6	58.1	4.69
TOTAL	54.0	56.8	60.2	63.1	65.8	68.9	71.7	74.7	4.28
Latin America									
Argentina	4.6	4.7	4.9	5.0	5.1	5.3	5.4	5.5	2.49
Brazil	16.2	17.0	17.8	18.7	19.5	20.4	21.3	22.3	4.43
Chile	-	-	-	-	-	-	-	-	-
Peru	-	-	-	-	-	-	-	-	-
Venezuela	-	-	-	-	-	-	-	-	-
TOTAL	20.8	21.7	22.7	23.7	24.7	25.7	26.7	27.8	4.04
Asia—Pacific									
Australia	3.0	3.2	3.3	3.4	3.6	3.7	3.8	4.0	3.76
China	20.6	21.2	21.8	22.4	23.1	23.8	24.4	25.1	2.87
Hong Kong	-	-	-	-	-	-	-	-	-
India	26.3	27.6	28.9	30.3	31.7	33.1	34.6	36.1	4.43
Indonesia	-	-	-	-	-	-	-	-	-
Japan	2.7	2.7	2.7	2.8	2.8	2.9	2.9	2.9	1.45
Malaysia	1.0	1.0	1.1	1.1	1.2	1.2	1.3	1.3	4.13
New Zealand	0.5	0.5	0.5	0.6	0.6	0.6	0.6	0.6	3.30
Philippines	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	3.87
Singapore	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	4.99
South Korea	0.6	0.6	0.6	0.6	0.7	0.7	0.7	0.7	3.18
Taiwan	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3	2.34
Thailand	2.8	2.9	3.0	3.1	3.2	3.3	3.4	3.5	2.75
TOTAL	60.5	62.8	65.1	67.6	70.1	72.7	75.3	78.0	3.62

Figure 6-2 (Continued)

Decision Support Database: Prevalence of obese population over 15 years of age in Million (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Western Europe									
Austria	1.3	1.3	1.4	1.4	1.4	1.4	1.5	1.5	1.66
Belgium	1.4	1.4	1.5	1.5	1.5	1.6	1.6	1.7	2.37
Denmark	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	2.23
Finland	0.8	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.96
France	5.2	5.4	5.6	5.8	6.1	6.3	6.5	6.7	3.68
Germany	13.1	13.4	13.7	14.0	14.3	14.6	14.9	15.2	2.13
Greece	2.0	2.1	2.1	2.1	2.2	2.2	2.2	2.2	1.18
Iceland	-	-	-	-	-	-	-	-	-
Ireland	0.5	0.5	0.6	0.6	0.6	0.6	0.7	0.7	3.93
Italy	4.3	4.4	4.6	4.8	4.9	5.0	5.2	5.3	2.75
Luxembourg	-	-	-	-	-	-	-	-	-
Netherlands	1.2	1.2	1.2	1.2	1.3	1.3	1.3	1.4	2.20
Norway	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5	2.94
Portugal	-	-	-	-	-	-	-	-	-
Spain	4.9	5.1	5.3	5.4	5.6	5.8	6.0	6.2	3.09
Sweden	0.9	0.9	0.9	1.0	1.0	1.0	1.1	1.1	3.27
Switzerland	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.5	2.82
United Kingdom	9.5	10.2	10.8	10.9	11.4	12.0	12.7	13.4	5.57
TOTAL	46.4	48.1	49.8	51.0	52.5	54.2	56.0	57.7	3.23
Eastern Europe									
Czech Republic	1.6	1.7	1.7	1.7	1.7	1.8	1.8	1.8	1.41
Hungary	1.6	1.6	1.7	1.7	1.7	1.8	1.8	1.8	1.84
Poland	5.7	5.8	5.9	6.0	6.1	6.2	6.2	6.3	1.45
Russia	23.3	23.7	24.1	24.4	24.8	25.1	25.4	25.7	1.23
Turkey	-	-	-	-	-	-	-	-	-
TOTAL	32.2	32.7	33.3	33.8	34.3	34.8	35.3	35.7	1.31
Middle East									
Egypt	-	-	-	-	-	-	-	-	-
Israel	-	-	-	-	-	-	-	-	-
Saudi Arabia	2.5	2.6	2.7	2.9	3.0	3.1	3.2	3.4	4.22
TOTAL	2.5	2.6	2.7	2.9	3.0	3.1	3.2	3.4	4.22

Figure 6-2 (Continued)

Decision Support Database: Prevalence of obese population over 15 years of age in Million (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Africa									
South Africa	5.8	5.8	5.9	5.9	5.9	6.0	6.0	6.1	0.67
TOTAL	5.8	5.8	5.9	5.9	5.9	6.0	6.0	6.1	0.67
WORLD TOTAL	222.2	230.6	239.6	248.0	256.4	265.4	274.3	283.3	3.39

Definition: The above figures represent above 15 years population with Body Mass Index (BMI) above 30. Body Mass index is the ratio of Weight to square of Height, where weight is in Kilograms and Height is in Meters. Body Mass Index (BMI) = Weight / (Height ^2)

Note: 1. Hyphen indicates non-availability of data

Note: All figures are rounded; the base year is 2003. Source: Frost & Sullivan

Hospitals

Figure 6-3 provides the number of hospitals from 1999 to 2006.

Figure 6-3

Decision Support Database: Number of Hospitals (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
North America									
Canada	950	938	926	915	904	894	884	874	(1.12)
Mexico	18,918	19,107	19,294	19,478	19,658	19,834	20,006	20,170	0.86
United States	5,890	5,847	5,801	5,761	5,725	5,692	5,664	5,640	(0.50)
TOTAL	25,758	25,892	26,021	26,154	26,287	26,420	26,554	26,684	0.50
Latin America									
Argentina	1,299	1,313	1,327	1,340	1,353	1,365	1,377	1,388	0.85
Brazil	7,381	7,376	7,372	7,368	7,363	7,358	7,353	7,349	(0.06)
Chile	398	399	400	401	402	403	403	404	0.17
Peru	134	133	132	131	130	130	129	129	(0.26)
Venezuela	364	377	391	405	420	436	453	471	3.89
TOTAL	9,576	9,598	9,622	9,645	9,668	9,692	9,715	9,741	0.25

Figure 6-3 (Continued)

Decision Support Database: Number of Hospitals (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Asia—Pacific									
Australia	1,257	1,265	1,275	1,286	1,298	1,308	1,319	1,326	0.71
China	66,935	66,509	65,424	64,606	63,960	63,448	63,068	62,690	(0.67)
Hong Kong	52	53	53	54	55	56	57	58	1.79
India	16,200	16,550	16,897	17,247	17,588	17,933	18,256	18,575	1.84
Indonesia	1,098	1,116	1,136	1,156	1,175	1,194	1,211	1,227	1.45
Japan	9,286	9,266	9,239	9,211	9,183	9,154	9,125	9,095	(0.32)
Malaysia	339	338	343	348	353	357	362	366	1.21
New Zealand	408	424	444	445	458	469	479	489	2.21
Philippines	1,794	1,712	1,721	1,734	1,752	1,771	1,790	1,808	1.05
Singapore	28	28	29	29	30	31	31	32	2.17
South Korea	964	1,058	1,080	1,122	1,164	1,206	1,247	1,282	3.27
Taiwan	-	-	-	-	-	-	-	-	-
Thailand	1,779	1,867	1,958	2,051	2,147	2,246	2,346	2,442	4.38
TOTAL	100,140	100,186	99,599	99,289	99,163	99,173	99,291	99,390	0.08
Western Europe									
Austria	325	321	317	314	311	309	307	305	(0.65)
Belgium	235	227	224	221	218	216	214	212	(0.93)
Denmark	81	76	72	69	66	64	62	61	(2.59)
Finland	389	389	388	386	384	383	382	381	(0.26)
France	3,057	3,076	3,050	3,027	3,008	2,995	2,982	2,972	(0.40)
Germany	3,650	3,635	3,621	3,609	3,599	3,590	3,582	3,575	(0.22)
Greece	339	337	333	330	327	325	323	321	(0.62)
Iceland	23	22	22	21	21	20	20	19	(3.28)
Ireland	100	100	100	99	99	99	98	98	(0.34)
Italy	1,344	1,321	1,298	1,276	1,255	1,234	1,214	1,195	(1.62)
Luxembourg	19	18	19	18	18	17	17	16	(3.85)
Netherlands	212	208	205	201	198	195	193	191	(1.19)
Norway	-	-	-	-	-	-	-	-	-
Portugal	221	224	227	229	231	232	233	233	0.29
Spain	798	802	798	801	804	806	808	809	0.21
Sweden	121	121	126	123	122	118	115	112	(2.81)
Switzerland	392	376	364	354	346	339	332	326	(1.97)
United Kingdom	-	-	-	-	-	-	-	-	-
TOTAL	11,306	11,253	11,164	11,078	11,007	10,942	10,882	10,826	(0.55)

Figure 6-3 (Continued)

Decision Support Database: Number of Hospitals (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Eastern Europe									
Czech Republic	371	370	366	362	358	355	352	349	(0.85)
Hungary	172	178	183	187	191	195	198	201	1.72
Poland	805	801	796	793	791	788	786	784	(0.30)
Russia	10,195	9,946	9,869	9,649	9,449	9,264	9,094	8,934	(1.85)
Turkey	1,213	1,226	1,241	1,256	1,272	1,287	1,301	1,314	1.09
TOTAL	12,756	12,521	12,455	12,247	12,061	11,889	11,731	11,582	(1.34)
Middle East									
Egypt	3,520	3,678	3,834	3,987	4,137	4,283	4,426	4,569	3.37
Israel	327	343	354	366	378	389	400	410	2.75
Saudi Arabia	314	320	326	331	335	339	343	346	1.08
TOTAL	4,161	4,341	4,514	4,684	4,850	5,011	5,169	5,325	3.16
Africa									
South Africa	721	740	761	783	803	821	837	852	1.99
TOTAL	721	740	761	783	803	821	837	852	1.99
WORLD TOTAL	164,418	164,531	164,136	163,880	163,839	163,948	164,179	164,400	0.11

Definition: The above figures represent total number of hospitals

Note: 1. Figures for Argentina and Peru include Public Hospitals only
2. Hyphen indicates non availability of data
3. Figures for Mexico represent number of Medical Units

Note: All figures are rounded; the base year is 2003. Source: Frost & Sullivan

Cardiovascular Mortality

Figure 6-4 shows the prevalence of death due to circulatory disease 1999 to 2006.

Figure 6-4

Decision Support Database: Circulatory Disease Mortality (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
North America									
Canada	80,100	80,405	80,700	80,990	81,270	81,550	81,790	82,020	0.31
Mexico	111,680	115,300	118,940	122,600	126,480	130,380	134,280	138,200	3.00
United States	950,314	936,923	922,234	917,839	913,500	909,200	904,950	900,750	(0.47)
TOTAL	1,142,094	1,132,628	1,121,874	1,121,429	1,121,250	1,121,130	1,121,020	1,120,970	(0.01)
Latin America									
Argentina	98,930	91,506	89,000	86,700	84,600	82,600	80,800	79,200	(2.17)
Brazil	228,330	227,300	226,250	225,180	224,080	223,060	222,015	220,950	(0.47)
Chile	20,980	20,770	20,560	20,350	20,135	19,920	19,700	19,480	(1.10)
Peru	-	-	-	-	-	-	-	-	-
Venezuela	36,350	37,450	38,570	39,700	40,850	42,000	43,170	44,350	2.78
TOTAL	384,590	377,026	374,380	371,930	369,665	367,580	365,685	363,980	(0.52)
Asia—Pacific									
Australia	51,352	49,471	49,381	50,294	49,910	49,535	49,170	48,820	(0.73)
China	3,236,100	3,307,000	3,376,000	3,443,500	3,509,500	3,574,000	3,636,000	3,696,000	1.74
Hong Kong	9,157	9,372	9,592	9,817	10,047	10,287	10,537	10,790	2.41
India	2,930,500	3,006,000	3,082,000	3,158,500	3,235,500	3,312,900	3,390,600	3,468,600	2.35
Indonesia	-	-	-	-	-	-	-	-	-
Japan	277,100	272,800	268,714	264,814	261,084	257,514	254,114	250,864	(1.32)
Malaysia	4,457	4,778	5,159	5,550	5,950	6,355	6,765	7,180	6.46
New Zealand	10,750	10,645	10,545	10,450	10,360	10,275	10,195	10,120	(0.78)
Philippines	104,050	107,050	110,100	113,200	116,350	119,550	122,800	126,100	2.72
Singapore	5,780	5,850	5,922	5,995	6,070	6,147	6,225	6,305	1.27
South Korea	54,320	55,670	54,470	53,450	52,500	51,700	51,000	50,500	(1.29)
Taiwan	23,930	23,884	24,144	23,450	23,100	22,770	22,450	22,150	(1.39)
Thailand	-	-	-	-	-	-	-	-	-
TOTAL	6,707,496	6,852,520	6,996,027	7,139,020	7,280,371	7,421,033	7,559,856	7,697,429	1.87
Western Europe									
Austria	42,111	41,650	41,175	40,690	40,200	39,700	39,200	38,700	(1.26)
Belgium	38,345	38,190	38,045	37,905	37,769	37,636	37,507	37,382	(0.34)
Denmark	17,992	17,757	17,537	17,327	17,127	16,937	16,757	16,597	(1.04)
Finland	21,348	20,878	20,360	19,864	19,400	18,970	18,570	18,180	(2.14)
France	166,464	165,938	165,403	164,858	164,308	163,748	163,178	162,608	(0.35)
Germany	398,420	387,476	377,558	368,000	359,200	350,700	342,500	334,500	(2.35)
Greece	50,851	50,700	50,570	50,450	50,340	50,235	50,135	50,040	(0.20)

Figure 6-4 (Continued)

Decision Support Database: Circulatory Disease Mortality (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Iceland	787	783	779	775	771	768	765	762	(0.39)
Ireland	13,010	12,281	11,914	11,554	11,214	10,894	10,564	10,264	(2.91)
Italy	235,643	224,218	222,000	219,850	217,750	215,700	213,700	211,700	(0.93)
Luxembourg	1,492	1,480	1,475	1,460	1,444	1,428	1,410	1,390	(1.26)
Netherlands	49,594	49,191	47,643	47,992	47,622	47,272	46,922	46,580	(0.73)
Norway	19,240	18,191	17,704	17,269	16,849	16,444	16,044	15,649	(2.43)
Portugal	42,106	41,720	41,370	41,050	40,750	40,470	40,200	39,950	(0.66)
Spain	129,960	129,280	128,600	127,950	127,320	126,700	126,100	125,500	(0.48)
Sweden	44,554	43,277	42,597	41,927	41,277	40,647	40,027	39,427	(1.52)
Switzerland	25,306	24,489	24,057	23,649	23,265	22,892	22,543	22,193	(1.56)
United Kingdom	245,800	237,800	230,000	222,500	215,200	208,000	201,000	194,500	(3.31)
TOTAL	1,543,023	1,505,299	1,478,787	1,455,070	1,431,806	1,409,141	1,387,122	1,365,922	(1.56)
Eastern Europe									
Czech Republic	62,410	61,831	61,251	60,681	60,120	59,570	59,030	58,500	(0.91)
Hungary	74,970	68,270	66,032	65,541	65,060	64,590	64,120	63,650	(0.73)
Poland	187,670	168,700	167,000	165,350	163,750	162,250	160,800	159,400	(0.89)
Russia	1,185,369	1,214,388	1,240,400	1,264,400	1,286,400	1,307,400	1,327,400	1,346,400	1.53
Turkey	-	-	-	-	-	-	-	-	-
TOTAL	1,510,419	1,513,189	1,534,683	1,555,972	1,575,330	1,593,810	1,611,350	1,627,950	1.10
Middle East									
Egypt	209,100	214,100	219,120	224,150	229,200	234,270	239,350	244,450	2.17
Israel	11,637	11,450	11,265	11,082	10,900	10,720	10,550	10,380	(1.62)
Saudi Arabia	-	-	-	-	-	-	-	-	-
TOTAL	220,737	225,550	230,385	235,232	240,100	244,990	249,900	254,830	2.00
Africa									
South Africa	50,200	52,565	54,940	57,330	59,730	62,150	64,600	67,050	3.93
TOTAL	50,200	52,565	54,940	57,330	59,730	62,150	64,600	67,050	3.93
WORLD TOTAL	11,558,559	11,658,777	11,791,076	11,935,983	12,078,252	12,219,834	12,359,533	12,498,131	1.15

Definition: Figures in the table represent "Death due to Circulatory Disease". It include death due to IHD, RHD, Hypertensive Disease, Cerebrovascular Disease etc. (International Classification of Diseases—9:390 to 459)

Note: 1. Hyphen indicates non availability of data

2. Figure for Malaysia represents death due to Heart Diseases & Diseases of Pulmonary Circulation only

3. Figures for Taiwan represent heart and cerebrovascular disease mortality

Note: All figures are rounded; the base year is 2003. Source: Frost & Sullivan

Cardiologists

Figure 6-5 provides the number of registered cardiologists from 1999 to 2006.

Figure 6-5

Decision Support Database: Number of Registered Cardiologist (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
North America									
Canada	837	862	889	922	955	986	1,016	1,045	3.05
Mexico	-	-	-	-	-	-	-	-	-
United States	20,205	21,025	21,726	21,968	22,563	23,143	23,713	24,275	2.47
TOTAL	21,042	21,887	22,615	22,890	23,518	24,129	24,729	25,320	2.49
Latin America									
Argentina	5,862	5,953	6,047	6,142	6,240	6,340	6,442	6,545	1.60
Brazil	-	-	-	-	-	-	-	-	-
Chile	-	-	-	-	-	-	-	-	-
Peru	-	-	-	-	-	-	-	-	-
Venezuela	-	-	-	-	-	-	-	-	-
TOTAL	5,862	5,953	6,047	6,142	6,240	6,340	6,442	6,545	1.60
Asia—Pacific									
Australia	788	806	822	837	850	863	875	887	1.43
China	-	-	-	-	-	-	-	-	-
Hong Kong	-	-	-	-	-	-	-	-	-
India	-	-	-	-	-	-	-	-	-
Indonesia	-	-	-	-	-	-	-	-	-
Japan	-	-	-	-	-	-	-	-	-
Malaysia	79	86	93	101	109	118	127	136	7.66
New Zealand	137	139	142	145	148	151	153	155	1.55
Philippines	-	-	-	-	-	-	-	-	-
Singapore	-	-	-	-	-	-	-	-	-
South Korea	-	-	-	-	-	-	-	-	-
Taiwan	759	813	859	923	976	1,030	1,085	1,142	5.38
Thailand	-	-	-	-	-	-	-	-	-
TOTAL	1,763	1,844	1,916	2,006	2,083	2,162	2,240	2,320	3.66

Figure 6-5 (Continued)

Decision Support Database: Number of Registered Cardiologist (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Western Europe									
Austria	634	659	683	705	726	745	763	781	2.46
Belgium	343	362	381	401	421	442	463	485	4.83
Denmark	665	700	735	771	808	845	883	922	4.50
Finland	652	666	680	693	706	719	732	745	1.81
France	1,895	1,933	1,970	2,006	2,045	2,085	2,127	2,172	2.03
Germany	4,074	4,275	4,472	4,662	4,849	5,035	5,209	5,379	3.52
Greece	1,678	1,706	1,735	1,764	1,793	1,822	1,852	1,882	1.63
Iceland	47	51	55	59	62	65	68	71	4.62
Ireland	155	165	175	185	196	207	218	229	5.32
Italy	7,057	7,097	7,138	7,179	7,222	7,266	7,312	7,360	0.63
Luxembourg	-	-	-	-	-	-	-	-	-
Netherlands	849	885	921	957	993	1,025	1,057	1,089	3.12
Norway	580	596	612	627	642	656	668	680	1.94
Portugal	621	640	660	682	705	728	753	779	3.38
Spain	2,327	2,411	2,501	2,597	2,701	2,811	2,928	3,050	4.13
Sweden	1,096	1,107	1,118	1,129	1,141	1,153	1,165	1,177	1.04
Switzerland	325	345	365	387	410	435	461	489	6.05
United Kingdom	1,067	1,093	1,119	1,145	1,172	1,200	1,227	1,255	2.31
TOTAL	24,065	24,691	25,320	25,949	26,592	27,239	27,886	28,545	2.39
Eastern Europe									
Czech Republic	547	568	589	610	633	656	681	706	3.71
Hungary	1,546	1,576	1,606	1,640	1,676	1,716	1,758	1,802	2.45
Poland	3,052	3,136	3,219	3,301	3,383	3,464	3,541	3,612	2.21
Russia	-	-	-	-	-	-	-	-	-
Turkey	695	755	818	883	950	1,019	1,090	1,163	6.98
TOTAL	5,840	6,035	6,232	6,434	6,642	6,855	7,070	7,283	3.12
Middle East									
Egypt	-	-	-	-	-	-	-	-	-
Israel	433	451	469	488	507	526	546	566	3.74
Saudi Arabia	-	-	-	-	-	-	-	-	-
TOTAL	433	451	469	488	507	526	546	566	3.74

Figure 6-5 (Continued)

Decision Support Database: Number of Registered Cardiologist (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Africa									
South Africa	173	180	187	194	201	209	216	224	3.68
TOTAL	173	180	187	194	201	209	216	224	3.68
WORLD TOTAL	59,178	61,041	62,786	64,103	65,783	67,460	69,129	70,803	2.48

Definition: The figures in table represent number of cardiologist registered with cardiology association/ Society of the respective countries

Note: 1. Figures for 2003 are Frost & Sullivan Estimates
2. Figures for Argentina represent number of practicing cardiologist

Note: All figures are rounded; the base year is 2003. Source: Frost & Sullivan

Cerebrovascular Mortality

Figure 6-6 represents mortality due to cerebrovascular disease from 1999 to 2006.

Figure 6-6

Decision Support Database: Cerebrovascular Disease Mortality in '000 (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
North America									
Canada	16.4	16.6	16.7	16.9	17.1	17.2	17.4	17.5	0.87
Mexico	26.2	26.9	27.6	28.3	28.9	29.5	30.2	30.8	2.13
United States	167.4	167.7	163.6	163.0	162.5	161.9	161.4	160.8	(0.33)
TOTAL	210.0	211.1	207.9	208.2	208.4	208.6	208.9	209.1	0.12
Latin America									
Argentina	23.2	22.4	22.7	22.6	22.6	22.5	22.5	22.4	(0.21)
Brazil	77.6	77.4	77.2	77.1	76.9	76.7	76.5	76.3	(0.25)
Chile	7.9	8.0	8.1	8.2	8.3	8.3	8.4	8.5	1.00
Peru	3.8	3.9	4.0	4.0	4.1	4.2	4.3	4.3	1.67
Venezuela	9.0	9.3	9.5	9.7	9.9	10.2	10.4	10.6	2.01
TOTAL	121.5	120.9	121.4	121.6	121.7	121.8	122.0	122.1	0.10

Figure 6-6 (Continued)

Decision Support Database: Cerebrovascular Disease Mortality in '000 (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Asia—Pacific									
Australia	12.7	12.7	12.6	12.5	12.5	12.5	12.5	12.5	(0.11)
China	1,648.0	1,651.0	1,653.9	1,656.8	1,659.6	1,662.3	1,665.0	1,667.7	0.16
Hong Kong	3.5	3.6	3.1	3.2	3.4	3.4	3.5	3.5	1.36
India	549.7	558.7	568.1	577.5	587.1	596.9	606.9	617.1	1.68
Indonesia	-	-	-	-	-	-	-	-	-
Japan	139.0	132.5	131.9	130.3	128.7	127.2	125.7	124.2	(1.18)
Malaysia	2.9	2.8	2.7	2.7	2.7	2.7	2.7	2.7	(0.49)
New Zealand	2.4	2.4	2.3	2.3	2.2	2.2	2.2	2.1	(1.83)
Philippines	25.3	26.8	28.3	29.7	31.1	32.5	33.8	35.1	4.16
Singapore	1.6	1.6	1.4	1.4	1.4	1.4	1.3	1.3	(1.48)
South Korea	34.2	34.6	35.0	37.0	37.5	38.1	38.6	39.1	1.43
Taiwan	12.6	13.3	13.1	12.0	11.8	11.7	11.5	11.3	(1.37)
Thailand	11.3	11.2	11.1	11.0	10.9	10.9	10.8	10.6	(1.14)
TOTAL	2,443.2	2,451.2	2,463.5	2,476.4	2,488.9	2,501.5	2,514.4	2,527.2	0.51
Western Europe									
Austria	9.4	8.7	8.1	7.7	7.4	7.1	6.9	6.7	(3.04)
Belgium	9.1	9.0	8.8	8.7	8.6	8.5	8.4	8.3	(1.34)
Denmark	3.3	3.2	3.2	3.1	3.1	3.0	3.0	2.9	(1.77)
Finland	4.7	4.6	4.5	4.3	4.2	4.0	3.9	3.7	(3.67)
France	41.2	40.2	39.3	38.4	37.5	36.7	35.9	35.1	(2.22)
Germany	83.8	77.6	74.6	71.7	68.8	65.9	63.0	60.2	(4.34)
Greece	18.2	17.9	17.7	17.5	17.2	17.0	16.8	16.5	(1.41)
Iceland	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	(2.00)
Ireland	2.7	2.8	2.6	2.4	2.3	2.2	2.1	2.1	(2.88)
Italy	65.1	62.4	61.4	60.5	59.6	58.7	57.9	57.1	(1.42)
Luxembourg	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4	(0.82)
Netherlands	11.9	11.6	11.4	11.2	11.0	10.8	10.6	10.5	(1.60)
Norway	4.5	4.3	4.0	3.9	3.7	3.6	3.4	3.3	(4.03)
Portugal	21.6	21.3	21.0	20.8	20.5	20.3	20.1	19.9	(1.02)
Spain	36.7	36.0	35.4	34.9	34.4	33.9	33.4	32.9	(1.43)

Figure 6-6 (Continued)

Decision Support Database: Cerebrovascular Disease Mortality in '000 (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Sweden	10.3	10.2	10.1	10.0	10.0	9.9	9.8	9.8	(0.51)
Switzerland	2.9	2.7	2.6	2.6	2.5	2.4	2.4	2.3	(2.89)
United Kingdom	64.3	62.5	60.8	59.1	57.4	55.8	54.1	52.6	(2.91)
TOTAL	390.1	375.4	366.1	357.1	348.6	340.3	332.2	324.3	(2.38)
Eastern Europe									
Czech Republic	15.8	15.7	15.4	15.1	14.8	14.4	14.0	13.7	(2.55)
Hungary	18.0	17.3	16.9	16.4	16.0	15.6	15.2	14.8	(2.57)
Poland	31.1	29.9	29.7	29.5	29.2	29.0	28.8	28.6	(0.70)
Russia	440.5	451.7	457.2	460.8	466.4	472.0	477.3	482.6	1.14
Turkey	-	-	-	-	-	-	-	-	-
TOTAL	505.3	514.6	519.2	521.8	526.4	531.0	535.3	539.7	0.83
Middle East									
Egypt	16.8	17.2	17.7	18.2	18.6	19.1	19.6	20.2	2.65
Israel	2.2	2.2	2.1	2.0	1.9	1.8	1.7	1.7	(4.26)
Saudi Arabia	-	-	-	-	-	-	-	-	-
TOTAL	19.0	19.4	19.8	20.1	20.5	20.9	21.4	21.8	2.05
Africa									
South Africa	-	-	-	-	-	-	-	-	-
TOTAL	-	-	-	-	-	-	-	-	-
WORLD TOTAL	3,689.0	3,692.7	3,697.9	3,705.1	3,714.4	3,724.1	3,734.0	3,744.2	0.27

Definition: The above figure represents mortality due to Cerebrovascular disease. Cerebrovascular disease include all types of hemorrhage, occlusion and stenosis, cerebral ischemia, ill-defined Cerebrovascular disease, late effects of Cerebrovascular disease, etc.

Note: 1. Hyphen indicates non availability of data

Note: All figures are rounded; the base year is 2003. Source: Frost & Sullivan

Cerbrovasular Hospital Discharge

Figures 6-7 represent the number of patients discharged from hospital's after being treated for cerebrovascular diseases from 1999 to 2006.

Figure 6-7

Decision Support Database: Number of Cerebrovascular Disease Hospital Discharges in '000 (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
North America									
Canada	63.5	63.6	63.7	63.8	63.9	64.1	64.2	64.4	0.26
Mexico	-	-	-	-	-	-	-	-	-
United States	888.5	925.8	964.2	1,003.8	1,044.4	1,086.2	1,129.1	1,173.2	3.95
TOTAL	952.0	989.4	1,027.9	1,067.5	1,108.3	1,150.3	1,193.3	1,237.6	3.74
Latin America									
Argentina	-	-	-	-	-	-	-	-	-
Brazil	-	-	-	-	-	-	-	-	-
Chile	-	-	-	-	-	-	-	-	-
Peru	-	-	-	-	-	-	-	-	-
Venezuela	-	-	-	-	-	-	-	-	-
TOTAL	-	-	-	-	-	-	-	-	-
Asia—Pacific									
Australia	43.9	44.9	45.9	46.9	48.0	49.1	50.2	51.3	2.24
China	1,682.5	1,723.1	1,763.7	1,804.4	1,845.1	1,885.8	1,926.6	1,967.5	2.16
Hong Kong	16.4	17.0	17.6	18.2	18.9	19.5	20.2	20.9	3.46
India	-	-	-	-	-	-	-	-	-
Indonesia	-	-	-	-	-	-	-	-	-
Japan	170.2	174.4	178.6	182.8	187.1	191.4	195.7	200.0	2.25
Malaysia	17.8	18.8	19.8	20.8	21.8	22.8	23.9	24.9	4.58
New Zealand	6.5	6.6	6.8	7.0	7.2	7.4	7.6	7.8	2.75
Philippines	-	-	-	-	-	-	-	-	-
Singapore	9.9	10.4	10.9	11.5	12.0	12.6	13.1	13.7	4.43
South Korea	-	-	-	-	-	-	-	-	-
Taiwan	-	-	-	-	-	-	-	-	-
Thailand	175.7	181.4	187.3	193.3	199.4	205.6	212.0	218.5	3.10
TOTAL	2,122.7	2,176.5	2,230.6	2,284.9	2,339.4	2,394.2	2,449.3	2,504.6	2.30

Figure 6-7 (Continued)

Decision Support Database: Number of Cerebrovascular Disease Hospital Discharges in '000 (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Western Europe									
Austria	15.6	15.9	16.3	16.6	16.9	17.2	17.5	17.9	1.88
Belgium	23.6	23.9	24.3	24.6	25.0	25.4	25.7	26.1	1.45
Denmark	10.3	10.5	10.6	10.8	11.0	11.1	11.3	11.5	1.59
Finland	10.5	10.2	10.0	9.8	9.6	9.5	9.3	9.2	(1.58)
France	143.9	145.8	147.5	149.1	150.6	151.9	153.1	154.1	0.77
Germany	214.2	220.2	226.6	233.6	240.7	248.0	255.4	263.1	3.01
Greece	20.9	21.3	21.8	22.3	22.7	23.2	23.7	24.2	2.11
Iceland	-	-	-	-	-	-	-	-	-
Ireland	7.3	7.5	7.7	7.9	8.1	8.3	8.5	8.7	2.57
Italy	130.0	135.1	140.3	145.6	151.0	156.5	162.1	167.8	3.58
Luxembourg	1.1	1.2	1.2	1.2	1.2	1.3	1.3	1.4	3.13
Netherlands	34.8	35.4	36.0	36.7	37.3	38.0	38.7	39.4	1.76
Norway	14.3	14.4	14.5	14.6	14.8	14.9	15.1	15.2	1.01
Portugal	26.6	26.9	27.3	27.6	27.9	28.2	28.6	28.9	1.20
Spain	87.2	88.3	89.5	90.6	91.8	92.9	94.1	95.2	1.25
Sweden	17.7	18.1	18.5	18.8	19.2	19.6	20.0	20.3	1.94
Switzerland	14.6	14.9	15.3	15.6	15.9	16.2	16.6	16.9	2.11
United Kingdom	164.5	167.8	171.3	174.9	178.6	182.4	186.3	190.2	2.12
TOTAL	937.0	957.4	978.5	1,000.2	1,022.3	1,044.6	1,067.2	1,090.1	2.16
Eastern Europe									
Czech Republic	13.0	13.3	13.6	13.9	14.3	14.6	14.9	15.3	2.33
Hungary	52.1	52.9	53.7	54.5	55.3	56.1	56.9	57.7	1.46
Poland	62.6	63.7	64.8	65.9	67.1	68.2	69.3	70.4	1.65
Russia	368.9	376.6	385.0	394.1	404.4	414.7	425.1	435.6	2.51
Turkey	70.3	73.1	76.0	78.8	81.8	84.7	87.7	90.7	3.50
TOTAL	566.8	579.6	593.1	607.3	622.7	638.3	653.9	669.7	2.45
Middle East									
Egypt	54.4	56.3	58.3	60.4	62.6	64.9	67.3	69.7	3.67
Israel	11.0	11.3	11.6	11.8	12.1	12.4	12.7	13.0	2.34
Saudi Arabia	-	-	-	-	-	-	-	-	-
TOTAL	65.4	67.6	69.8	72.2	74.7	77.3	80.0	82.7	3.46

Figure 6-7 (Continued)

Decision Support Database: Number of Cerebrovascular Disease Hospital Discharges in '000 (World), 1999-2006

Region / Country	1999	2000	2001	2002	2003	2004	2005	2006	CAGR % (2003-2006)
Africa									
South Africa	-	-	-	-	-	-	-	-	-
TOTAL	-	-	-	-	-	-	-	-	-
WORLD TOTAL	4,643.9	4,770.5	4,899.9	5,032.2	5,167.4	5,304.7	5,443.7	5,584.7	2.62

Definition: Figures in the tables represent number of patients discharged from Hospital's after being treated for Cerebrovascular diseases

Note: 1. Hyphen indicates non availability of data

Note: All figures are rounded; the base year is 2003. Source: Frost & Sullivan