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Non-Confidential

Mitral Valve Repair Device

The following information resulted from the analysis of this innovation by the e-Zassi™ Technology Assessment Software Platform. The Mitral Valve Repair Device is a medical device used in the cardiovascular surgery segment of the cardiovascular market. It is designed for long-term use or permanent implantation. It is expected to be used in the hospital (inpatient department) by a surgeon. Improved procedural efficiency is expected as a result of using the Mitral Valve Repair Device.

Nature of Technology – Summary Table

Type of Device:	Medical Device	Learn more
Device Regulatory Classification:	US: Class II EU: Class III	Learn more
Regulatory Status:	US: A regulatory submission is required, but not yet filed. EU: A regulatory filing is required but has not been submitted.	Learn more
Primary Intended Use:	Treatment	Learn more
Primary and Secondary Users:	Surgeon	Learn more
Key Purchasing Decision Maker:	Surgeon	Learn more
Reimbursement Outlook:	Likely existing coverage applies	Learn more
Intellectual Property Status:	One or more patents are issued. Patent applications are pending.	Learn more
Clinical Specialty / Market:	Cardiovascular	Learn more
Market Segment / Sub-Segment:	Cardiovascular surgery / Prosthetic heart valve (including heart valve repair devices).	Learn more
Pre-Clinical / Clinical Research Status:	Pre-clinical in-vitro testing is complete. Animal testing is complete. First-in-man trial is complete.	Learn more
Advantages and Benefits:	Improved procedural efficiency. Shorter surgical procedure time.	Learn more
Grant Matching Results:	6 Federal/State Grant(s)	Learn more
Manufacturing Build Status:	Three dimensional computer model(s). Functional prototype(s) for in-vitro/animal testing.	Learn more

Maturity of Innovation



Regulatory

This section of the report includes the likely US and EU regulatory parameters and classifications for the technology.

US Regulatory

US Regulatory Status: A regulatory submission is required, but not yet filed

FDA Submission No.: Not Applicable

FDA Clearance/Approval Date: Not Applicable

FDA Regulation / Device Classification / Predicate Product Code / Regulatory Pathway:

FDA Regulation No: 870.3800

FDA Regulation Name: annuloplasty ring

Product Code	Product Code Title	Classification	Regulatory Pathway
KRH	Ring, Annuloplasty	Class II	510(k)

European Union (EU) Regulatory

EU Regulatory Status: A regulatory filing is required but has not been submitted

EU Device Classification / Regulatory Pathway:

Classification	Regulatory Pathway
Class III	CE Mark / Design Dossier / Full Quality Management System

The Mitral Valve Repair Device may be classified as a Class III device according to the European Union (EU) Medical Device Directive. Class III devices typically involve the most risk to patients; they include devices that contact the central nervous system or heart, or are absorbed by the body.

The information presented within this report does not represent or intend to be an opinion, a suggestion, a comment, or a decision from the FDA, or any of its authorities, agents, employees, or third party representatives. This information is an estimate and is intended as preparation for conversations with the appropriate regulatory authority or regulatory consultant. All aspects of the technology must be evaluated in order to make an accurate classification. The regulatory authority or regulatory consultant can assist in fully assessing the technology. Ultimately, the regulatory authority reserves responsibility for classifying a new medical device.

Clinical

Pre-Clinical Research Status

The following table is an overview of the pre-clinical trials that involve the use of animals.

Table I – Pre-Clinical Research Status	
In-Vitro Bench Testing Status: Pre-clinical in-vitro testing is complete	Animal Testing Status: Animal testing is complete

Clinical Research Status

The following table is an overview of the clinical trials that involve the participation of human subjects.

Table II – Clinical Research Status	
Types of Human Clinical Research Conducted: First-in-man Trial	Pilot Trial Results (US, EU): None Provided
Clinical Trials Location: European Union	Pivotal Trial Results (US, EU): None Provided
Clinical Data Available to Support Claims: User reports the data does not support any claim at this time	Regulatory Confirmation of US/EU GCP Compliance: Yes
Clinical Research Published: No	Which regulatory body confirmed GCP Compliance? EU Notified Body
FDA Clinical Strategy Meeting: Met with FDA prior to clinical trials	

Table III – Overview of Essential Documents Collected for Clinical Trial(s)	
Type of Essential Documents Collected for Clinical Trial(s): Essential documents collected before the clinical phase of the trial started as outlined in ICH GCP Section 8.2 Essential documents were collected during the clinical conduct of the trial as outlined in ICH GCP Section 8.3 No essential documents were collected	Specific Essential Documents Collected During the Trial(s) (ICH GCP 8.3]*: Signed informed consents Subject screening and enrollment logs

Reimbursement

US Reimbursement

The overall potential coverage was calculated as a function of a variety of inputs. The following table describes the likelihood of the Mitral Valve Repair Device having existing reimbursement coverage in the US:

Overall Potential Coverage:	Likely existing coverage applies
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The author completing this assessment has provided the following US reimbursement code status:

ICD-9-CM:	An ICD-9-CM code is identified
CPT:	An associated CPT code is expected to exist
HCPCS:	An associated HCPCS code is expected to exist

German Reimbursement

In Germany there are two different reimbursement systems; the German Diagnostic Related Group (G-DRG) system; and the doctor's fee scale reimbursement system, EBM-Code: (Einheitlicher Bewertungsmaßstab = EBM). The following table describes the likelihood of the Mitral Valve Repair Device having existing reimbursement coverage in Germany:

G-DRG:	A G-DRG code is identified
EBM-Code:	An EBM-Code is identified
OPS:	An associated OPS code is expected to exist
Therapeutic Appliance List:	A Therapeutic Appliances List code is identified
ICD-10:	An ICD-10-CM code exists

Intellectual Property

The following information characterizes the intellectual property status of the Mitral Valve Repair Device.

Patent Status

- One or more patents are issued
- Patent applications are pending
- Patent #1 is issued in the U.S.
- The Patent #1 patent application was a Provisional Application
- 04/26/07

An oral opinion from a patent attorney evaluating the patentability of the Mitral Valve Repair Device was rendered.

Intellectual Property Ownership and Encumbrances

The following individuals or organizations may have intellectual property rights to the Mitral Valve Repair Device:

Co-inventor may have rights, Academic institution may have rights, Research organization may have rights

It is uncertain if encumbrances or contractual obligations for the Mitral Valve Repair Device exist. More information is needed to determine if such obligations exist for the Mitral Valve Repair Device.

Public Disclosure and Public Use

The following table provides information on the status of public disclosure and public use for the Mitral Valve Repair Device:

Public Disclosure and Use	Status	Date of Occurrence
Public Use:	No Public Use has occurred	None Provided
Public Disclosure:	Public Disclosure has occurred	02/23/08

Trademark and Copyright Status

The following table provides information on the trademark and copyright status of the Mitral Valve Repair Device:

Trademarks and Copyrights	Status	Type
Trademarks:	Trademark filed but not issued	Trade mark
Copyrights:	None Provided	None Provided

Litigation Status

The Mitral Valve Repair Device is currently involved in litigation or a legal dispute.

Technology Platform Considerations

The Mitral Valve Repair Device is identified as a product versus a technology platform.

Product Development and Manufacturing

The innovator has reported the following information regarding the manufacturing status of the Mitral Valve Repair Device:

- manufacturer not selected or being considered

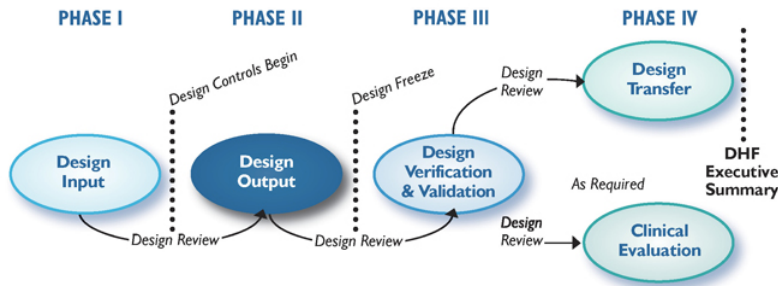
Medical Device Design Control Development Phase

The innovator has reported the following for the Mitral Valve Repair Device:

Level of planning:	Business Plan, High Level Plan (25 to 100 lines)
Level of documentation:	Engineering drawing package (bench/animal prototypes)

Product build status:	Three dimensional computer model(s), Functional prototype(s) for in-vitro/animal testing
Design control system:	In compliance to Good Manufacturing Practices (GMP)
Development stage:	Phase II Design Output

The following chart depicts the typical formal design control process phase with the current phase of development (Phase II Design Output) highlighted.



The following depicts the status of the design control deliverables at the time of this report:

Phase I Design Input

The concept document complete and released to formal documentation control	Complete
The marketing/user needs specification complete and released to formal document control	Complete
The design specification complete and released to formal document control	Complete
The hazard analysis complete and released to formal document control	Complete
The design failure mode and effects analysis (DFMEA) complete and released to formal document control	Complete
The process failure mode and effects analysis (PFMEA) drafted	Complete
The phase I design input design review conducted and approved	Complete

Phase II Design Output

The design input document updated and under formal document control	Incomplete
The device master record (DMR) complete, updated, and under formal document control	Incomplete
The risk analysis updated and under formal document control	Incomplete
The master design verification and validation plan established	Incomplete
The suppliers selected and qualifications in process	Incomplete
The initial transfer cost of goods sold (TCOGS) drafted	Incomplete

The phase II design output design review conducted and approved. The minutes from the design I input design review examined and all action items sufficiently closed out.	Incomplete
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Phase III Design Verification and Validation

The design specification testing including all label performance claims complete	Incomplete
The biocompatibility and accelerated aging and/or ship testing complete	Incomplete
The manufacturing and quality procedures under formal document control and training initiated	Incomplete
The process validation (PV) protocols drafted, installation qualifications (IQs) and/or operational qualifications (OQs) complete, and the process qualifications (PQs) and product performance qualifications (PPQs) approved	Incomplete
The final manufacturing plan and the transfer cost of goods sold (TCOGS) established and up to date	Incomplete
The regulatory submission, clinical investigational exemption (IDE), or the institution review board (IRB) protocols and preparation fully complete	Incomplete
The phase III design verification and validation design review conducted and approved. The minutes from the phase II design output design review examined and all action items sufficiently closed out.	Incomplete

Phase IV Design Transfer

The process validation (PV), installation qualification (IQ), operational qualification (OQ), process qualification (PQ), product performance qualifications (PPQs), and supplier qualifications approved	Incomplete
The device master record (DMR) complete, updated, and under formal document control	Incomplete
The training and pertinent documentation updated and complete	Incomplete
The design-related material review boards (MRB) closed and corrective action requests (CAR) implemented	Incomplete
The bill of materials (BOM) successfully transferred to manufacturing and/or the procurement specialist. Also, ownership of tools, machines, and gauges documented	Incomplete
The initial build order submitted and the forecast updated	Incomplete
The phase IV design transfer design review conducted and approved. The minutes from the phase III design verification and validation design review examined and all action items closed.	Incomplete

Material Biocompatibility Considerations and Status

The user provided the following information for the technology during the interview process:

Device Type:	Surgical Implant
Patient Contact Type:	Direct patient contact with tissue, tissue fluid, bone or dentin, organs(s), blood, directly (circulating) for more than 30 days
Sterility Requirements:	Sterile when used

Biocompatibility Test:	Current Status:
Cytotoxicity	Incomplete
Sensitization	Incomplete
Irritation or Intracutaneous Reactivity	Incomplete
System Toxicity (Acute) and Pyrogenicity	More Information Required
Sub-chronic Toxicity (Sub-acute)	Incomplete
Biocompatibility Genotoxicity Test Status	More Information Required
Biocompatibility Implantation Test Status	Complete
Haemocompatibility	Incomplete
Chronic Toxicity	Incomplete
Carcinogenicity	Complete
Reproductive Developmental	Not Required
Biodegradable	Not Required

Grant Eligibility

The following grant opportunities have been identified as potential matches for the Mitral Valve Repair Device.

Grant Name	Description	Contact Info
National Institute of Health SBIR 2008 - 2009 National Heart, Lung, and Blood Institute Division of Cardiovascular Diseases http://www.nhlbi.nih.gov	Cardiovascular implants (heart valves, vascular grafts, stents, pacemakers, defibrillators, etc)	J. Timothy Baldwin, Ph.D. Pothur R. Srinivas, PhD 301-435-0513, 301-435-0550 baldwint@nhlbi.nih.gov ; srinivap@nhlbi.nih.gov
National Institute of Health SBIR 2008 - 2009 National Heart, Lung, and Blood Institute Division of Cardiovascular Diseases http://www.nhlbi.nih.gov	Cardiovascular Medical Implants-Preservation methods	J. Timothy Baldwin, Ph.D. Pothur R. Srinivas, PhD 301-435-0513, 301-435-0550 baldwint@nhlbi.nih.gov ; srinivap@nhlbi.nih.gov ;
National Institute of Health SBIR 2008 - 2009 National Institute of Biomedical Imaging and Bioengineering http://www.nibib.nih.gov	Biomaterials. Development of new or novel biomaterials that can be used for a broad spectrum of biomedical applications such as implantable devices; drug and gene delivery; tissue engineering; imaging agents; and biosensors and actuators. Research that is	Mr. Todd Merchak 301-496-8592 Tm311u@nih.gov
National Institute of Health SBIR 2008 - 2009 National Institute of	Biomechanics and Rehabilitation Engineering. Research on	Mr. Todd Merchak 301-496-8592 Tm311u@nih.gov

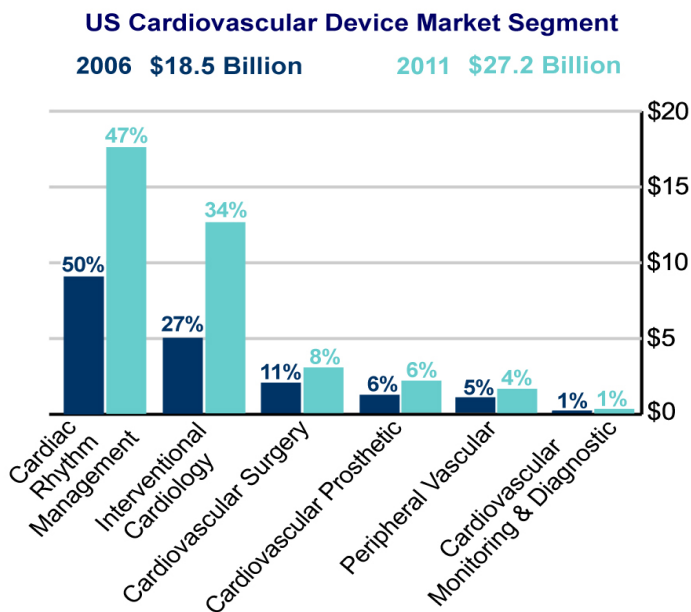
Biomedical Imaging and Bioengineering http://www.nibib.nih.gov	biomechanics which can be applied to a broad range of applications including implants, prosthetics, clinical gait and posture biomechanics, traumatic injury, repair processes, rehabilitation, sports	
National Institute of Health SBIR 2008 - 2009 National Institute of Biomedical Imaging and Bioengineering http://www.nibib.nih.gov	Medical Devices and Implant Science. Design, development, evaluation and validation of medical devices and implants. This includes exploratory research on next generation concepts for diagnostic and therapeutic devices; development of tools for assessing	Mr. Todd Merchak 301-496-8592 Tm311u@nih.gov
Florida Opportunity Fund (S/E) http://floridaopportunityfund.com/	Florida Opportunity Fund ("FOF") is a fund of funds that directs investments into venture capital fund managers who in turn invest in seed and early stage concepts in Florida. Sponsored by Enterprise Florida, it is in-start-up phase.	mailto:jennifer@floridaopportunityfund.com

Market Landscape

Market Overview / Environmental Assessment United States Cardiovascular Market

The United States (US) market for cardiovascular devices in 2006 was the largest in the world with revenues of between \$13.5 billion (Millennium) and \$18.5 billion (GMD). The difference between the market estimates may be the result of how each research organization recognizes, places, and/or calculates data and products within the cardiovascular device market segments and categories. By 2011, GMD projects the cardiovascular device market at \$37.2 billion in revenues. As in the global market, the largest share of the market in the US is held by cardiac rhythm management (CRM) devices (50%), followed by interventional cardiology devices (27%).

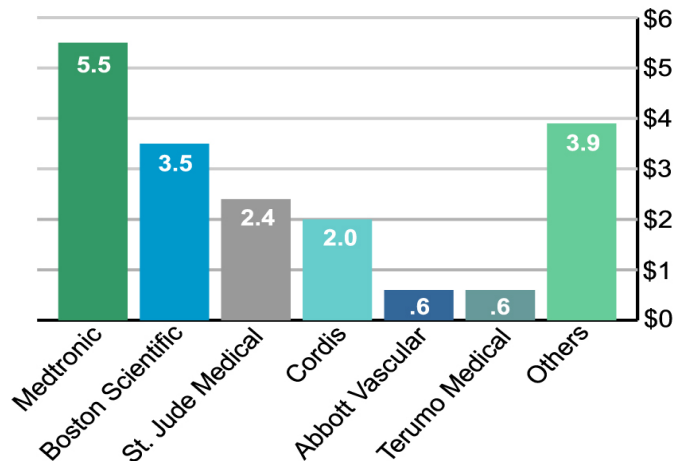
(Global Markets Direct, *Cardiovascular Device Market Profile*, 2008)
(Millennium Research Group, *US Markets for Cardiac Surgery*, 2007)



The most rapidly growing segments of the US market - interventional cardiology, rhythm management, and prosthetic devices - mirror the global market. By 2011, the interventional cardiology segment will generate a compound annual growth rate (CAGR) of 20% in revenues. Whereas, rhythm management, and prosthetic devices will each generate a CAGR of 12% in revenues.

With the exception of cardiovascular monitoring and diagnostic devices, more than 85% of all cardiovascular devices are distributed to hospitals. Rehabilitation centers, clinics, long-term care (LTC) centers, acute care centers, and laboratories receive 25% of the monitoring and diagnostic devices.

2006 US Cardiovascular Device Revenues
Total \$18.5 Billion



Competition

The two leading manufacturers of cardiovascular devices in the US, based on market share, are Medtronic and Boston Scientific. Other leading competitors, in descending order of market share, are: St. Jude Medical, Cordis, Terumo Medical Corporation, and Abbott.

In the US, some of the cardiovascular device segments have one company as the dominant market share leader, while other segments are lead by a group designated as "others." This designation may represent many companies that individually have a niche product or products in that segment. Market segments and leading shareholders are:

- Interventional cardiology, Cordis (33%)
- Peripheral vascular devices, Cordis (31%)
- Cardiac rhythm management, Medtronic (48%)
- Cardiovascular surgery, Others (47%)
- Cardiovascular prosthetic devices, Others (39%)

In the US, GE Healthcare emerges as the leading manufacturer of cardiovascular monitoring and diagnostic devices with a 34% market share; however, these devices make up only 1% of the total market for cardiovascular devices.

(Global Markets Direct, *Cardiovascular Device Market Profile*, 2008)
(Millennium Research Group, *US Markets for Cardiac Surgery*, 2007)

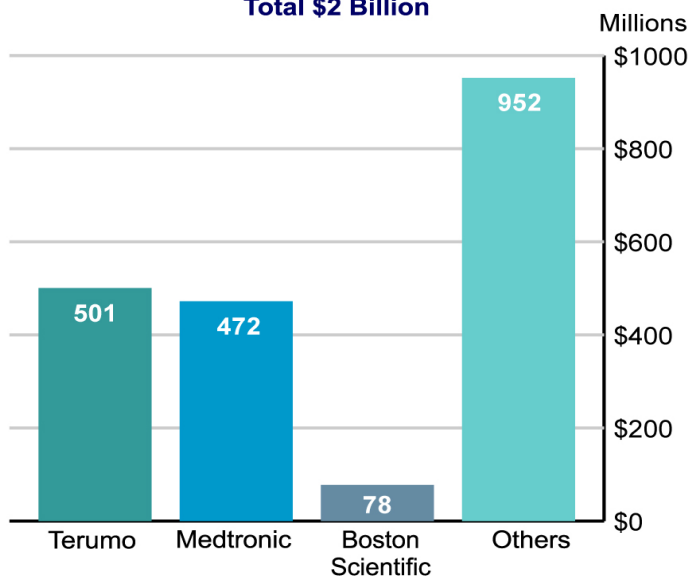
Cardiovascular Surgery & Prosthetic Devices Segment

It is important to know that statistics and information about the cardiovascular surgery and prosthetic device segments of the cardiovascular marketplace are provided by market research organizations in either a separated or combined format. In order to facilitate identification of the innovation, the segments are combined in this section of the Innovation Diagnostic Tool.

Leading products in the current US cardiovascular surgery device market are known as “beating heart surgical systems” that allow surgery to be performed while the heart continues to function. Some heart valve devices and coronary artery bypass graft (CABG) devices, both on and off pump, are also included in this segment. With new innovations and the introduction of less invasive surgical procedures, the population that is treatable is expected to expand. As a result, the current market is expected to grow substantially by 2011 from approximately \$2 billion in 2006.

Other products within the cardiovascular surgery segment are endoscopic vessel harvesting (EVH) devices, cardiac ablation devices, anastomosis assist devices (AAD)s, and transmyocardial laser revascularization (TMR) devices.

2006 US Cardiovascular Surgery Device Segment
Total \$2 Billion



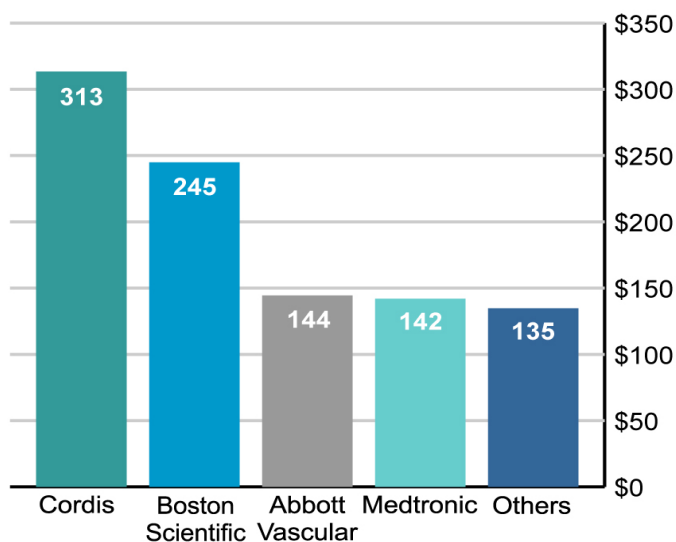
Products in the US cardiovascular prosthetic device market segment include tissue and mechanical heart valves, artificial hearts, and cardiac assist devices. Cardiac assist devices provide support to a poorly functioning heart by allowing it to rest and heal, eventually returning the heart to normal function. This device can be a full or total artificial heart (TAH) or a left ventricular assist device (LVAD). This segment also includes intra-aortic balloon pumps (IABP) used most often in emergency situations.

In the US, more than five million individuals have been diagnosed with congestive heart failure; of these, 20% are expected to develop disease of the aortic or mitral valve. Treatment involves medical management or surgical intervention. In 2006, the heart valve market was estimated to be over \$500 million.

By 2011, market growth in the valve market segment will be enhanced by the highly anticipated introduction of two minimally invasive percutaneous heart valve therapy (PHVT) procedures - percutaneous mitral valve repair (PMVR) and percutaneous aortic valve replacement (PAVR). Both procedures are expected to have an impact on the market providing an alternative for patients who are not suited to the more invasive open-heart surgery procedure.

Revenues in the US for cardiovascular prosthetic devices are expected to increase by a compound annual growth rate (CAGR) of over 12% by 2011.

**2006 US Peripheral Vascular Device Segment
Total Market \$979 Million**



Competition

The manufacture of cardiovascular surgery devices in the US is led by "others" (47%), indicating there are many companies in this segment. Some of these companies specialize in a particular segment of the surgery device market and/or may own a niche segment of this market. Terumo is second after "others" in this segment (25%), followed by Medtronic (24%) and Boston Scientific with a 4% market share.

In the cardiovascular prosthetic device segment, the market is led by a group designated as "others" with 40% of the revenue share. This designation may represent many companies that individually have a niche product or products in that segment. The "others" group is followed by Edwards Lifesciences (19%), St. Jude Medical (13%), Medtronic (8%), Thoratec (8%), Datascope (7%), and Arrow International (5%).

Approximately 18 companies participate in the US heart valve marketplace. The leaders in order of market share are Edwards Lifesciences, Medtronic, and St. Jude Medical.

(Global Markets Direct, *Cardiovascular Devices Market Profile*, 2008)

(Millennium Research Group, *US Markets for Cardiac Surgery*, 2007)

Prosthetic Heart Valve Segment

The entire US heart valve device market segment, which includes tissue and mechanical valves and valve repair devices, was valued just under \$570 million in 2006. Supported by an aging population, new devices and techniques, and minimally invasive procedures, the market is expected to grow.

Heart valve replacement is accomplished with either tissue (biological), or mechanical valves. The use of mechanical valves continues to decline due to issues with safety and long-term management of anticoagulation therapy post surgery. The market for mechanical valves was reported to be slightly under \$100 million in 2006.

The tissue valve market in 2006 was 50% of the total heart valve market and is expected to grow to \$400 million by 2011. However, the introduction of percutaneous heart valve technology (PHVT) procedures may affect the upward momentum of tissue heart valves. The usual choices for tissue heart valve devices are allografts and xenografts, either as stent grafts or stentless grafts.

Heart Valve Repair Devices

In the current market, heart valve repair devices continue to be preferred over heart valve replacement devices due to positive clinical results and surgeon acceptance. Repair devices are of four types: rigid, semi-rigid, bands, and flexible. This market will continue to grow, but may be negatively influenced by the introduction of percutaneous mitral valve repair (PMVR). In 2006, this market was estimated at just above \$70 million.

Percutaneous Heart Therapy

By 2011, market growth in the heart valve segment will be enhanced by the highly anticipated introduction of two minimally invasive percutaneous heart valve therapy (PHVT) procedures - percutaneous mitral valve repair (PMVR) and percutaneous aortic valve replacement (PAVR). Both procedures are expected to have an impact on the market providing an alternative for patients who are not suited to the more invasive open-heart surgery procedure.

Revenues in the US for all cardiovascular prosthetic devices are expected to increase by a compound annual growth rate (CAGR) of over 12% by 2011.

Competition

Approximately 18 companies participate in the heart valve marketplace. The leaders in the US in order of market share are Edwards Lifesciences, Medtronic, and St. Jude Medical.

Each company within this market has its own specialty. Edwards Lifesciences leads in heart valve replacement and repair, while Medtronic is second in the heart valve market alone. St. Jude Medical has the leading share of the mechanical heart valve device market.

The entire valve replacement market is expected to grow with the increase in use of biological valves, which last longer and are considered to have less risk of failure. The life of a biological tissue valve replacement is likely to last the life of the recipient.

(Millennium Research Group, *US Markets for Interventional Cardiology Devices 2008, 2007*)

Market Overview / Environmental Assessment European Cardiovascular Market

In 2006, the European market for cardiovascular devices was valued at \$9.4 billion. By 2011, this market is projected to generate \$16.2 billion in revenues. As in the global market, in Europe, the largest share of the market is held by cardiac rhythm management devices (47%), followed by interventional cardiology devices (21%). The most rapidly growing segments of the market include; interventional cardiology, rhythm management, and prosthetic devices. These device segments closely resemble the growth of the global market, and are expected to exceed a 11% compound annual growth rate (CAGR) for revenues by 2011.

The European Cardiovascular Market includes:

- Cardiac rhythm management devices (47%)
- Interventional cardiology devices (21%)
- Cardiovascular surgery (17%)
- Cardiovascular prosthetic devices (6%)
- Peripheral vascular devices (6%)
- Monitoring and diagnostic catheters (3%)

Forecast Revenue and Market Share Growth

In Europe, cardiovascular devices in the interventional cardiology and peripheral vascular categories are distributed to either hospitals (90%) or to rehabilitation centers (10%). Cardiac rhythm management, cardiovascular surgery, and cardiac prosthetic devices are distributed exclusively to hospitals. Rehabilitation centers, clinics, long-term care, and acute care centers combined, receive 25% of the cardiovascular monitoring and diagnostic devices. The remaining 75% of devices in this category are distributed to hospitals.

(Global Markets Direct, *Cardiovascular Devices Market Profile*, 2008)

Competition

In Europe, the two leading manufacturers of cardiovascular devices, based on market share are Medtronic and Boston Scientific. Other leading competitors, in declining order of market share, are; St. Jude Medical, Cordis, Sorin, Biotronik, Terumo Medical Corporation, and Guidant.

In Europe, some of the cardiovascular device categories have one company as the dominant market share leader, while other categories are led by an "other" companies designation. This designation may represent many companies that individually have a niche product or products in that category.

Market category and leading shareholders are:

- Interventional cardiology, Others (31%)
- Peripheral vascular devices, Cordis (35%)
- Cardiac rhythm management, Medtronic (36%)
- Cardiovascular surgery, Others (47%)
- Cardiac prosthetic devices, and Others (41%).

In Europe, Philips Medical Systems emerges as the major manufacturer of cardiac monitoring and diagnostic devices with a 32% market share. However, these devices make up only 3% of the total market for cardiovascular devices.

(Global Markets Direct, *Cardiovascular Devices Market Profile, 2008*)
(Millennium Research Group, *US Markets for Cardiac Surgery 2007, 2007*)

European Cardiovascular Surgery and Prosthetic Devices Market Segment

It is important to know that statistics and information about the cardiovascular surgery and prosthetic device segments of the cardiovascular marketplace are provided by market research organizations in either a separated or combined format. In order to facilitate identification of the innovation, the segments are combined in this section of the Innovation Diagnostic Tool.

In 2006, the cardiac surgery device market in Europe was valued at over \$400 million. The market is comprised of three main segments: heart valve replacement, coronary assist devices and coronary artery bypass surgery devices. A smaller market exists for vein harvesting, atrial assist devices and surgical ablation devices. In 2011, the market will shift as coronary artery bypass graft (CABG) procedures stabilize and heart valve replacement procedures increase. Endovascular vein harvesting to provide a conduit for bypass grafts, either in the peripheral vascular device sector or for coronary surgery, will show a slight growth as will atrial assist devices. The coronary assist device market will remain constant with small growth.

The cardiovascular surgery market may grow for the first time in years due to the failure of coronary stents prompting many clinicians to favor bypass over stenting. The increase includes:

- Endoscopic vessel harvesting for the bypass conduits
- Anastomosis assist devices to facilitate the bypass around heart blockages
- Cardiac assist devices such as the intra-aortic balloon pump and atrial fibrillation ablation devices
- Mitral, aortic and tricuspid valve replacement
- A small market exists for cardiac revascularization devices. Cardiac revascularization devices are used to help the heart build collateral circulation and new arteries. Lasers are used to bore a hole near the blockage and encourage the blood to move through collateral arteries which grow from the laser opening. This procedure is declining as most of the scientific proof of the benefit has not been definitively or clinically proven.

Included in the European cardiovascular surgery market are cardiovascular prosthetic devices such as stent grafts and prosthetic synthetics grafts made from biocompatible materials; two examples are polyurethane and polytetrafluoroethylene (ePTFE). Initial results have been less than successful due to the nature of the artery these devices are meant to replace. An artery has a muscular characteristic that keeps the blood flowing without clotting. The prosthetic devices have a tendency to clot easily. Unless a superior material is found with the ability to address clotting, it is unlikely that the grafts made from non-biological materials will gain increased adoption.

Other types of prosthetic devices include mechanical valves and ventricular assist devices. This is a rapidly growing segment as patients are symptomatic before the valve or ventricle fails, providing an opportunity for medical intervention. The mechanical heart valve market in Europe is expected to grow at

approximately 20% in the next five years and is a viable use of non- biologic devices to treat a growing market segment.

Competition

The manufacture of cardiovascular surgery devices in Europe is led by "others" (37%), indicating there may be many companies in this category. Some of these companies specialize in a particular area of the surgery device market and/or may focus on a niche product or products. Terumo (22%) is followed by Medtronic (16%), Sorin (14%), Edwards Lifesciences (5%), Boston Scientific (5%) and Guidant (1%).

The cardiovascular prosthetic device market segment is also led by "others" (41%), followed by Edwards Lifesciences (18%), St. Jude Medical (14%), Sorin (9%), Medtronic (7%), Datascope (7%), and Thoratec (4%).

(Global Markets Direct, *Cardiovascular Devices Market Profile*, 2008)

(Millennium Research, *European Markets for Cardiac Surgery Devices*, 2007)

Prosthetic Heart Valve Segment

The European market for heart valve devices in 2006 was over \$150 million. This includes tissue valves, mechanical valves and valve repair annuloplasty devices.

Heart valve replacement is accomplished with either tissue, biological, or mechanical valves. The use of mechanical valves continues to decline due to issues with safety and long term management of anticoagulation therapy following surgery. The introduction of percutaneous heart valve technology (PHVT) procedures may affect the upward momentum of tissue heart valves. The usual choices for tissue heart valve devices are allografts and xenografts, either as stent grafts or stentless grafts.

Heart Valve Repair Devices

In the current market, heart valve repair devices continue to be preferred over heart valve replacement devices due to positive clinical results and surgeon acceptance. Repair devices are of four types: rigid, semi-rigid, bands, and flexible.

Percutaneous Heart Therapy

By 2011, market growth in the heart valve segment will be enhanced by the highly anticipated introduction of two minimally invasive percutaneous heart valve therapy (PHVT) procedures - percutaneous mitral valve repair (PMVR) and percutaneous aortic valve replacement (PAVR). Both of these procedures are expected to have an impact on the market providing an alternative for patients who are not suited to the more invasive open heart surgery procedure.

Competition

Sorin controls approximately 25% of the cardiac surgery device and prosthetic market segment in Europe. Along with Sorin, Medtronic, Edwards Lifesciences, and St. Jude Medical comprise the top four companies that supply the cardiac surgery device market. There are over 30 smaller competitors whose entry into this market segment may include niche products.

(Millennium Research Group, *European Markets for Cardiac Surgery Devices*, 2007)

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