



DESIGNED WITH THE PATIENT AT HEART

JenaValve™

Company Profile

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AN IDEA...BECOMES A COMPELLING VALUE PROPOSITION

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Correct positioning and
ease-of-handling are key.
JenaValve will offer the market
2nd generation systems
that will enable both.

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A promising idea

The company's product idea was first conceived by Prof. Dr. med. Hans-Reiner Figulla and PD Dr. Dr. med. Markus Ferrari, both cardiologists at the Friedrich Schiller University Clinic in Jena, Germany. Early experiments and tests were promising and led the scientists to believe that their developments could very well be the right product for physicians and their patients.

In 2006, a seasoned professional, Helmut J. Straubinger, was appointed CEO and quickly built the organization needed to lead the company to CE certification for its systems. In the interim, an experienced management, scientific and engineering team has been established and is guided by the highest ethical standards. Today, the company's corporate vision is to advance the science of heart valve replacement treatment with life-enhancing transapical and transfemoral systems. JenaValve's aim is to provide the best and safest minimally-invasive aortic valve replacement products.

Aortic stenosis is the most frequent heart valve disease in Western countries, where its prevalence steadily increases with age. The decision to operate surgically raises specific problems in elderly patients because of mortality and morbidity risks. In fact, elderly patients with severe symptoms are often denied surgery for reasons of cardiac and other pathological conditions. Being much less invasive than surgical valve replacement, JenaValve's minimally-invasive systems are designed for this type of patient. Moreover they are improved, second generation systems that overcome the disadvantages of currently available commercialized products. They enable correct positioning and ease-of-handling and reduce the long learning curves associated with products being used by physicians now.

The decision between open heart surgery and a minimally-invasive approach must take many factual and emotional aspects into consideration. JenaValve will help patients and their physicians in their decision-making process because its transcatheter systems are less traumatic than open heart surgery and offer potential safety for patients and ease-of-use for doctors. Now that the company's pre-clinical trials for the transapical system are completed, the company management recognizes that its initial hopes were well-founded and that it can offer cardiac surgeons and cardiologists products which are easy to maneuver, position and deploy.

In all its efforts to produce the world's most advanced aortic valve replacement systems, the company adheres to the provisions of international and national standards, striving without reserve for the greatest possible reliability and quality in its products. JenaValve management is recognized for its integrity and dedication to the company's principles and goals which, it is confident, will meet the expectations of future customers in terms of quality, service and innovation.

THE MINIMALLY-INVASIVE AORTIC VALVE REPLACEMENT SYSTEMS

JenaValve is focused on developing transcatheter systems designed for transapical and transfemoral delivery. Each delivery approach features a separate valve design that is customized for enhanced valve performance and delivery. Both prosthesis designs integrate the unique features of the JenaClip stent to optimize the prosthesis and ease of transcatheter delivery.

The Prosthesis Design

Both prosthesis platforms were developed to provide superior hemodynamics and durability with proprietary features intended to address the limitations of other transcatheter valve technologies. The valves leverage the unique design advantages of the JenaClip self-expanding Nitinol stent that enables a gentle, patient-protecting, minimally-invasive procedure. The valves are constructed with biological materials that were chosen based on a proven history of use in heart valves. While the transapical system utilizes a porcine valve, bovine pericardium was selected for the transfemoral system, allowing for a smaller catheter diameter. The integral design of the valve with the JenaClip stent minimizes valve stresses and avoids contact between the leaflets and stent for enhancing durability.



JenaValve transapical prosthesis*

Unique features of the prosthesis design provide JenaValve opportunities for advantages over other transcatheter technologies:

- ▶ **The JenaClip design** – With its integrated feelers, this clipping mechanism provides easy and accurate positioning of the prosthesis and additional anchoring support to avoid migration and reduce the need for excessive radial forces at the annular level. This unique feature reduces the potential for mitral valve distortion and heart block. The clipping mechanism also captures the diseased leaflets, which along with proper positioning avoids potential coronary flow obstruction.
- ▶ **Low profile design** – The overall valve height is only 30 mm for the largest size. This low profile design helps the catheter delivery, especially for navigating tight turns such as through the aortic arch. The low profile design also helps to avoid obstructing flow to the coronaries.

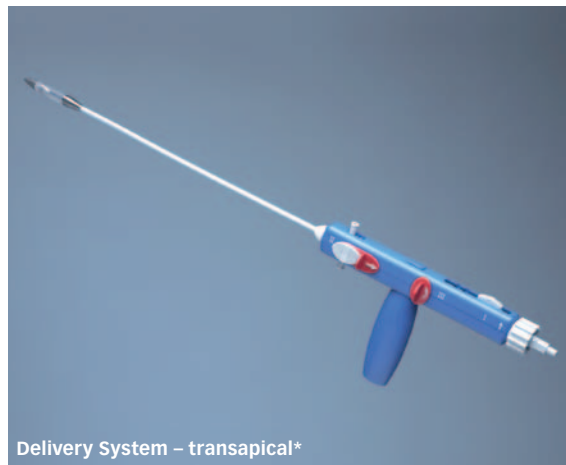
- ▶ **Multiple valve sizes from 19mm to 27mm** – A full range of sizes will be offered to allow a valve to be selected that closely matches the native annulus and helps to optimize the anchoring forces for each patient. Correctly matching the valve size to the patient’s annulus reduces the potential for paravalvular leakage, prevents prosthesis migration and eliminates the need for excessive radial forces that result in distortion of the mitral valve and heart block. Transapical valves will be available in sizes 19-25 mm; it is expected that transfemoral valves will be available in sizes 19 to 27 mm.

There are over 5.5 million people in the US suffering from congestive heart failure. Of those people, more than one million will develop severe aortic or mitral heart valve disease.¹

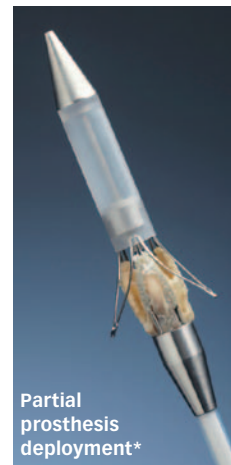
The Delivery Systems

Two catheter-based delivery systems are being developed so the prosthesis can be placed at the aortic annulus retrograde in a transfemoral approach, or antegrade in a transapical approach. Both systems provide easy maneuverability, positioning and repositioning capabilities. The systems can deploy the prosthesis with the heart beating, without the use of cardiopulmonary bypass, disruption of blood flow or rapid pacing.

In the first deployment step, the feelers of the JenaClip stent are unsheathed from the catheter to allow the physician to assure proper positioning. The feelers can be fully retracted back into the catheter sheath for repositioning and re-deployment, if necessary. Once the feelers are determined to be in the proper position, the rest of the prosthesis can be deployed in two distinct steps to securely anchor the valve base in the native annulus and to be released from the delivery system.



Delivery System – transapical*



Partial prosthesis deployment*

Features of the delivery systems:

- ▶ **Control and interface** – The systems are user-friendly and have an ergonomic design. They are over-the-wire designs with 1:1 torque and are easily steerable for locating the native valve. The longer transfemoral system (120 cm) is highly flexible with a low profile valve and a soft tip for navigating tight turns. The shorter transapical system (50 cm) provides excellent control with a stiff trocar-like tip for the direct apical approach.
- ▶ **Visibility** – Good radiopacity of key components of the distal section of the catheter and in addition radiopaque markers on the feelers provide excellent fluoroscopic visibility for prosthesis rotational and longitudinal positioning.
- ▶ **Repositioning capability** – The JenaClip feelers can be deployed and retracted for repositioning and redeployment if necessary.

¹Source: Millennium Research Group Inc. Toronto, Canada: European Markets for Heart Valves 2008 (published Oct. 2007) and US Markets for Heart Valves 2007 (published June 2007)

*Previous versions shown; current versions not yet disclosed

THE PROCEDURE AND BENEFITS

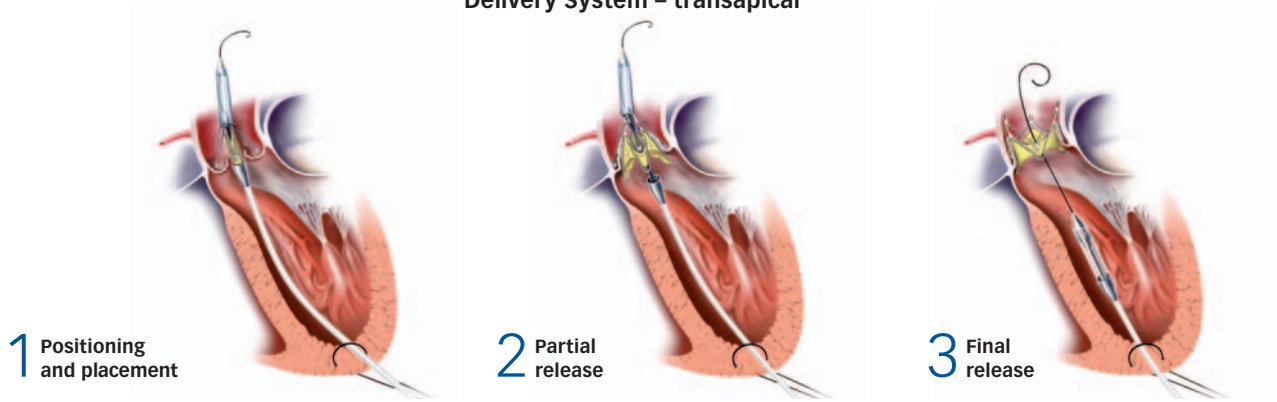
The delivery and implantation procedure

Delivery and implantation of the prosthesis is accomplished through three basic steps for both the transapical and transfemoral systems:

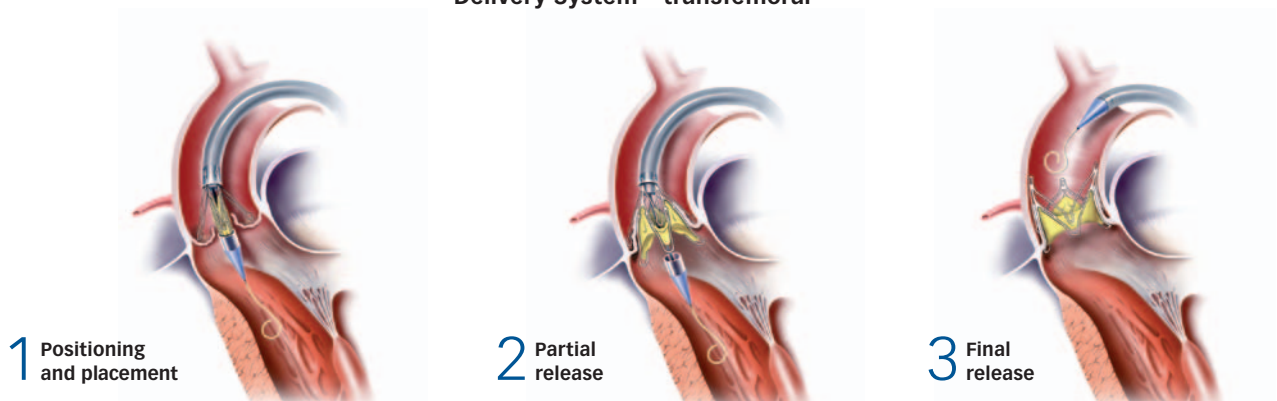
1. The catheter positions the sheathed prosthesis onto the diseased native valve. Then the feelers are released from the catheter, which allows the physician to locate the "landing zone" and position the prosthesis correctly.
2. Once the feelers are determined to be in the proper position, the prosthesis can be partially deployed from the sheath. The Nitinol stent will self-expand to securely anchor the valve base in the native annulus and the new valve will immediately begin to function.
3. The prosthesis, still connected to the delivery system, is then separated from the catheter in the final release step.

The delivery system can then be safely retracted.

Delivery System – transapical



Delivery System – transfemoral



THE INTELLECTUAL PROPERTY POSITION

JenaValve is pursuing

an active program of patent filing, licensing and acquisition to generate a portfolio of patents and other intellectual property to protect its JenaClip and delivery system, as well as its pipeline products and methodologies.

JenaValve appreciates

that patents are not the only form of protection for medical devices and is actively pursuing design, utility model and trade mark protection. The company also ensures that all valuable know-how, trade secrets and special materials are identified and appropriately managed.

JenaValve recognizes

the importance of competitor monitoring and freedom to operate. It actively searches and analyzes third party patents for potential risks or obstacles to market, taking appropriate action where and when necessary.

JenaValve's patent portfolio comprises

18 patent families that are being actively managed:

- ▶ The stent *per se* is protected by many of these patent families, the earliest dating from 1995 onwards. The families include granted patents and pending patent applications in Europe, Japan and the United States and applications pending before the World Intellectual Property Organization (WIPO). Specific features of the JenaClip are further protected by registered designs in Europe.
- ▶ Features to allow stent location, anchoring and repositioning are protected by several of the patent families that date from 2000 onwards. The families include granted patents and pending applications in Europe, Japan and the United States and applications pending before the WIPO.
- ▶ The delivery systems and associated catheters are protected by a number of the patent families dating from 2002 onwards, covering the territories of Canada, Europe and the United States, as well as applications pending before the WIPO.
- ▶ Further patent applications have been made and are being prosecuted to protect JenaValve's commercial position both from a product development and a defensive point of view. All granted patents are currently in force and pending applications are being actively prosecuted.

The availability of [...] percutaneous aortic valve replacement systems in Europe will have a significant impact on the performance of aortic valve replacement

procedures.¹

¹Source: Millennium Research Group Inc. Toronto, Canada: European Markets for Heart Valves 2008 (published Oct. 2007) and US Markets for Heart Valves 2007 (published June 2007)



Helmut J. Straubinger (1958) – CEO, JenaValve

Helmut J. Straubinger has more than fifteen years experience in medical device technology including product development, manufacturing, sales and marketing, his main focus being peripheral stents, catheters and systems. He has held various positions in international companies with offices in Germany including CEO and CFO at the German subsidiary of C. R. Bard, Inc. and CFO at Nucletron Electronic AG. As CEO at OptiMed Medizinische Instrumente GmbH, in addition to responsibilities in manufacturing, Straubinger set up an international sales and marketing organization, distributing interventional products in more than 40 countries and attaining a sales volume of more than US \$15 million. He holds a Master of Business Administration from the University of Applied Science, Munich, received in 1984.



Stephan Wehselau (1968) – CFO, JenaValve

Life sciences market funding, alliances, M&A and restructuring are Stephan Wehselau's core competencies. He also has extensive experience in starting up and managing early stage life sciences companies. At JenaValve, Wehselau is responsible for all financial affairs, fundraising, the patent portfolio and legal, administrative and organizational matters. He is also a member of the supervisory board of two biotechnology companies. Wehselau was co-founder of Xantos Biomedicine AG where as CEO and CFO he raised over US \$40 million in venture capital and closed nine technology-based deals with pharmaceutical and biotechnology companies in the USA and Europe. He has also been Head of Controlling and Finance Analyst for the Molecular Medicine Business Unit of Roche Diagnostics GmbH.



Peter Duijst, MD, PhD (1951) – Chief Medical Officer, JenaValve

Dr. Duijst's career spans 19+ years in extensive regulatory and clinical affairs. He is specialized in mechanical and tissue heart valve prostheses and other circulatory systems devices and technologies. As Medical Director and member of the board at AorTech International plc, he was responsible for regulatory and clinical affairs, involved in strategic business development and worked closely with R&D and sales/marketing for a decade. With Practiguide Ltd, he provided consultancy services for various medical device companies in the areas of mechanical heart valve prostheses, bioprosthetic heart valves, PTCA catheters and other technologies. He is a member of the board of directors at Mediqol Limited.



Prof. Dr. med. Hans-Reiner Figulla (1949) – Cardiologist, Clinic Director, Co-Founder, Technology Inventor, Medical Advisor and Head of SAB, JenaValve

One of the world's leading cardiologists, Prof. Dr. med. Figulla has been full Professor for internal medicine and Clinic Director, Internal Medicine I at the Friedrich Schiller University Jena, Germany since 1997. He was promoted to Professor for internal medicine at the University of Göttingen, Germany in 1988 where he held several key positions for nine years. His R&D focus includes cardiomyopathy, heart failure and the development of new interventional devices. He has a distinguished record of over 250 publications in the most prestigious internationally-acclaimed scientific media.



PD Dr. Dr. med. Markus Ferrari (1967) – Cardiologist, Clinic Co-Director, Co-Founder, Technology Inventor, Medical Advisor, Member of the BOD and SAB, JenaValve

PD Dr. Dr. med. Ferrari, who received his PhD in human medicine in 1993, is Co-Director and Associate Professor, Internal Medicine at the Clinic of Internal Medicine I at the Friedrich Schiller University Jena. In addition to his professorial dissertation in 2004, Dr. Dr. Ferrari has written over 100 articles and presentations. He has filed 15 patents and is reviewer for several scientific publications.

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We can give no assurance regarding the achievement of these forward-looking statements, as they are only estimates and the actual outcomes may be significantly different. Additionally, we expect that these forward-looking statements will change in the normal course of our business. The management specifically disclaims any obligation to update forward-looking statements that we may make in regard to this information.



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