

Company Profile

DESIGNED WITH THE PATIENT AT HEART™



JenaValve™

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A message from the CEO

Over the past few years, transcatheter aortic valve implantation (TAVI) has become an established therapeutic alternative to surgical aortic valve replacement for high-risk patients suffering from aortic heart valve stenosis. Several thousand patients have been effectively treated with minimally-invasive procedures and the majority has attained very favorable results.

Since the company's founding, JenaValve™ Technology has endeavored to develop safe implantation systems for both the transapical, as well as the transfemoral approach. In collaborating with our scientific team, it has become clear that the correct and precise placement of a new prosthesis in the patient annulus is key to treatment safety and success, and ultimately, patient well-being. Not only are system design and features pivotal, but equally important are the dexterity, skill and experience of the user, whether heart surgeon or cardiologist.

To create a system that ensures precise placement, JenaValve has focused its product development on three fundamental, patented, design features: unique positioning feelers, the JenaClip™ and the low profile of the JenaValve prosthesis. These are the elemental differentiators with which the implantation can be accomplished more precisely and more easily than with other available TAVI systems.

Safety is our highest priority, for the patient as well as for the user. The JenaValve systems are designed so that physicians can become familiar with them quickly and can implant the aortic valve prosthesis safely.

In the years ahead, TAVI will become the treatment of preference for a growing world market. However, to treat other patients with this innovative method – in addition to high-risk cases – positive long-term evidence is needed to confirm the durability of the heart valve prosthesis. JenaValve has chosen the finest valve material available for its prosthesis and will employ biological valves for both systems. In fact, the transapical system features a valve that has many years of proven durability in clinical application.

Quality is of overriding importance to us, the mainstay of every aspect of our technology development, design process and product engineering, reflecting our outstanding German tradition. We look forward to producing the highest quality TAVI systems in the service of medical science and contributing life-enhancing products for patients worldwide.



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

Helmut J. Straubinger
CEO, JenaValve Technology

COMPANY HISTORY AND VISION

A promising idea

The company's product idea was first conceived by Prof. Dr. med. Hans-Reiner Figulla and Prof. 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.

JenaValve Technology was founded in 2006. A seasoned medical technology professional, CEO Helmut J. Straubinger, 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 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 transcatheter aortic valve implantation systems for beating heart procedures.

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 not considered candidates for surgery because of the risks associated with cardiac and other pathological conditions. JenaValve's TAVI systems are designed for this type of patient. Moreover they are improved, next generation systems that overcome the disadvantages of commercially available products. They enable correct positioning and ease-of-handling to reduce the long learning curves associated with products being used by physicians now.

In all its efforts to produce the world's most advanced aortic valve implantation 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.

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As awareness for TAVI is created in the minds not only of physicians, but also of the elderly and their caretakers in today's more health-conscious societies, the call for the procedure will increase.

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“
... the number of [U.S.] individuals over the age of 65 will grow from approximately 40 million in 2009 to over 45 million by 2014 ... and will fuel demand for heart valve treatments.¹”

¹Source: International Data Base (DB), U.S. Census Bureau. www.census.gov/population/www/projections/natdet-D1A.html.

The cause

The most common cause of aortic valve disease which requires valve replacement is aortic valve narrowing due to calcification that occurs when the valve has begun to wear with age. Over time, the body deposits calcium on the valve which restricts the motion of the valve leaflets. This may restrict the valve from fully opening, causing stenosis, or from fully closing which causes central leakage. If left untreated, either with conventional open heart surgery or with TAVI, the heart will eventually fail.

High-risk patients

Elderly patients, especially those who are not suitable for open heart surgery, including those suffering from aortic valve stenosis, with or without aortic valve insufficiency, can benefit from the TAVI procedure. High-risk patients with co-morbidities such as diabetes mellitus, renal insufficiency or myocardial infarction can now be adequately treated. For these patients, open heart surgery would be a life threatening event in itself.

"...a large number of patients with severe aortic stenosis are not considered surgical candidates. These patients have poor prognosis with continued medical therapy. In this population, catheter-based approaches for valve replacement/insertion show promising initial results." Eur Heart J (2009) 30 (17): 2079-2086

Treatment

TAVI is an emerging technique which restores a normal aortic valve function in patients with severe aortic stenosis. Unlike open heart surgery, the implantation is performed without removing the native valve leaflets, on a beating heart, with



The JenaValve prosthesis

neither sternotomy nor cardiopulmonary bypass. The prosthesis can be implanted either transfemorally or transapically.

The patient benefits

The JenaValve TAVI system is a true, safe alternative to conventional surgery, and as such, the most important benefit to patients. It offers the promise of enhanced quality of life for years and indeed survival for the many patients that would die prematurely if untreated.

Due to minimally-invasive TAVI methods, patients can expect fewer possible associated complications and significantly reduced pain and trauma. As a result, the recovery will be faster and the hospital stay and rehabilitation shorter. Even the transapical approach involves just a small incision, resulting in only a minor cosmetic wound.

Notably, normal life at home can recommence earlier, enabling patients to regain their mobility and resiliency.

THE JENAVALVE TAVI 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 stent, especially the positioning feelers and the JenaClip mechanism, to ensure correct positioning and to optimize the prosthesis performance.

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 JenaValve self-expanding Nitinol stent that enables a gentle, patient-protecting, beating heart 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 root valve, a pericardial tissue construction was selected for the



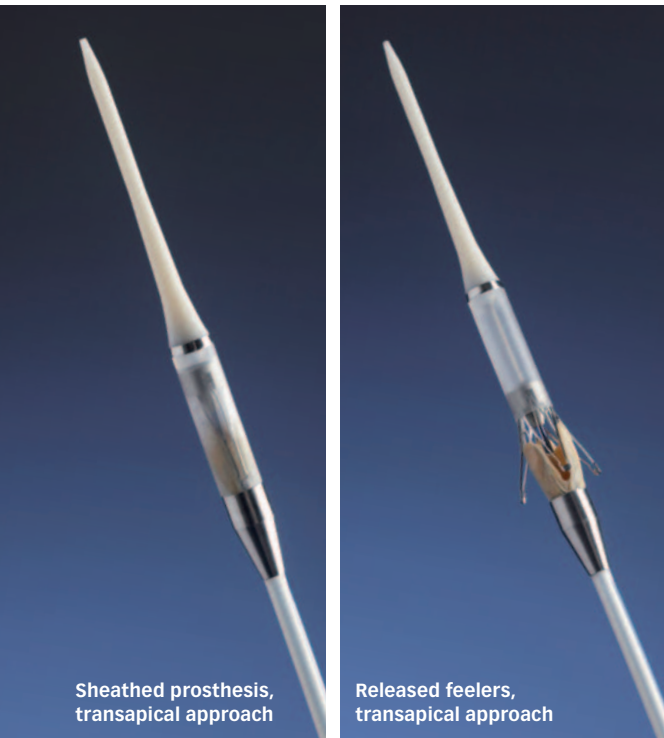
transfemoral system, allowing for a smaller catheter diameter. The integral design of the valve with the JenaValve stent minimizes valve stresses and avoids contact between the leaflets and stent for enhancing durability.

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



► **The JenaValve stent design** – The integrated positioning feelers provide easy and accurate placement of the prosthesis. While the unique JenaClip mechanism provides additional anchoring support to prevent migration, it also minimizes the need for excessive radial force at the annular level. This unique anchoring system reduces the potential for mitral valve distortion and heart block. The latter can result from excessive radial force towards the septum. The JenaClip mechanism captures the diseased leaflets which, along with proper positioning, avoids potential coronary flow obstruction.

The JenaValve stent also incorporates flexible commissure posts for supporting the valve leaflets. This important feature reduces tissue stresses during valve closure, which leads to enhanced valve durability. Flexible valve commissure supports are



common in proven state-of-the-art surgical valve designs, but are unique to JenaValve when compared to other TAVI valve and stent designs.

► **Low profile design** – The JenaValve prosthesis is constructed with a low profile valve. This, along with the open stent structure design, maintains appropriate flow to the coronaries and access to the ostia for potential future coronary artery interventions.

► **Solutions for annuli up to 27mm** – A full range of sizes will be offered to allow the correct valve to be selected that closely matches the native annulus and helps to optimize the anchoring force 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 force that increases the risk of heart block. The JenaValve prosthesis will be available in multiple sizes.

The Delivery Systems

Two catheter-based delivery systems are available so that 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 without cardiopulmonary bypass. Rapid pacing is not necessary at any time during the entire deployment procedure. The features of the delivery systems include:

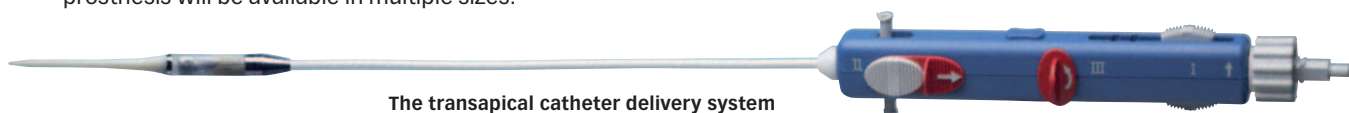
► **Control and interface** – The systems are user-friendly and have an ergonomic design. They are over-the-wire designs with 1:1 torque and are easily steerable for locating the native valve. The longer transfemoral system is highly flexible with a low profile valve and a soft tip for navigating tight turns. The shorter transapical system provides excellent control with a flexible tip for the direct apical approach and atraumatic guidance through the aorta ascendens.

► **Visibility** – High radiopacity of key components of the distal section of the catheter and radiopaque markers on the feelers provide excellent fluoroscopic visibility for rotational and longitudinal positioning of the prosthesis.

► **Repositioning capability** – After feeler positioning, the prosthesis can be repositioned or retrieved if necessary.

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Unequivocally, JenaValve’s performance advantages address the clinical challenges that exist with currently available TAVI technologies.

Michael J. Dormer,
Chairman of the Board
of Directors, JenaValve
Technology

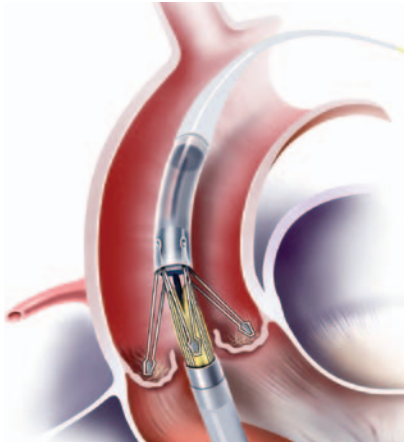


The transapical catheter delivery system

THE PROCEDURE

DELIVERY SYSTEM – TRANSAPICAL

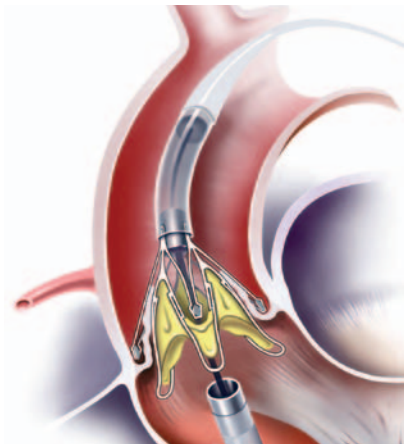
1



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

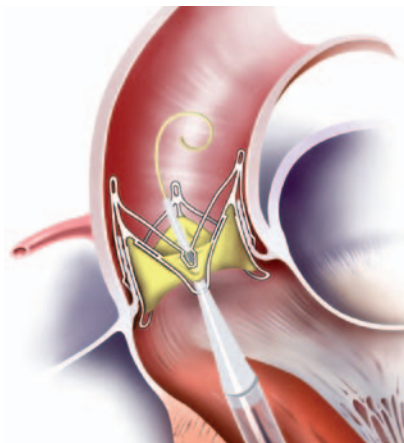
Positioning and Placement

2



Partial Release

3

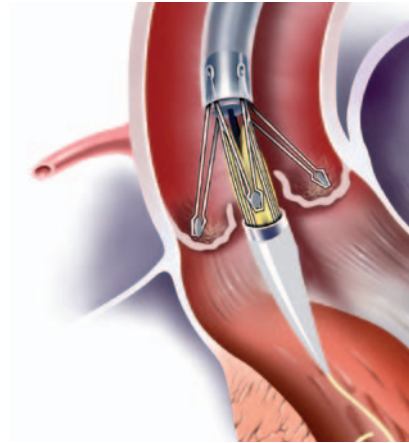


Final Release

DELIVERY SYSTEM – TRANSFEMORAL

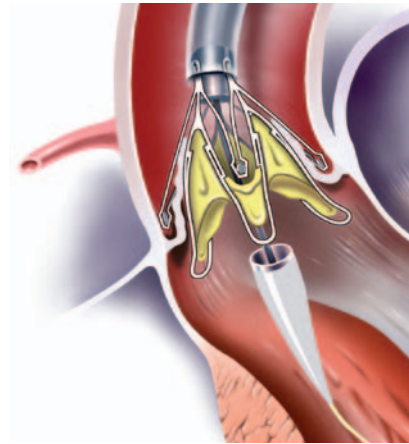
STEP 1: The catheter positions the sheathed prosthesis above the diseased native valve.

The positioning feelers are released by partially retracting the sheath of the catheter, which allows the physician to locate the feelers in the sinus region at the base of the cusps, the "landing zone" between the diseased leaflets and the aortic wall. Under beating heart conditions, repositioning or retrievability is possible.



1

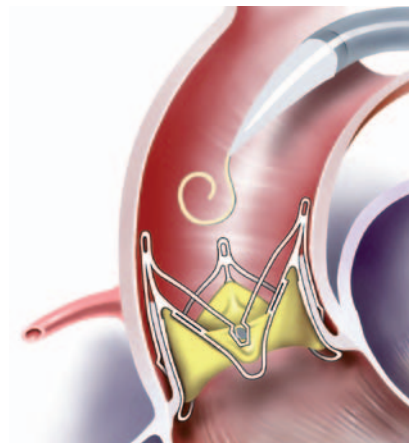
STEP 2: Once the feelers are determined to be in the proper position, the prosthesis will be partially released at its proximal end. The Nitinol stent will self-expand to securely anchor in the native annulus and the new valve will immediately begin to function.



2

STEP 3: The prosthesis, still connected to the delivery system at the distal end, is then completely separated from the catheter. The JenaClip mechanism clips the stent on the diseased native leaflets and the prosthesis attaches firmly to the aortic wall.

The delivery system can then be safely retracted.



3

UNIQUE JENAVALVE PRODUCT FEATURES

JenaValve TAVI System Features for Safe and Easy Implementation

Unique Features

Benefits

- | | |
|---|--|
| <p>1</p> <p>Prosthesis constructed with low profile valve and open stent structure</p> | <p>▶ Low profile prosthesis and proprietary stent design</p> <ul style="list-style-type: none"> ▶ Allows deployment without balloon dilation ▶ Prosthesis moves naturally with rhythmic contractions of heart and pulsating blood flow in stable position ▶ Ensures open flow to coronaries ▶ Allows access to coronary ostia for potential future interventions ▶ Prevents septal and mitral irritation because of minimal left ventricular embedment ▶ Avoids heart block – no need for pacemaker implantation ▶ Perfects valve alignment and visibility by design |
| <p>2</p> <p>Precise orientation and correct positioning for safe and accurate prosthesis placement</p> | <p>▶ Feeler-guided positioning</p> <ul style="list-style-type: none"> ▶ Enables feelers, after controlled "Step 1" release, to be advanced, rotated, repositioned or retracted into the sheath ▶ Takes advantage of physician's tactile skills to locate optimal position in "landing zone" ▶ Prevents retrograde movement into ventricle, once positioned |
| <p>3</p> <p>Clipping of diseased native valve leaflets between stent body and feelers</p> | <p>▶ JenaClip™ anchoring mechanism</p> <ul style="list-style-type: none"> ▶ Maintains final prosthesis position and improves paravalvular sealing, providing additional anchoring security ▶ Captures native leaflets, keeping coronary ostia open and fully perfused |
| <p>4</p> <p>Dynamic pulsation of new biological valve commissures is provided</p> | <p>▶ Flexible stent posts</p> <ul style="list-style-type: none"> ▶ Minimizes tissue stress during diastolic pressure ▶ Enhances valve durability |
| <p>5</p> <p>Prosthesis can be repositioned and retrieved prior to final release from delivery system</p> | <p>▶ Repositioning and retrievability</p> <ul style="list-style-type: none"> ▶ Provides physician with added control and guidance during delivery ▶ Makes both TA and TF implantation techniques flexible and safer in clinical use |
| <p>6</p> <p>Conclusive three-step release and deployment mechanism</p> | <p>▶ Three-step delivery system</p> <ul style="list-style-type: none"> ▶ Offers a simple-to-learn system ▶ Guides user stepwise through procedure to render best possible result ▶ Affords ease-of-handling and correct prosthesis orientation |
| <p>7</p> <p>Radiopaque markers embedded in positioning feelers</p> | <p>▶ Enhanced radiopacity</p> <ul style="list-style-type: none"> ▶ Optimizes visual control ▶ Facilitates dependable feeler positioning ▶ Reduces radiation time and contrast media |

For information on JenaValve Technology patents, see www.jenavalve.de



The JenaValve stent frame

Clinical 
demand for minimally-invasive aortic heart valve treatment will continue to grow rapidly within the European region, proving the viability of these procedures. This trend will extend into the US market [where] adoption rates ... will be even stronger than in Europe ...²

Made in Germany

JenaValve has chosen to center its stent development in Germany, gleaning the country's technical culture which is recognized internationally for its advanced stent technology and high quality precision engineering.

²Source: US Markets for Heart Valve Devices 2010, Millennium Research Group

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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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