

# Glossary of terms: The Lotus™ Valve System

# Adaptive Seal<sup>™</sup>

A unique design feature specific for the Lotus<sup>™</sup> Valve System designed to minimise paravalvular leakage, which is one of the main predictors of mortality<sup>1,2,3</sup>, by conforming to irregular surfaces of the native anatomy.

# Aortic Regurgitation (AR)

Also known as aortic insufficiency (AI) – the leaking of the aortic valve, which causes blood to flow in the reverse direction during ventricular diastole (the period during which the ventricles are relaxing), from the aorta into the left ventricle. The condition is attributable to diverse congenital and acquired abnormalities of the aortic valve or the wall of the aortic root. AR can be either chronic or acute.<sup>4</sup>

# **Balloon Aortic Valvuloplasty (BAV)**

A procedure that widens a narrowed aortic valve and which is currently the only approved catheter-based option using an inflatable balloon to treat patients with severe aortic stenosis, who are at high risk of cardiac surgery. The procedure has been underused in those patients relegated to medical therapy alone.<sup>5</sup>

# **Bovine Pericardium**

A thin membrane surrounding the heart, principally composed of collagen. The thickness of the tissue is suitable for fabrication of heart valve leaflets.<sup>6</sup> The Lotus<sup>™</sup> Valve leaflets are made from highly selected bovine pericardium tissue that has been proven to be a durable, long-term material.

# Cardiopulmonary Bypass (CPB)

A technique that temporarily takes over the function of the heart and lungs during surgery, maintaining the circulation of blood and the oxygen content of the body.<sup>7</sup> Often also referred to as a "heart-lung machine".

# Catheter

A thin, flexible tube which is, for example, placed in a vein to provide a pathway for giving drugs, nutrients, fluids, blood products or devices.

# **Clinical Endpoint**

Overall outcome that the protocol is designed to evaluate. Common endpoints of clinical trials are, for example, disease progression, stroke or death.



# **Congestive Heart Failure (CHF)**

Occurs when the heart is not able to pump enough blood to meet the needs of the body. This can be a result of a weakened heart muscle or when a defect in the heart prevents blood from entering into circulation. When the heart does not circulate blood normally, fluid congestion occurs – the kidneys filter less fluid out of the circulation into the urine and the extra fluid in the circulation builds up in different parts of the body such as the lungs and the liver.<sup>8</sup>

# **Degenerative Aortic Stenosis (AS)**

The most common form of aortic valve disease with predominance in older patients who have had aortic valve replacement. AS is most commonly seen in the Western world and represents a major healthcare burden. There are currently no effective medical treatments capable of altering the course of AS.<sup>9</sup>

# **Diastolic Dysfunction**

Diastolic dysfunction with preserved left ventricular function is a condition where abnormal stiffening of the heart ventricles leads to abnormal filling during their relaxation period. As the condition advances, fluid extravasates into the lungs, and the situation is elevated to diastolic heart failure (DHF).

# Echocardiography

A diagnostic test which uses ultrasound waves to produce images of the heart chambers, valves and surrounding structures. It can measure cardiac output and is a sensitive test for thrombi in or liquid accumulations around the heart. It can also be used to detect abnormal anatomy or infections of the heart valves or to assess the size of the left atrial appendage.

# **Ectopic Valve Placement**

Release of a catheter-delivered prosthetic valve at a site other than the native aortic valve. Ectopic means away from normal.

# **Femoral Artery**

A large artery in the thigh which divides into smaller branches to provide blood to muscles and superficial tissues in the thigh. Often used to implant an aortic valve replacement via a small incision (trans-femoral approach).<sup>10,11</sup>

# Morbidity vs. Mortality

Morbidity is another term for illness or an unhealthy/diseased condition. Mortality is the fatal outcome of morbidity and another term for death. A person can have more than one co-morbidity at a time. The level of morbidity is often determined within a population and the measure used is called prevalence of morbidity. The mortality rate, however, is the number of deaths due to a disease, or morbidity, divided by the total population.<sup>12</sup>



# Paravalvular Leakage (PVL) or Paravalvular Regurgitation

A defect that most commonly occurs after surgical and interventional valve replacement. It refers to blood flowing through a channel between the structure of the implanted valve and cardiac tissue as a result of a lack of appropriate sealing.<sup>13</sup> Depending on the size of the PVL, the regurgitation can cause congestive heart failure (CHF) and pulmonary edema, as well as increase risk of or directly provoke other complications.<sup>14</sup> PVLs can be isolated or multiple and vary from asymptomatic and benign to life-threatening. Approximately one to five percent of patients undergoing mitral<sup>15</sup> or aortic valve replacement experience PVL, with an incidence up to 70 percent in patients undergoing Transcatheter Aortic Valve Replacement.<sup>16</sup>

#### Percutaneous

Term used for any medical procedure where access to inner organs or other human tissue is achieved via needle-puncture of the skin instead of using a surgical approach with an incision.

# **Permanent Pacemaker**

A device that corrects causes of slow heart beats by providing electrical signals telling the heart to beat at proper rates and by delivering the signal to the appropriate chambers of the heart. Extreme slowing or complete stopping of the heartbeat can be fatal.<sup>17</sup>

# **REPRISE Clinical Programme**

Short name of the ongoing clinical trial programme evaluating the safety and performance of the Lotus<sup>™</sup> Valve System. Stands for **RE**positionable **P**ercutaneous **R**eplacement of Stenotic Aortic Valve through Implantation of Lotus Valve **S**yst**E**m). The programme includes the following trials – REPRISE I, REPRISE II and REPRISE III, a planned IDE<sup>a</sup> (Investigational Device Exemption) trial randomising Lotus versus another valve in 1,000 patients.

# Severe Symptomatic Aortic Stenosis

The process of thickening and stiffening in the aortic valve, which can result in an abnormal narrowing of the aortic valve opening, and reduction in blood flow. As a consequence, the heart needs to work harder to pump the sufficient amount of blood past the narrowed valve and throughout the body.<sup>18</sup> Left untreated, severe aortic stenosis can eventually lead to heart failure, severe infection and even sudden death.<sup>19</sup>

# Transcatheter Aortic Valve Implantation (TAVI)

Also referred to as Transcatheter Aortic Valve Replacement (TAVR) – a minimally invasive treatment alternative to traditional surgical valve replacement. It is performed on the beating heart without the need for cardiopulmonary bypass, while introducing a replacement valve. In most cases, the valve is implanted through an artery via a small incision or, less often, surgically with an

<sup>&</sup>lt;sup>a</sup> An IDE trial allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval Application (PMA) or a Premarket Notification submission in the US to the Food and Drug Administration (FDA).



incision into the chest and then into the left ventricular apex.<sup>20,21</sup> The prosthetic valve, which is premounted on a catheter, is gently inserted and threaded across the native aortic valve. The prosthetic valve is then deployed and displaces the native aortic valve leaflets.

#### Valve Embolisation

A rare, but serious complication which may occur during Transcathether Aortic Valve Implantation (TAVI) and the process by which a valve is obstructed by an embolus.

#### **Valve-in-Valve Placement**

A procedure during which the transcatheter valve is implanted within an existing prosthetic valve and which is often used to treat acute aortic annular rupture during a TAVI procedure.

# Ventricle

One of the two large chambers of the heart that receives blood from an atrium and pumps it to the arteries.

#### **Ventricle Diastole**

The period during which the ventricles are relaxing. During ventricle diastole, the pressure in both – the left and the right – ventricles drops from the peak that it reaches in systole.

# **About Boston Scientific**

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<sup>15</sup> Mitral valve (also known as the bicuspid valve or left atrioventricular valve) is a dual-flap (bi- from the Latin, meaning double, and mitral- valve) in the heart that lies between the left atrium and the left ventricle. <sup>16</sup> Buellesfeld L, Meier B et al. Treatment of paravalvular leaks through interventional techniques, OJ MMCTS 2011,

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