



GrownValve's Regenerative Heart Valve Implanted in First Human Patient

Breakthrough autologous solution aims to provide lifelong durability for young heart patients

Berlin, June 2025 — **GrownValve**, a pioneering heart valve company which evolved out of German Heart Center of the Charité–Universitätsmedizin Berlin is proud to announce the **first successful implantation of its regenerative, autologous heart valve in a human patient**. This milestone marks the beginning of a first-in-human study evaluating the long-term safety of the GrownValve system, a living valve derived from the patient's own tissue.

The procedure was performed as part of the **GECT-DZHK28 clinical trial**, which is assessing the GrownValve technology in seven young adults with congenital pulmonary valve defects. The implanted valve is designed to **regenerate and integrate** into the patient's body – potentially lasting significantly longer than current heart valve prostheses and avoiding repeated surgeries commonly required in conventional heart valve therapy.

A new era for Heart Valve Replacement

Unlike animal-derived prostheses that often eventually calcify and deteriorate, GrownValve's innovation uses **endogenous tissue**, processed and shaped with personalized 3D modeling. In preclinical studies, including in sheep, the valve demonstrated robust regeneration, endothelialization, and mechanical durability over 21 months.

"Implanting our valve into a human patient for the first time is a huge leap forward; not just for our team, but for the future of regenerative medicine. Our goal has always been to offer a lifelong solution for patients born with heart valve defects. This is the beginning of what we hope will be a new standard in valve therapy: one that restores life with living tissue.", states Dr. Boris Schmitt, Pediatrician at the German Heart Center of the Charité (DHZC) and Co-Founder of GrOwnValve.

This breakthrough carries significant global relevance. Each year, more than 400,000 children are born with congenital heart valve defects — many of whom require repeated surgeries throughout their lives as current prosthetic valves fail to grow with them. GrownValve offers a new path forward: a patient-specific, regenerative heart valve built from the individual's own tissue, designed to heal, adapt, and potentially last a lifetime. Delivered via a minimally invasive catheter-based procedure, the technology not only reduces surgical risk and recovery time, but also represents a fundamental shift in how structural heart disease can be treated across all ages.