Xeltis’ Bioabsorbable Cardiovascular Technology

Endogenous Tissue Restoration
Xeltis is spearheading a revolutionary therapeutic approach in cardiovascular and regenerative medicine called Endogenous Tissue Restoration (ETR).

Xeltis’ first-ever bioabsorbable cardiovascular valves and vessels are designed to harness the body’s innate healing process and enable ETR, the natural restoration of complex anatomical parts within the body.

ETR is a new transformational therapeutic approach in cardiovascular treatment:
1. Working cardiovascular implant: Xeltis’ bioabsorbable cardiovascular devices are designed to work as normal valves or vessels once implanted
2. Enabling ETR: their porous structure is a matrix designed to enable ETR, by allowing the body’s natural healing process to pervade it with new healthy tissue
3. Getting bioabsorbed: the device is designed to be absorbed by the body over time, as components of native tissue form
4. Leaving a new heart valve or blood vessel: collagen, endothelial lining and capillary blood vessels develop and organize themselves into natural functioning tissue within the implant, eventually forming a new healthy, functioning valve or vessel made of patient’s own tissue as the implant is bioabsorbed

Figure 1: The Xeltis implant has a porous structure
Figure 2: The Xeltis implant is pervaded by patient’s own cells forming a healthy heart valve or blood vessel

Technology based on Nobel-prize awarded science
Xeltis products are synthetic matrices made of novel bioabsorbable supramolecular polymers through electrospinning, a fiber production method using electric force to draw liquid polymers into very fine fibers.

At the foundation of Xeltis’ technology is Nobel prize-awarded science of supramolecular chemistry, or chemistry of assembled molecules. Supramolecular chemistry is a science focused on the way molecules organize and assemble using non-covalent, bonds such as hydrogen bonding.

Two first-in-human feasibility studies completed
Xeltis has successfully completed the first two feasibility trials for its bioabsorbable cardiovascular device technology, showing significant improvement in patients’ conditions, functional stability of the implants and no device-related adverse events a year after surgery.¹²
The studies have been conducted in pediatric patients suffering from severe congenital heart conditions and requiring right ventricular outflow tract (RVOT) reconstruction:

- **Cardiovascular pulmonary graft feasibility study**: Five patients, aged between 4 and 12 received a bioabsorbable graft, or conduit, as part of their Fontan procedure. Results of the study have been presented as late breaker at the 96th AATS annual meeting.

- **Right atrial patch feasibility study**: Five patients, aged between 1 and 16 received patches as part of their Glenn procedure.

Both Xeltis clinical studies have been led by world-renowned cardiac surgeon, Professor Leo Bockeria at the Bakoulev Center in Moscow, Russia – one of the largest centers for the treatment of complex congenital heart diseases in children worldwide.

The clinical trials were encouraged by excellent results from in-vivo studies, showing ongoing replacement of the bioabsorbable conduit by new, well-vascularized and functioning tissue, as a result of ETR one year after surgery.

**Potential cardiovascular applications**

Xeltis’ technology has the potential for broad application across a number of cardiovascular conditions and patient populations, serving as a platform to address hundreds of thousands of patients that require cardiac valve replacements and vascular interventions every year.

The first product Xeltis is planning to bring to market is a bioabsorbable pulmonary valve that could benefit around 80,000 children born each year world-wide with congenital heart defects that require right ventricular outflow tract (RVOT) reconstruction. Clinical trials for Xeltis pulmonary valve are planned to begin in 2016.

![Figure 3](image)

**Figure 3**

A normal heart compared with a heart with congenital heart defect (Tetralogy of Fallot). Xeltis’ pulmonary valve may be used to reconstruct the malformed pulmonary valve (A).

Xeltis is also exploring a number of additional applications, including a bioabsorbable aortic valve, which is currently in pre-clinical phase.

**Healthcare impact**

Xeltis bioabsorbable technology has the potential to reduce the risk of complications and of repeated interventions associated with available cardiovascular implants, to help reduce disease burden for patients and costs for the healthcare systems.

Under the current standards of care, surgeons may implant synthetic non-absorbable grafts or animal heart valves to repair the damaged or malformed heart valves and blood vessels. However, these techniques have limited efficacy and are plagued with complications, including the potential for rejection, stenosis, calcification and chronic infection. As a result, patients must undergo multiple surgeries as they age.

**References:**


2. Xeltis data on file