

- 1 Porcine pericardium sample
- 2 Tissue-based cardiac-valve prosthesis

## DECELLULARIZATION, UVA TREATMENT, STERILIZATION

### Fraunhofer Institute for Organic Electronics, Electron Beam and Plasma Technology FEP

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### Preparation of pericardial tissue for cardiac-valve prosthesis

Electron beam technology is one of the main areas of expertise at the Fraunhofer FEP, having been developed and enhanced over many years for numerous novel applications. Many different substrates, such as polymers, metals, biological tissue, and sensors, can be treated under STP conditions through non-thermal electron beam technology. During treatment with accelerated electrons, free radicals emerge that lead not only to the destruction of pathogens, but also to modification of biological macromolecules. This is already a standardized procedure (DIN EN ISO 11137 and ANSI/AAMI/ISO 11137) for sterilization of medical products such as surgical instruments.

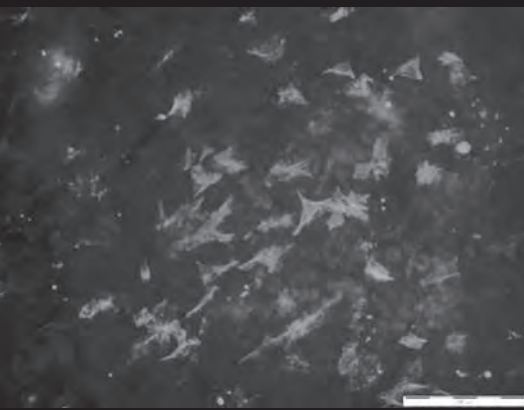
and sterilization of porcine pericardial tissue by means of accelerated electrons (patent pending).

In this process, the tissue is initially decellularized, by which the immunogenicity can be reduced to a minimum. Subsequently, the tissue is pre-crosslinked through photo-initialized UVA treatment, thereby avoiding employment of cytotoxic substances such as glutaraldehyde, for example. Subsequent treatment with accelerated electrons leads to further cross-linking as well as a final sterilization step that cannot be achieved with conventional procedures. Treatment of human pericardium used as patching material in cardiac and vascular surgery is similarly feasible with this procedure.

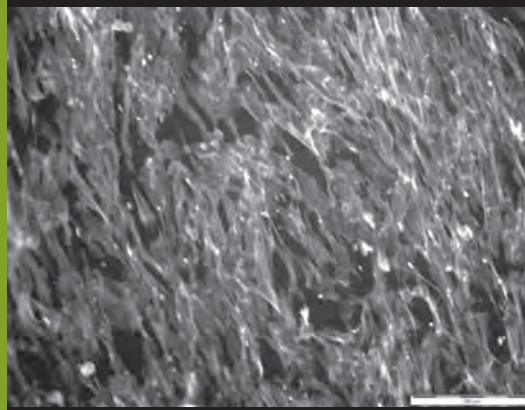
The treatment of delicate biological substrates represents a special challenge due to the high quality standards required. Fraunhofer FEP has been successful in developing a novel process for preservation

The tissue quality and properties required were monitored during the development of this procedure through close cooperation





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with Prof. Tugtekin of the Herzzentrum Dresden GmbH cardiac center at University Hospital, Technische Universität Dresden, Germany. The cardiac center carries out about 300 interventions each year to replace cardiac valves.

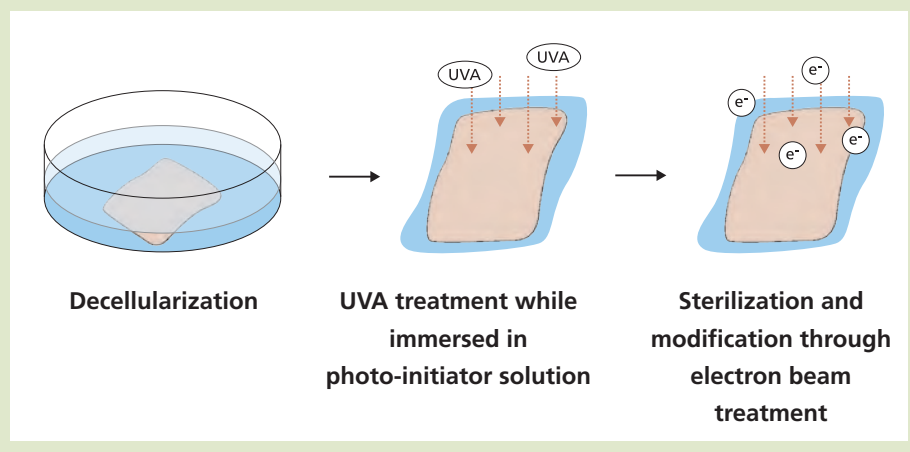
### Advantages

- Minimal immunogenicity
- Avoids employment of cytotoxic substances such as glutaraldehyde
- Sterilization achieved in milliseconds
- Final sterilization after packaging
- No radioactive sources
- Can be integrated in fabrication processes
- Fabrication process feasible within five days

### Our offer

- Sterilization and modification through low-energy electrons
- Compact sterilizers for systems integration
- In-line capable or batch-processing systems
- Qualification and validation by means of recognized microbiological, cell biological and chemical testing procedures
- Feasibility studies
- R&D services
- Complete technological development incl. pilot-scale production

### 6 Schematic diagram of tissue preparation process



3-4 Fluorescence microscopy images of human fibroblasts located on glutaraldehyde-crosslinked and electron beam treated porcine pericardium

5 REAMODE electron beam facility



We focus on quality and the ISO 9001.