

NOVEL & SAFE ALLOGRAFTS & XENOGRAPTS TISSUES FOR ORTHOPAEDIC & DENTAL RECONSTRUCTION SURGERIES PROCESSED USING SUPERCRITICAL CO₂ TECHNOLOGY

OssiTiss Pvt. Ltd. (OssiTiss) sources, imports, and sells novel decellularized & sterilized allograft & xenograft-derived Bone Graft Substitutes & Collagen membranes (BGSs) processed using scCO₂ technology, with minimal/no damage to the native extracellular matrix (ECM) composition & growth factors, resulting in biocompatible & improved tissue integration upon implantation for dental, orthopedic, & wound care applications. OssiTiss has multiple GMP-ISO 13485-Certified CMOs that manufacture CE/FDA-approved allografts & xenografts tissues using platform scCO₂ technology.

THE CHALLENGE

Limited & timely availability of autografts & other Bone Graft Substitutes (BGSs) with minimal osteo-inductivity and biocompatibility has led OssiTiss to develop scCO₂ technology for processing allografts & xenografts tissues to meet the unmet clinical need. The current processing methods of these tissues involve various chemicals, such as acids & bases, hypotonic & hypertonic solutions, detergents, alcohol & other solvents, which denature the native ECM & activate host immune responses, resulting in tissue rejection.¹⁻²

THE TECHNOLOGY, ADVANTAGES & APPLICATION OF scCO₂

CO₂ at given temperature & pressure reaches supercritical phase with penetrative properties of gas & washing properties of a liquid (Figure 1). This enables deep tissue penetration & decellularization of tissue material without damaging ECM components & heat-sensitive native growth factors. OssiTiss, together with multiple CMOs, currently manufactures CE/FDA-approved porcine/bovine-derived pericardium membranes, allografts, & Xenografts bone void fillers for dental & orthopedic applications (Figure 2).

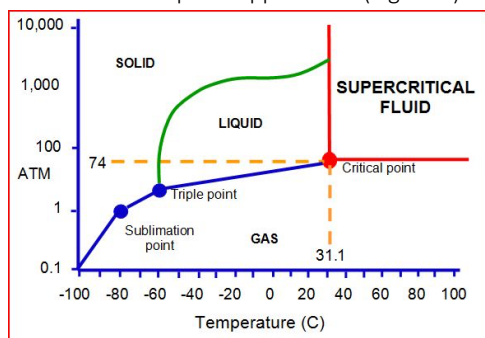


Figure 1. The supercritical property of CO₂

Furthermore, the scCO₂ equipment is supplemented with co-solvent pumps, which can be used to impregnate with any APIs or antibiotics of your interest. In addition, the decellularized tissues can be sterilized using scCO₂ using a combination of solvents at low temperatures without compromising native ECM components & growth factors⁴.

STAGE OF DEVELOPMENT & COMMERCIALIZATION

Radier Medical B.V., with OssiTiss Pvt Ltd is actively looking for international partners to import, sell, and further develop novel products to various geographical markets to meet unmet clinical needs.

- Allograft or xenograft-derived tissue products
- Develop new products using scCO₂ technology.
- Sterilization of biological/tissue products using scCO₂
- Impregnation or Extraction of active molecules

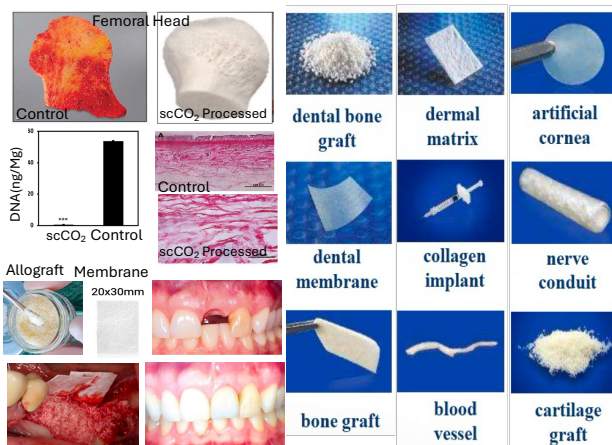


Figure 2. Representative tissue images of allograft tissues decellularized using scCO₂ Technology. The Cells and DNA are removed without compromising ECM structure of the tissue. The potential application of scCO₂ Technology to develop various allograft tissues is indicated on the right side of the image⁵⁻⁸

AVAILABLE COMMERCIAL PRODUCTS FROM OSSITISS

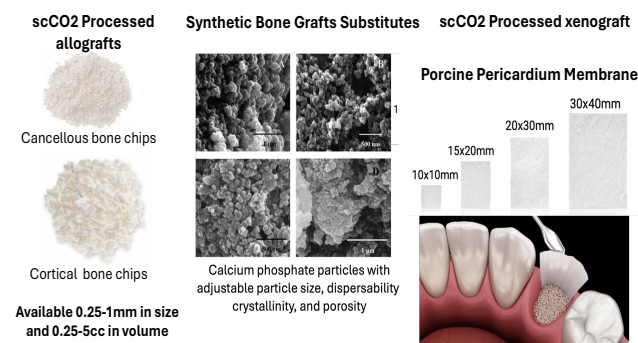


Figure 3. Product Combination of synthetic, allograft, and xenograft-based tissues for dental and orthopedic applications.

PRODUCT PIPELINE

- Combination of BCP/HA/TCP⁷⁻⁸
- BCP/Allograft DBM
- Porcine pericardium collagen membrane in different sizes
- Allografts in sizes (0.25mm-1mm) & volumes (0.25cc- 5cc) with pericardium membrane (10X10 mm - 30X40 mm)

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