

HCM-Medical has developed a novel decellularization & sterilization of xenograft & allograft-derived biological scaffold tissues using scCO₂ technology with minimal/no damage to native Extracellular Matrix (ECM) composition & growth factors, resulting in excellent biocompatibility & tissue integration upon implantation. HCM currently manufactures CE/FDA-approved collagen membranes, bone void fillers derived from xenografts & allografts using scCO₂ technology.

THE CHALLENGE

Limited & timely availability of donor-derived tissues & allograft material for clinical application has led to the use of xenograft-derived tissues to meet clinical need. However, to meet current regulatory requirements of complete decellularization of xenografts using various agents, such as acids & bases, hypotonic & hypertonic solutions, detergents, alcohol & other solvents, leads to denaturation of native ECM composition & activates host immune response, resulting in tissue rejection.¹⁻²

THE TECHNOLOGY

CO₂ at given temperature & pressure reaches supercritical phase with penetrative properties of a 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. HCM-Medical is currently manufacturing CE-approved porcine/bovine-derived pericardium membranes for dental & orthopedic applications³ & bone fillers derived from bovine & equine source (Figure 2).

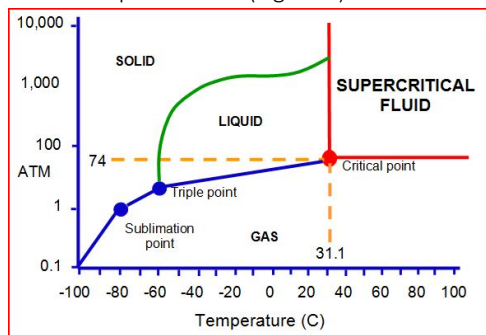


Figure 1. supercritical property of CO₂

The scCO₂ equipment is equipped with a co-solvent pump, 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 factors.

STAGE OF DEVELOPMENT

HCM-Medical is actively looking for collaborative partners to develop

- Allograft or xenograft-derived tissue products using scCO₂ technology.
- Sterilization of biological/tissue products using scCO₂⁴
- Impregnation or Extraction of active molecules

ADVANTAGES & APPLICATIONS

- Minimal/no damage on native ECM components
- Complete proven decellularization of soft & hard tissues using scCO₂
- Proven regulatory sterilization requirements of temperature-sensitive growth factors-coated tissues/material using scCO₂ without inactivating the growth factor's biological activity⁴.

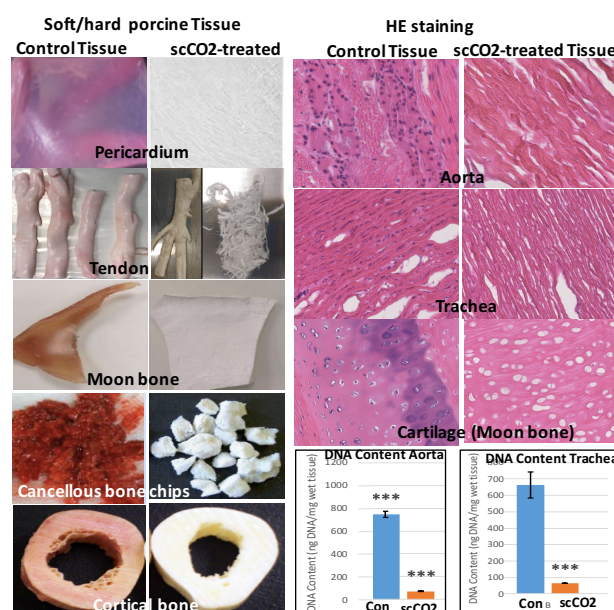


Figure 2. Representative tissues images of porcine pericardium, tendon, cartilage, Aorta, Trachea, cancellous bone chips, cortical bone before & after scCO₂-treatment (left). H/E and DNA Quantification demonstrate complete cell removal (right)

COMMERCIAL OPPORTUNITY

HCM-Medical is actively looking for partners to develop novel allografts, xenograft-derived tissue products & further explore sterilization, impregnation of tissue products/medical devices using scCO₂ technology.

REFERENCE

1. Keane T.J et al., Biomaterials 33 (2012) 1771-1781
2. Crapo P.M et al., Biomaterials. 2011 Apr; 32(12): 3233-3243.
3. <http://www.regedent.com/en/professionals/products/ossix-plus-smartbrane/>
4. Bernhardt A et al., PLoS One. 2015; 10(6): e0129205