



March 2017

NovaKill™/Supercritical CO₂ Process Seen as a Method of Choice for the Sterilization of Decellularized Heart Valves.

Damage induced by gamma irradiation to decellularized porcine heart valves prompted scientists at the Mayo Clinic to seek an alternative method of sterilization. Sterilization using electrolyzed water, low-dose (3kGy) gamma radiation, ethanol/peracetic acid solution, liquid hydrogen peroxide and the NovaKill™/supercritical CO₂ process were compared directly for their ability to inactivate micro-organisms in heart valves and avoiding physical and biological damage to the collagen matrix.

The post-treatment analysis of heart valves found only the ethanol/peracetic acid solution and the NovaKill™/supercritical CO₂ process produced sterile samples, and demonstrated the value of NovaKill™/supercritical CO₂ process over other sterilization methods: Looking at tensile strength, the researchers found that the stiffness of decellularized valve leaflets was virtually unchanged following NovaKill™/supercritical CO₂ sterilization whereas the other treatments either increased or decreased stiffness. In addition, electrolyzed water, low-dose gamma radiation and liquid hydrogen peroxide treatments all lowered the ultimate tensile strength of decellularized leaflets, whereas, remarkably, ethanol/peracetic acid and NovaKill™/supercritical CO₂ sterilization restored tensile strength to the level seen in native tissue. Finally, collagen cross-linking testing using DSC analysis found that collagen in leaflets sterilized using NovaKill™/supercritical CO₂ does not exhibit evidence of cross-linking seen in a glutaraldehyde-treated positive control or in leaflets treated with ethanol or peracetic acid in solution.

The authors of the study concluded that *“the scCO₂ sterilization technique proved superior to other techniques evaluated. It maintained good mechanical properties and structural integrity during the sterilization process”*, confirming what has been observed by NovaSterilis and other independent researchers with different collagen-based products

Disclaimer: NovaSterilis was contracted completed all NovaKill™/supercritical CO₂ sterilization in a Nova2200™ vessel. NovaSterilis did not fund or support this project.

New Publication: Hennessy et al., J. Am. Coll. Cardiol. Basic Trans. Science. 2017;2(1):71-84.

Current scCO₂ applications

The NovaKill™ / scCO₂ technology is being utilized by US and International Tissue Banks to produce sterile allograft tissue in final packaging ready for transplantation. To date over 100,000 NovaKill™/scCO₂-sterilized allograft transplants have been performed with no adverse reports. This sterilization technology has also been validated for sterilization of two medical devices with

regulatory approval. NovaSterilis licenses processes utilizing a larger 100 liter scCO₂ sterilization unit, the Nova8800™, to meet the high throughput needs of larger tissue processors and medical device manufacturers. NovaSterilis' scCO₂ process provides the medical materials industry with a safe and effective, in house, low-cost terminal sterilization alternative.

For more information on NovaSterilis and supercritical carbon dioxide visit www.novasterilis.com or call 607-330-2772.