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Press Release

New Publication: Development of a Sterile Amniotic Membrane Tissue Graft Using Supercritical Carbon Dioxide. Wehmeyer *et al.*, *Tissue Eng. Part C* 21:649-59.

Scientists at the US Army Institute of Surgical Research in Fort Sam (Houston, TX) published a study in which they used the Nova $scCO_2$ process to sterilize high-quality amniotic membranes. Amniotic Membranes have become increasingly popular as tissue grafts and their preparation and preservation are extremely important. With the documented damage induced by γ-radiations to the collagen structure in amniotic membranes and other ECMs, the group of Robert Christy sought to identify a better sterilization method that can achieve effective micro-organism inactivation without damaging the ECM.

SAL6 sterility was verified against *Staphylococcus epidermis* and spores of *Clostridium sporogenes* inoculated onto amniotic membranes using just 2mL NovaKill™ additive added in a 20-Liter Nova2200 vessel and $scCO_2$ exposure time of 10 minutes. The quality of sterilized membranes was then assessed, starting with a histological evaluation that showed excellent conservation of the ECM structure and found no membrane lipids.

Strikingly, both Differential Scanning Calorimetry (DSC) and Fourier Transform Infrared Spectroscopy (FITR) analyses showed very similar results for native and for Nova $scCO_2$-sterilized amniotic membranes, with no evidence of any denaturation of the tissue being associated during sterilization. Biochemical analyses found no significant differences in type IV collagen, elastin, GAGs and hydroxyproline, and stem cells successfully attached and proliferated onto sterilized membranes, indicating non-cytotoxicity.

These results show great promise for the development of an effective non-damaging sterilization method applicable to ECM-based products, for wound healing and regenerative medicine applications.

Current $scCO_2$ applications

The NovaSterilis technology is being utilized by both US and International Tissue Banks to produce sterile allograft tissue in final packaging ready for transplantation. To date over 90,000 $scCO_2$ sterilized allograft transplants have been performed with no adverse reports. This sterilization technology is currently employed for sterilization of 2 medical devices with regulatory approval. NovaSterilis is now offering a larger 80 liter $scCO_2$ sterilization unit, the Nova8800, to meet the high throughput needs of larger tissue processors and medical device manufacturers. NovaSterilis' $scCO_2$ process provides the

medical materials industry with a safe and effective, in house, low cost terminal sterilization alternative.

About NovaSterilis

NovaSterilis currently markets terminal sterilization technology and equipment related to their supercritical carbon dioxide platform. The supercritical or fluid phase of CO_2, occurs at low pressure (72.9 atm) and moderate temperatures (31.1 °C). $ScCO_2$ retains advantageous properties of the gas and liquid phases of carbon dioxide making it an ideal fluid for manufacturing processes. The company currently markets the Nova 2200 (20 liter) and Nova8800 (80 liter) fully automated $scCO_2$ terminal sterilization equipment. NovaSterilis is a privately held biotechnology company located in Lansing, New York. NovaSterilis is the recipient of a 2007 Presidential Green Chemistry Challenge Award presented by the Environmental Protection Agency.

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