

NovaSterilis Awarded NIH Phase I Grant for Sporocidal Mechanism and Inline Monitoring of Peracetic Acid in Supercritical CO₂

Lansing, NY; March 18, 2015 – NovaSterilis Inc., which specializes in developing applications for supercritical carbon dioxide (SCCO₂), has been awarded a NIH Phase I grant to explore two important projects: the sporocidal mechanism of action, and inline monitoring of peracetic action in supercritical CO₂.

Ensuring the safety of surgical materials is of primary concern for manufacturers, surgeons and patients. Sterilization has taken center stage in the effort to reduce or eliminate healthcare acquired infections (HAI), what with the recent involvement of the FDA in a growing number of medical product recalls and the increased incidence of antibiotic resistant infections. Recent reports of CRE bacteria infection (carbapenem resistant Enterobacteriaceae) linked to unsterile duodenoscopes highlight the need for better sterilization processes, and a better understanding of the mechanism of spore inactivation.

NovaSterilis has completed two NIH Phase II grants validating Supercritical CO₂ sterilization of allograft tissue and absorbable sutures. These data demonstrated the ability to achieve a sterility assurance level of 10⁻⁶ or SAL6, the industry standard for medical devices while preserving the vital product characteristics. The achievement of SAL6 demonstrates a probability that one item in one million could be contaminated. For this grant Dr. Julien Fey NovaSterilis Director of Research and Development is collaborating with Dr. Peter Setlow, the Board of Trustees Distinguished Professor of Molecular Biology and Biophysics, UCHC, Farmington, CT and foremost expert in the mechanism of bacterial spore inactivation. Dr. Setlow has spent 50+ years exploring how sterilization technologies inactivate bacterial spores and his expertise will assist NovaSterilis to further define our process and these data will provide our customers with additional evidence for regulatory approvals.

We also propose to develop an inline monitoring system to ensure that the concentration of our proprietary biocide NovaKill™, is at the correct concentration throughout the

system. This development further builds on the desire to provide the most effective, predictable yet gentle sterilization process for allograft tissue, biomaterials, pharmaceuticals and medical devices.

Building on the success of past grants, which established effective SCCO₂ sterilization cycles while maintaining product characteristics, the Setlow collaboration will establish a definitive mechanism of kill providing vital information. “The NovaSterilis process is raising the bar in sterilization of biomaterials, but in order to ensure that all our customers achieve regulatory success we must definitively establish the mechanism by which we inactivate spores, stated David Burns President and CEO of NovaSterilis. Collaborating with Dr. Peter Setlow will provide this vital piece of data, and the development of an inline monitoring system will add additional value to the Nova2200 and Nova8800 sterilization systems.”

NovaSterilis technology is being utilized by both US and International tissue banks to produce sterile allograft tissue in final double (terminal) packaging ready for transplantation, to date over 70,000 SCCO₂ sterilized allograft transplants have been performed with no adverse reports. NovaSterilis is now offering larger 80 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, 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 CO₂, occurs at low pressure (72.9 atm) and moderate temperatures (31.1 °C). SCCO₂ 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 SCCO₂ 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.

** (SAL6) – Sterility Assurance Level 10⁻⁶ is a standard for medical devices. It is the probability of 1 nonsterile item in 1 million. For more information on NovaSterilis and supercritical carbon dioxide visit www.novasterilis.com