

NovaSterilis Awarded NIH Phase II Grant for Sterilization of Absorbable Sutures or Biomaterials Using Proprietary Supercritical CO₂ Technology

Lansing, NY; June 26, 2012 – NovaSterilis Inc., which specializes in developing applications for supercritical carbon dioxide (SCCO₂), has been awarded a NIH Phase II grant to further develop a commercial process for the sterilization of absorbable sutures using SCCO₂. Sutures are the number one wound closure device, with market of nearly \$2 billion annually.

Ensuring the safety of surgical materials is of primary concern for manufacturers, surgeons and patients. Sterilization, although an expected safety measure, is extremely difficult to accomplish without toxic chemicals or harsh physical environments. Given the recent involvement of the FDA in a growing number of medical product recalls, and EPA and OSHA environmental concerns related to suture sterilization by ethylene oxide (ETO), a new more environmentally friendly process is needed.

The requirement to sterilize absorbable sutures (device standard SAL6**) proves particularly challenging with respect to maintaining their mechanical properties. Sterilization technologies in wide use today, such as autoclaving, hydrogen peroxide, and gamma irradiation, cannot achieve SAL6 without incurring significant damage to the suture. ETO, a toxic, carcinogenic, environmentally dangerous and explosive chemical is currently the only method available for the sterilization of absorbable sutures, but residues in the product can impair healing or cause severe reactions. These limitations have resulted in product recalls, delayed healing, suture-induced inflammation, and compromised mechanical properties.

Building on the success of a Phase I grant, which established effective SCCO₂ sterilization cycles while maintaining the physical characteristics of the sutures, the Phase II grant will establish *in vivo* safety and efficacy of SCCO₂ sterilized sutures. It is vital to perform *in vivo* studies to provide manufacturers and regulators with the necessary proof of safety, efficacy, and improved outcomes. Commercial readiness testing will be performed to establish scale-up potential and shelf-life

parameters, providing regulators with a process that will pass all scrutiny and can be applied immediately to sutures and other biomaterials.

“The NovaSterilis process will improve the quality and safety of absorbable sutures by reducing patient exposure to toxic chemical residuals” stated David Burns, President and CEO NovaSterilis. “We initially developed this technology from concept to reality for the sterilization of allograft tissue, but there are many more delicate biomaterials that will benefit from this sterilization technology.”

NovaSterilis technology is being utilized by US and International tissue banks to produce sterile allograft tissue in final double (terminal) packaging ready for transplantation. Recent experiments at NovaSterilis utilizing larger scale SCCO₂ units provided important data to support the scale up of this technology 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, a 20 liter fully automated SCCO₂ terminal sterilization chamber and is in final development of an 80 liter unit. 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