

NovaSterilis Reports Significant Findings from Sterilization of Absorbable Suture Study

Lansing, NY; November 1, 2011 – NovaSterilis Inc. a leader in the development and commercialization of supercritical carbon dioxide (SCCO₂) technology in collaboration with CC Chu Ph.D (Cornell) reports successful findings from research funded by a National Institutes of Health (NIH) phase I grant. These results meet the study goal to sterilize absorbable sutures to a sterility assurance level 10⁻⁶ (SAL6) without chemical or mechanical degradation. NovaSterilis intends to apply for phase II funding to develop the process ready for commercial application.

Sterilization technologies in wide use, such as autoclaving, hydrogen peroxide, and gamma irradiation cannot achieve SAL6 without incurring significant damage to the absorbable suture. Ethylene oxide (ETO) is the only commercially available sterilization process for polymeric medical devices for example; suture materials, hydrogels, and many wound dressings. Although ETO sterilization is the standard in absorbable suture sterilization due to its effectiveness and lack of alternative methods, suture manufacturers have expressed interest in alternative methods due to the short- and long-term effects of residual ETO in sterilized products (e.g. cytotoxicity, delayed healing, etc.). ETO is also a recognized carcinogen, and requires precautionary measures because of toxicity to process technicians and its explosive nature. Recently, the EPA and other government agencies started to monitor ETO, and increased regulations on its use to limit environmental release and reduce acceptable residual chemical levels in response to personal and environmental issues.

In this study NovaSterilis intended to develop a process that would achieve a FDA acceptable sterilization process for commercially available absorbable sutures using their supercritical carbon dioxide process. In order to meet the needs of the market, NovaSterilis chose 4 of the largest selling sutures from Covidien and Johnson & Johnson. The focus of this research was to examine the tensile strength, absorption properties and cytotoxicity of the product post SCCO₂ sterilization, and to compare these results to the current standard of care which in this case are the commercially available sutures.

All mechanical property testing was performed in the lab of CC Chu Ph.D, a leader in the development of absorbable biomaterials. Testing included: tensile property, degradation (through *in vitro* immersion for a predetermined duration), and early absorption (scanning electron microscopy (SEM)). In all tests, supercritical carbon dioxide sterilized sutures performed as well as the commercial Covidien and Johnson & Johnson sutures. A preliminary shelf life study was also performed in

phase I and the SCCO₂ sterilized sutures were equivalent to controls.

The most significant data came from the comparison of cytotoxicity scores, or test to determine the quality of being toxic to cells. In this study the commercially available sutures showed mild to moderate cytotoxicity, which is most likely due to residual EtO in the thread. This residual chemical may retard the healing process or produce an inflammatory response at the site of the suture, which is counter to the desired outcome of a closure device. The NovaSterilis SCCO₂ sterilized sutures showed no cytotoxicity, which in theory would produce better outcomes and faster healing in the clinical setting. In addition, these test showed the NovaSterilis sterilization process removed residual EtO from the commercial sutures, in essence washing out the dangerous EtO residuals reducing the cytotoxicity scores of these sutures to zero. These data establish SCCO₂ sterilization as an effective and safe process, and highlight the processes ability to remove damaging chemical residuals from these sensitive materials.

“These results are exciting,” noted David Burns, President of NovaSterilis. “We have a safe and effective alternative to dangerous EtO sterilization. In addition to the safety and efficacy, our supercritical CO₂ process can be used to washout dangerous chemicals from sensitive materials. This is a new and exciting opportunity for NovaSterilis; there are many products currently available that contain dangerous residual chemicals, and NovaSterilis SCCO₂ may prove a viable commercial process to eliminate the residuals.”

Recent experiments at NovaSterilis utilizing larger scale SCCO₂ units provide data to support the scale up of this technology to meet the high throughput needs of medical device manufacturers. NovaSterilis supercritical CO₂ provides the medical materials industry a new, 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). Supercritical CO₂ 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 supercritical CO₂ 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.

For more information on NovaSterilis and supercritical carbon dioxide visit www.novasterilis.com