

NovaSterilis Issued US Patent 8658091 Using Supercritical CO₂ to Remove Residual Ethylene Oxide from Absorbable Sutures

Lansing, NY; March 25, 2014 – NovaSterilis Inc. specializing in the development of commercial applications for supercritical carbon dioxide (SCCO₂) was granted US Patent 8658091 for the removal of toxic ethylene oxide (EO) residuals.

This patent describes a process utilizing nontoxic CO₂ at or near its supercritical pressure to remove the toxic EO residual from absorbable sutures following sterilization. Currently used for sterilizing absorbable sutures, EO is a toxic, carcinogenic and explosive gas that is difficult to remove from many biomaterials. NovaSterilis successfully removed toxic levels of EO from sutures while maintaining all the vital physical and mechanical characteristics of the suture. Through additional work NovaSterilis was also able to eliminate the need for EO sterilization altogether, achieving a Sterility Assurance Level of 10⁻⁶ with supercritical CO₂ while maintaining the integrity of the product. Sutures are the number one wound closure device, and the market is dominated by Johnson & Johnson and Covidien.

David Burns, President of NovaSterilis noted “this new application is extremely exciting and can be applied across many classes of products that are sterilized with EO, potentially improving the performance of the product and outcomes of procedures utilizing these devices. We are confident that this process can be expanded to a broad range of products and chemicals including, for example the removal of residual solvents from pharmaceuticals.”

This new process builds on NovaSterilis portfolio of equipment, patents, and processes focused on the special qualities of supercritical CO₂. The Company provides instrumentation for use by the tissue bank industry to sterilize allograft tissue, and is currently expanding into the sterilization of regenerative scaffolds and medical devices. This new patent provides an important entry into the absorbable polymers industry.

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 the Nova8800 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