

NovaSterilis Awarded Soft Tissue Processing Patent

Lansing, NY; January 4, 2012 – NovaSterilis Inc. specializing in developing applications for supercritical carbon dioxide, has been granted US Patent 8,034,288 B2. The patent, dated October 11, 2011 entitled “Method and Apparatus for Cleaning of Viable Donor Soft Tissue”, covers a new method for cleaning soft allograft tissue including tendon, fascia, and skin with a supercritical fluid, thus avoiding other harmful chemical solvents that may leave residual chemicals.

The patent describes a process using carbon dioxide at temperatures $\geq 31.1^{\circ}\text{C}$ and a pressure of 1099 PSI. At this “critical point,” carbon dioxide achieves the “supercritical” or dense gas phase having valuable properties of both the liquid and gas states. In this state CO_2 is a potent organic non-polar solvent that liquefies fats, and as a penetrating fluid SCCO_2 can be utilized to extract the imbedded fats and antigenic matter, in essence deep-cleaning the material. Tissue exposed to this cleaning step is significantly cleaner throughout the entire thickness of the material than tissue cleaned with other soaps and solvents.

Removing antigenic material from allograft tissue leaves the final product free of residual donor material, for example fat, blood and cellular material, reducing the potential to induce an inflammatory or immune response. This deep cleaned tissue which is primarily collagen acts as a scaffold for cell infiltration and incorporation which may improve patient outcomes. Collagen scaffolds are playing a central role in the field of regenerative medicine and NovaSterilis is working with a few researchers in this field.

“Donor tissue is a valuable resource; it is our goal to assist tissue banks to produce the cleanest and highest quality allograft tissue. This invention is a natural progression in our exploration of supercritical CO_2 and sterilization noted David Burns, President of NovaSterilis. “We are proud of

this patent; it complements our tissue sterilization process and produces a tissue that is extremely clean, safe and sterile (SAL6). Feedback from processors, distributors and surgeons place tissue processed with our SCCO_2 technology among the best!”

NovaSterilis is currently commercializing patents based on supercritical CO_2 , including terminal sterilization of biomedical materials. This technology is being utilized by US and International tissue banks to produce sterile allograft tissue in final double packaging ready for transplantation. This patent validates an additional application of NovaSterilis technology utilizing the knowledge and experience gained from our allograft and biomedical material sterilization work. NovaSterilis expects to find additional applications and modifications for this cleaning technology.

Recent experiments at NovaSterilis utilizing larger scale SCCO_2 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 supercritical CO_2 provides the medical materials industry 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 CO_2 , occurs at low pressure (72.9 atm) and moderate temperatures (31.1°C). Supercritical CO_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, a 20 liter fully automated supercritical CO_2 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.