

NovaSterilis, Inc. Demonstrates Sterilization of Human Tissue Using Supercritical Carbon Dioxide

New technology, based on MIT invention, will help tissue banks address serious threat to public health

ITHACA, NY, May 17th, 2003 – **NovaSterilis Inc.**, of Ithaca, NY, has developed an application of the company's patented supercritical carbon dioxide (SCD) technology for the sterilization of musculoskeletal tissue. The company has demonstrated that bone tissue, used in allograft procedures, can be sterilized with no loss of strength or deterioration in bone density.

The importance of bone allograft tissue in orthopaedic medicine has grown rapidly during the last decade. In the past five years more than two million musculoskeletal allograft have been distributed to surgeons for transplant into patients. This large clinical demand for tissue has also increased the numbers of potential exposures to pathogens, thus making the safety of bone tissue a primary focus for the tissue banking industry, clinicians, and the FDA. Yet no method currently exists for sterilizing human transplant tissue, an industry that is largely served by private tissue banks.

Over the past two years, at least one death and more than two dozen serious infections have been attributed to the use of contaminated tissue in transplant procedures. Despite these and other reported cases linked to tainted tissue, the FDA has not yet acted to introduce appropriate regulatory procedures.

The **NovaSterilis** technology for SCD bone sterilization is the first effective method of bacterial decontamination of bone. The patented method, which uses carbon dioxide (an

inert natural gas), combines the physicochemical properties of SCD with a novel reactor design, innovative processing and proprietary additives. **David Burns, President and CEO of NovaSterilis** noted "SCD is the only technology that completely sterilizes bone tissue without damaging it. Current methods, which involve cold washings with disinfecting solutions, result in incomplete sterilization, which may lead to subsequent infection upon transplantation."

Gamma irradiation, a widely used sterilization method, only partially kills infectious organisms, while causing tissue damage that results in undesirable reductions in strength and autogenesis capabilities.

The potential for bacterial or viral contamination of allograft bone is high without adequate secondary sterilization processing. Recent occurrences of disease transmission have further heightened the concern about the safety of allograft bone and other human tissue. Tissues such as tendons and ligaments have been associated with clostridial infection, due to unsatisfactory disinfection or handling prior to transplantation.

Musculoskeletal disorders and diseases are the most frequently identified physical impairments in the United States. It is estimated that 36 million Americans have musculoskeletal conditions that limit their ability to function, and that these disorders are chronic and permanent, with costs to society exceeding \$100 billion annually. **NovaSterilis** develops supercritical carbon dioxide sterilization technology for biomedical applications.