An Overview of the BioCleanse® Tissue Sterilization Process

BioCleanse is covered by U.S. Patents 6,482,584; 6,613,278 and 6,652,818 and pending U.S. and foreign applications in the name of RTI Biologics Inc.

©2008 RTI Biologics Inc.

How does BioCleanse work?

First, blood, lipids and marrow are removed from the bone through a vacuum/pressure process. Removal of these elements, which are the primary disease reservoirs, reduces risk and recipient immune response.

Chemical sterilants then completely penetrate the bone. These sterilants (which are commonly used in tissue processing) are validated to inactivate pathogenic organisms including HIV, hepatitis B and C, bacteria, fungi and spores.

The final step removes germicides, leaving the tissue biocompatible.

Donor Screening:
Medical/Social History Evaluation
- Family / Next-of-Kin Interview
- Medical Record Evaluation / Hospital Records
- Behavioral / Lifestyle Risk Assessment
- Medical Examiner/Coroner’s report (autopsy report, when available)
- Laboratory, pathology & radiology reports

Blood Tests
- HCV Antibody
- HBV Surface Antigen
- HIV I & II Antibody
- HBV Total Core
- HTLV I & II Antibody
- RPR for Syphilis
- HIV-1/NAT
- HCV/NAT

Accredited by American Association of Tissue Banks
- ISO 13485 Certified

1 Method to Determine Germicidal Inactivation in Allograft Processing. C. Randal Mills, PhD, CTBS; Michael R. Roberts, MA, CTBS; John R. Bianchi, PhD. Presented at 2002 American Society for Testing and Materials meeting.
2 Dye Perfusion into Cadaveric Human Bone as an Indication of Sterilant Penetration. Michael R. Roberts, MA, CTBS; C. Randal Mills, PhD, CTBS; Jerry Chang, BS; Jeffrey Wang, MD. Presented at 2002 American Association of Tissue Banks annual meeting.
4 Biomechanical Integrity of Human Allograft Bone After Sterilization. Donna M.K. Squillace, MS; Matthew C. Summitt, MS; Gina Scurti, BS; John R. Bianchi, PhD. Presented at 2002 Society for Biomaterials meeting.
Unlike plastics and metal implants, human tissue has unique biological properties that help the body heal. However, along with the benefits of allograft come risks. Although the risk of disease transmission from a tissue transplant is low, the possibility still exists that it could occur, even with accepted donor screening and testing—unless the tissue is sterilized through an effective process.

Technology now exists that essentially eliminates the risk of disease transmission. The BioCleanse Tissue Sterilization Process is validated to sterilize tissue, while preserving the tissue strength and biocompatibility. It is scientifically proven, validated and clinically substantiated to address donor to recipient disease transmission risk. This chemical and mechanical process does not use excessive heat, irradiation or ethylene oxide.

A. Removes blood, lipids, marrow

Studies show that the BioCleanse chemicals and processing method effectively sterilize tissue-based products with complex matrices.

B. Thoroughly penetrates tissue

Studies found that after 5 minutes contact time (normal cycle: 218 minutes), the BioCleanse process completely perfused inner matrices of cortical and cancellous bone with sterilants.

C. Eliminates HIV, hepatitis, fungi, spores – the complete antimicrobial spectrum

Validated to Eliminate:

- Relevant and Model Viruses
  - Human Immunodeficiency Virus (HIV)
  - Hepatitis B Virus (HBV)
  - Hepatitis A Virus (HAV)
  - Parvovirus (PPV)

- Spores
  - Clostridium spongogenes
  - Bacillus stearothermophilus

D. Preserves biomechanical and structural integrity

Studies show BioCleanse eliminates contaminants while preserving tissue strength and biocompatibility.

What is the BioCleanse process?

The BioCleanse process is a low-temperature chemical sterilization technology that is validated to inactivate spores, but preserve the biomechanical integrity of the graft. It is a fully automated pharmaceutical grade process that offers an added measure of safety. The same strict donor screening and tissue testing, which has always been adhered to, is still performed.