The BioCleanse® Tissue Sterilization Process: A Proven Standard for Tissue Safety
Who is RTI Biologics?

RTI Biologics, Inc. (RTI) is the leading provider of sterile biological implants for surgeries around the world with a commitment to advancing science, safety and innovation.

- RTI prepares human donated tissue and bovine tissue for transplantation through extensive testing and screening, precision shaping and proprietary, validated sterilization processes.
- RTI’s allograft and xenograft implants are used in sports medicine, orthopedic, dental, hernia and other specialty surgeries.
- RTI was the first company to offer precision-tooled bone implants and assembled technology to maximize each gift of donation.
- RTI’s 65,000 square foot state-of-the-art processing facility is located in Alachua, FL.

One tissue bank has developed and implemented a low-temperature chemical-sterilization approach (BioCleanse) that kills spores but preserves the biomechanical integrity and function of some allografts.”

—New England Journal of Medicine

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Low-temperature chemical sterilization technologies that kill spores but preserve the biomechanical integrity and function of some allografts are being evaluated.

(Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, March 14, 2002)

Why is the BioCleanse® process important?

• Sterilizes tissue through an effective and validated process
• Scientifically proven to address the risk of donor to recipient disease transmission
• Thoroughly penetrates tissue
• Preserves biomechanical and structural integrity
• Preserves biocompatibility
• Inactivates or removes bacteria, fungi & spores
• Redundant safeguards such as computer monitoring have been designed into the process to ensure tissue safety.

More than a million implants. Zero incidence of allograft-associated infection. It’s not just our goal. It’s our track record.
Why is sterilization important?

- In order for a graft to be sterile and non-innougenic, viruses, bacteria, and spores must be inactivated or removed through a validated sterilization process. Aseptic processing and other methods do not inactivate or remove these contaminants.  
- To achieve sterilization, individual processes should be validated by tissue type:
  - Validation should include:
    - Tissue penetration
    - Viral inactivation
    - Removal of a wide-range of organisms using worst-case testing
    - Retention of biocompatibility and tissue functionality
- Because of window periods, false negative serological test results have been documented \(^1\) by tissue processors, which may risk transmission of disease to patients if the tissue has not been sterilized through a validated sterilization process.

What should you ask before using tissue?

- Has the tissue been sterilized?
- Is the sterilization process validated to completely penetrate the tissue matrix, inactivate or remove blood, lipids & marrow, bacteria, bacterial spores, fungi, yeasts and viruses (enveloped & nonenveloped)?
- What is the clinical history of the process?
- Does the sterilization process meet these requirements while maintaining the biomechanical integrity and biocompatibility of the tissue?

Sterilization at RTI

- Where possible, RTI has advanced beyond the use of aseptic processing, implants processed at RTI are sterilized through one of three processes. The BioCleanse® process sterilizes bone and sports medicine soft tissue grafts.
- To remove any surface bacteria, bone grafts are terminally sterilized using a validated method to achieve a 10\(^{-6}\) sterility level.
- RTI’s soft tissue grafts undergo a final post-processing 14-day sterility culture prior to release to achieve sterility without the use of irradiation.

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RTI uses many different review processes and tests, including but not limited to:

- Family/nest-of-kin interview
- Medical/hospital record review
- Behavioral/lifestyle risk assessment
- Medical examiner/coroner’s report (autopsy report, when available)
- Laboratory, pathology and radiology reports

Serological Testing
- HCV Antibody
- HBV Surface Antigen
- HIV 1 & 2 Antibody
- HBV Total Core
- HTLV 1 & 2 Antibody
- Syphilis
- HIV-1/NAT
- HCV/NAT

Microbiological Testing
- Pre-processing, culturing: Performed before processing begins, removes potentially unsuitable tissue from process
- Sterility confirmation: Performed at packaging for products that are not terminally sterilized
- Environmental controls: Monitors cleanliness of processing environment

Related Articles


New England Journal of Medicine, Vol. 350, No. 25; June 17, 2004


Michael R. Roberts, MA, CTBS; C. Randall Mills, PhD, CTBS; Jerry Chang, BS; Jeffrey Xiao, MD; “Dye Perfusion into Cadaveric Human Bone as an Indication of Sterilant Penetration.” Presented at 2002 American Association of Tissue Banks annual meeting.


Donna M.K. Squillace, MS; Matthew C. Summit, MS; Gina Scari, BS; John K. Bianchi, PhD. “Biomechanical Integrity of Human Allograft Bone After Sterilization.” Presented at 2003 Society for Biomaterials meeting.

RTI’s primary goal is to ensure patient safety. To fulfill this goal, RTI employs stringent donor screening, laboratory testing and tissue preparation validated to inactivate or remove pathogens. These redundant safeguards provide the highest level of confidence that patients will receive safe, high quality tissue.

Before processing tissue, a risk assessment is performed on every potential donor. Family members are interviewed, the donor’s medical records are evaluated, and if necessary, the donor’s physician is consulted. Blood samples from donors are tested for the presence of infectious diseases, including HIV and Hepatitis B & C.

The final determination of donor eligibility is made by RTI’s medical director – a licensed physician – utilizing all available, relevant information. After donor eligibility has been determined, tissue from a single donor is processed into final shapes, placed into an individual BioCleanse® chamber and sterilized.