

TUTOPLAST[®] Tissue Sterilization Process

for the ALLOMAX[™] Surgical Graft



Donor Screening

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



Blood Testing

Serological Testing

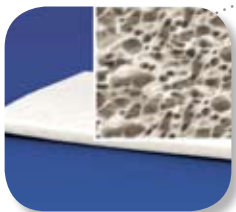
- HCV Antibody
- HBV Surface Antigen
- HIV I & II Antibody
- HBV Total Core
- HTLV I & II Antibody
- Syphilis
- HIV-1/NAT
- HCV/NAT

The final determination of donor eligibility is made by RTI's medical director – a licensed physician – utilizing all available, relevant information.



Tissue shaped into final form

- Validated chemical sterilization processes
- Thoroughly penetrates tissue
- Inactivates or removes HIV, hepatitis, fungi and spores
- Preserves biomechanical/biochemical integrity and collagen structure
- Scientifically proven and clinically successful
- Validated by individual tissue type based on worst-case testing using most difficult to kill organisms



Tutoplast[®] Tissue Process

Removal or inactivation of microorganisms:

The Tutoplast[®] Process is validated to inactivate the following viruses:

- Sindbis/Bovine Viral Diarrhea Virus (BVDV) Model
 - Human Immunodeficiency Virus (HIV)
 - Hepatitis C Virus (HCV)
 - Human T-lymphotropic Virus (HTLV)
- Pseudorabies Virus (PrV) Model
 - Hepatitis B Virus (HBV)
 - Herpes Virus Model (PrV)
 - CMV
- Human Poliovirus (Polio-1) Challenge
 - Hepatitis A Virus (HAV)
- Porcine Parvovirus (PPV) Challenge
 - Parvovirus B19

Validated low dose gamma irradiation achieves terminal sterility of SAL 10⁻⁶.



Sterilized finished product

YOU NEED TISSUE YOU CAN TRUST.

BARD gives you over a million reasons to trust the ALLOMAX[™] Surgical Graft.

BARD is committed to providing the safest possible implants to our customers. Our tissue processing partner, RTI Biologics[™], is the leading provider of sterilized biological implants for surgeries around the world. RTI has a proven record with zero incidence of allograft associated infection. This isn't just a goal – it's what RTI has achieved. RTI uses the fully validated Tutoplast[®] process to provide sterile tissue implants that have changed the lives of patients around the world.

The Tutoplast[®] process is a chemical sterilization methodology originally developed more than 30 years ago to sterilize and preserve tissue for implantation. Membrane and soft tissue augmentation grafts, as well as bone products, sterilized through Tutoplast[®] are used in hernia repair, breast reconstruction, dental, urological and other procedures.

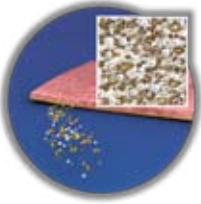
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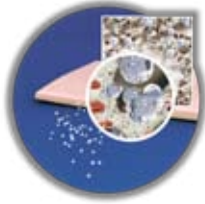
TECHNOLOGY
TECHNIQUE
TRAINING
TRUST

How does the Tutoplast® process work?

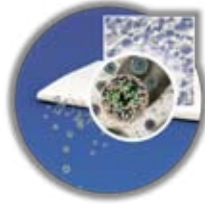
Osmotic, oxidative and alkaline treatments break down cell walls, inactivate pathogens, and remove bacteria. Solvent dehydration results in room temperature storage of tissue without damaging the collagen structure. Low dose gamma irradiation ensures sterility of final packaged product.



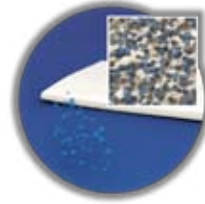
Delipidization
Removes lipids and red and white blood cells.



Osmotic Treatment
Disrupts cell membranes to allow easier removal of cellular components.



Oxidative Treatment
Removes immunogenic structures, enveloped and non-enveloped viruses.



Solvent Treatment
Preserves the natural tissue matrix and allows for five-year shelf life.



Irradiation
Low dose irradiation produces a terminally sterile graft, while preserving structural integrity.

ASEPTIC VS. TERMINALLY STERILE

“Aseptic” means that contaminants are not added during processing.

- Minimizes introduction of new organisms.
- Does not address existing organisms (endogenous contamination) or imply removal of contamination.
- Assumes all materials, including tissues, start sterile.
- United States Pharmacopeia (USP) sterility standards only show the absence of bacteria on the items cultured. The standards do not imply that the tissue is sterile.¹

“Sterile” means the state of being free from all living organisms.

- Sterilization is a process intended to inactivate or remove viable forms of microbial life, including bacterial spores, to achieve an acceptable sterility assurance level.
- Sterility Assurance Level (SAL): the probability of survival of microorganisms after a sterilization process and a predictor of the efficacy of the process.

Why is sterilization important?

Because of window periods, false negative serological test results have been documented² 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?
- 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?

“Aseptic processing does not eradicate contamination with organisms, and antibiotic/antifungal solutions will not eliminate spores or organisms such as Clostridium spp.”

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

Please consult product labels and inserts for uses, hazards, warnings and precautions. Not intended for purely aesthetic purposes.
References:

¹ United States Pharmacopeial Convention. (2002): <1211> Sterility Testing. In: United States Pharmacopeia and National Formulary (USP25-NF20). Rockville, Md: The United States Pharmacopeial Convention, Inc.

² MMWR (2002): Update: Allograft-Associated Bacterial Infections – United States, 2002. MMWR Morb Mortal Wkly Rep 51 (10), 207-210. The AlloMax surgical graft is processed by RTI Biologics.

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