

TUTOPLAST®

TISSUE STERILIZATION PROCESS

RTI Surgical's three sterilization processes have a proven combined record of more than five million biologic implants sterilized with zero confirmed incidence of implant-associated infection. This isn't just a goal – it's what we've achieved. We use fully-validated sterilization methods such as the Tutoplast® Tissue Sterilization Process to provide sterilized tissue implants that have changed the lives of patients around the world.

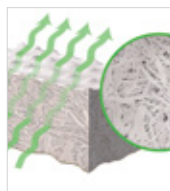
The Tutoplast Process is a chemical sterilization methodology originally developed more than 40 years ago by Tutogen Medical to sterilize and preserve tissue for implantation. Membrane and other soft tissue augmentation grafts, as well as bone implants sterilized through the Tutoplast Process, are used in hernia repair, dental, urological and other procedures.



DONOR SCREENING



BLOOD TESTING



TUTOPLAST® TISSUE
STERILIZATION PROCESS



STERILIZED
FINISHED GRAFT

Donor Screening

- > Donor risk assessment interview
- > Medical / hospital records review
- > Medical examiner/coroner's report (when provided)
- > Laboratory, pathology & radiology reports (when available)

Infectious Disease Testing

- > HIV-1/HIV-2 Antibody
- > Hepatitis C Virus Antibody
- > Hepatitis B Surface Antigen
- > Hepatitis B Core Antibody (Total)
- > Syphilis
- > Human T-Cell Lymphotropic Virus I/II Antibody
- > HIV-1/HCV/HBV NAT

The final determination of donor eligibility is made by an RTI medical director – who is a licensed physician – using all available, relevant information.

Tutoplast® Tissue Sterilization Process

- > Validated chemical sterilization process
- > 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
- > Validated low dose gamma irradiation achieves terminal sterility of SAL 10⁻⁶

Removal/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

How does the Tutoplast® Process work?

Osmotic, oxidative and alkaline (if indicated) treatments break down cell walls, inactivate pathogens, and remove bacteria. Solvent dehydration allows for room-temperature storage of tissue without damaging the native tissue structure. Low-dose gamma irradiation ensures a sterility assurance level (SAL) of 10^{-6} of the final packaged graft.

NATURAL DERMAL MATRIX



ALKALINE TREATMENT

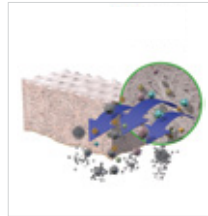
Removes cells and lipids which interfere with healing.

IN-PROCESS DERMAL MATRIX



OSMOTIC TREATMENT

Disrupts cell membranes to allow easier removal of cellular components.



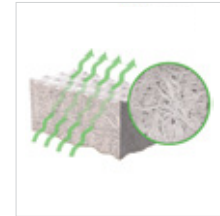
OXIDATIVE TREATMENT

Removes immunogenic structures, enveloped and non-enveloped viruses.



SOLVENT TREATMENT

Removes water from tissue, preserves the natural tissue matrix and allows for a five-year shelf life.



IRRADIATION

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

* Images depict dermal processing.

PRE-PROCESSED VS. TUTOPLAST® PROCESSED HUMAN DERMIS



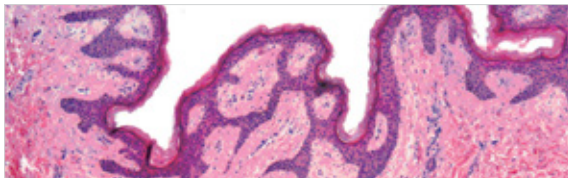
PRE-PROCESSED HUMAN DERMIS

Note presence of intact epidermis.



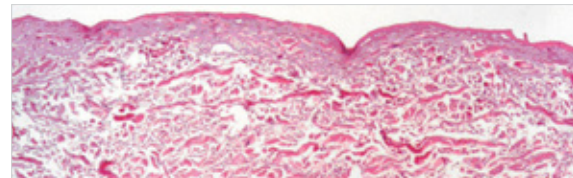
TUTOPLAST® PROCESSED HUMAN DERMIS

Note epidermis has been removed and underlying matrix has been preserved.



PRE-PROCESSED HUMAN DERMIS

Note the presence of cellular debris throughout (purple cell nuclei).



TUTOPLAST® PROCESSED HUMAN DERMIS

Note the absence of cellular debris and the intact tissue matrix.

*Data on file at RTI Surgical. H&E Stain. 50x magnification.



11621 Research Circle
Alachua, Florida 32615
Toll Free: 877.343.6832
Fax: 386.418.0342

www.rtisurgical.com

- Registered and inspected by the U.S. FDA
- Accredited by the American Association of Tissue Banks
- ISO 13485:2003 certification
- State Licensure: New York, California, Maryland, Florida and other states
- CLIA certified laboratory
- AdvaMed member

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