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 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® 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 40 years ago by Tutogen Medical to sterilize and preserve tissue for implantation. Membrane and soft tissue augmentation grafts, as well as bone implants sterilized through the Tutoplast process, are used in hernia repair, dental, urological and other procedures.

rti surgical™

Donor Screening

Blood Testing

Tutoplast® Tissue Sterilization Process

Sterilized Finished Graft

Donor Screening

- Donor risk assessment
- Medical / hospital records review
- Medical examiner/coroner's report (when available)
- 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 NAT-TMA

The final determination of donor eligibility is made by RTI's medical director – a licensed physician – utilizing 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

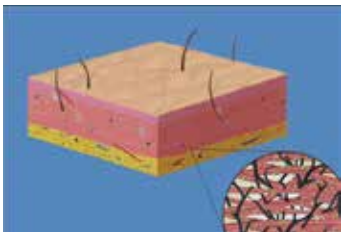
The Tutoplast process is validated to inactivate the following viruses:

- 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 sterility of the final packaged graft.

NATURAL DERMAL MATRIX



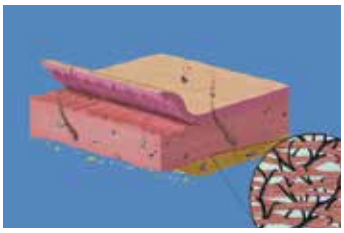
DELIPIDIZATION

Removes lipids and red and white blood cells.

OSMOTIC TREATMENT

Disrupts cell membranes to allow easier removal of cellular components.

IN-PROCESS DERMAL MATRIX



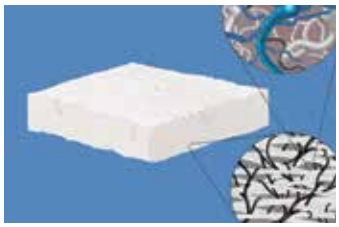
OXIDATIVE TREATMENT

Removes immunogenic structures, enveloped and non-enveloped viruses.

SOLVENT DEHYDRATION

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

IMPLANTABLE ACELLULAR MATRIX



IRRADIATION

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

**Alkaline step not depicted.*

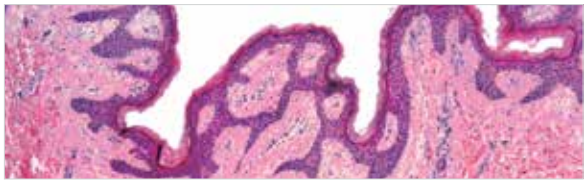
PRE-PROCESSED VS. TUTOPLAST® PROCESSED HUMAN DERMIS

PRE-PROCESSED HUMAN DERMIS

Note presence of intact epidermis.

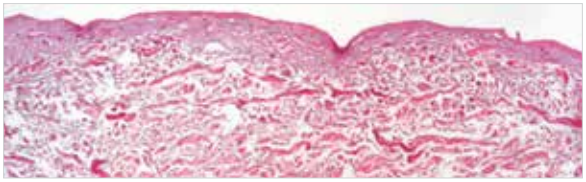
TUTOPLAST® PROCESSED HUMAN DERMIS

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.*

rti surgical™

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

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