rti surgical™

Sports Medicine Implants

A **HIGHER** STANDARD™

ABOUT **RTI SURGICAL**

- **Strong commitment to advancing science, safety and innovation**
- **Global leader in tissue-based innovations**
- **Precision-shaped allograft tissue for use in surgeries**
- **Sterilizes tissue with proprietary, validated sterilization processes that inactivate viruses—including the BioCleanse® Tissue Sterilization Process, the Tutoplast® Tissue Sterilization Process, and the Cancelle® SP DBM Sterilization Process**

RTI Surgical Inc. (RTI) is the leading global provider of sterile biologic, metal and synthetic implants for surgeries around the world with a commitment to advancing science, safety and innovation. RTI prepares human donated tissue for transplantation through extensive testing and screening, precision shaping and proprietary, validated sterilization processes.

RTI's innovations continuously raise the bar of science and safety for biologics–from being the first company to offer precision-tooled bone implants and assembled technology to maximize each gift of donation, to inventing fully-validated sterilization processes that include viral inactivation steps. These processes sterilize tissue and are scientifically proven to address donor-to-recipient disease transmission risk while preserving tissue strength and biocompatibility. RTI has a proven record of more than 5 million biologic implants sterilized through RTI's proprietary validated sterilization processes with zero incidence of implant-associated infection.

RTIs worldwide corporate headquarters are located in Alachua, Fla.

Additional U.S. locations: Marquette, Mich; Greenville, N.C.; Raleigh, N.C.; Austin, T.X.; Jacksonville, Fla.

International locations: Houten, The Netherlands; Metz, France; Neunkirchen, Germany

RTI Surgical is:

- Accredited by the American Association of Tissue Banks
- ISO 13485 Certified
- AdvaMed Member

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.

A **HIGHER**

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For more information, contact your RTI Surgical Sports Medicine Implant Representative.

TO ORDER DIRECTLY, CALL:
800.624.7238

REIMBURSEMENT INFO: Call 877.839.7152
or email: RTIReimbursementSupport@rtix.com

STANDARD™

THE **PATHWAY** FROM RECOVERY TO IMPLANTATION

Donor Screening

Infectious Disease & Microbiological Testing

Example of tissue before processing

BIOCLEANSE® TISSUE STERILIZATION PROCESS

Bone and sports medicine soft tissue

TUTOPLAST® TISSUE STERILIZATION PROCESS

Membrane tissue, soft tissue augmentation grafts, bone particulate

Infectious Disease Testing (for every donor):

- 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

After consent/authorization for donation is obtained, donor history screening and laboratory testing is performed in accordance with U.S. FDA regulations and AATB Standards.

Screening for Patient Safety

A complete donor risk assessment interview must be performed for every donor including:

- **Cause of death:** Donors are only accepted if cause of death is established.
- **Donor Risk Assessment:** RTI receives donated tissue from independently-licensed recovery agencies, which screen for safety prior to recovery, by conducting an interview with the family/next of kin and a behavioral/lifestyle risk assessment.

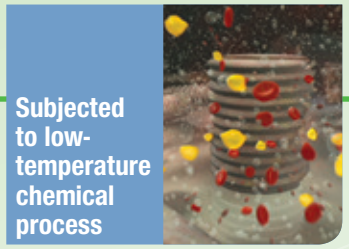
  Following receipt of tissue from the recovery agency, RTI evaluates records from the recovery agency and performs the following donor risk assessment:
  - » Medical record/hospital records review
  - » Medical examiner/coroner's report (when available)
  - » Laboratory, pathology and radiology reports (when available)

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

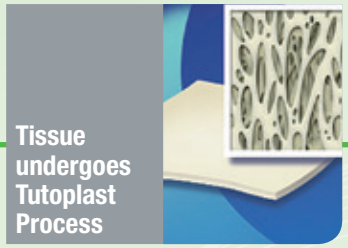
Testing for Patient Safety

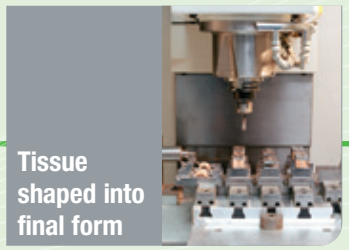
An extensive panel of infectious disease and microbiological tests are performed. These results are subject to stringent acceptance criteria in order to release the donor tissue.

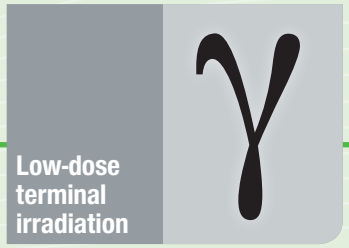
In addition to serological testing on the donor's blood, microbiological testing is used throughout the process (where appropriate) to screen for potential contamination and to provide confirmation of tissue suitability for transplant.

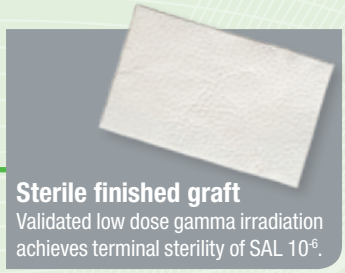


Note: Fresh-stored osteochondral allografts are cleansed, processed and preserved to maintain chondrocyte viability, and therefore are not sterilized through one of these processes.









BioCleanse® Tissue Sterilization Process

RTI's allograft constructs/ spacers and sports medicine soft tissue implants are sterilized to Sterility Assurance Level (SAL) 10^{-6} through its patented BioCleanse Tissue Sterilization Process, an automated, pharmaceutical-grade process.This SAL was established using most difficult case scenarios, which included Achilles tendon (because of its dense nature) and spores (because they are the most difficult microorganisms to remove).

How does the BioCleanse process work?

The BioCleanse system sterilizes tissue to SAL 10^{-6} using a complex, proprietary combination of mechanical and chemical processes, working in conjunction with each other. The mechanical component applies oscillating pressure in the presence of the chemical agents which gently perfuse and completely penetrate the tissue. This combination of chemical agents removes blood and lipids, and inactivates or removes pathogenic microorganisms. Repeated water rinses throughout the process remove debris, and final water rinses remove residual chemicals, leaving the tissue biocompatible. The BioCleanse process does not sterilize using irradiation.

Tutoplast® Tissue Sterilization Process

The Tutoplast process is a chemical sterilization methodology originally developed more than 40 years ago by Tutogen Medical, GmbH (now merged with RTI Surgical Inc.) to sterilize and preserve tissue for implantation. Membrane and soft tissue augmentation grafts and bone implants are sterilized through the Tutoplast process.

How does the Tutoplast process work?

Osmotic, oxidative and alkaline 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 implant.

WOUND COVERING AND SOFT TISSUE AUGMENTATION

MATRIX™ HD GRAFTS

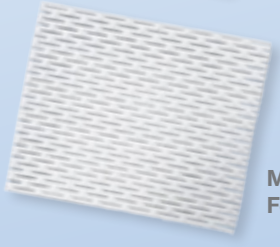
Sterilized through the Tutoplast® Tissue Sterilization Process

Storage: Room Temperature

- Sterile human dermis graft
- Stored dehydrated at room temperature for on-the-shelf use
- Well-suited for reconstructive surgical applications (dermal) and as a covering for chronic wounds

CODE	SIZE	AVG. THICKNESS
TD2203	2 x 3cm	0.3 – 0.7mm
TD0214	2 x 14cm	0.8 – 1.2mm
TD0405	4 x 5cm	0.8 – 1.2mm
TD0508	5 x 8cm	0.8 – 1.2mm
TD1010	10 x 10cm	0.8 – 1.2mm
TD1315	13 x 15cm	0.8 – 1.2mm
TDF405	Fenestrated, 4 x 5cm	0.8 – 1.2mm
TDF508	Fenestrated, 5 x 8cm	0.8 – 1.2mm

Matrix HD



Matrix HD
Fenestrated

LIGAMENT RECONSTRUCTION

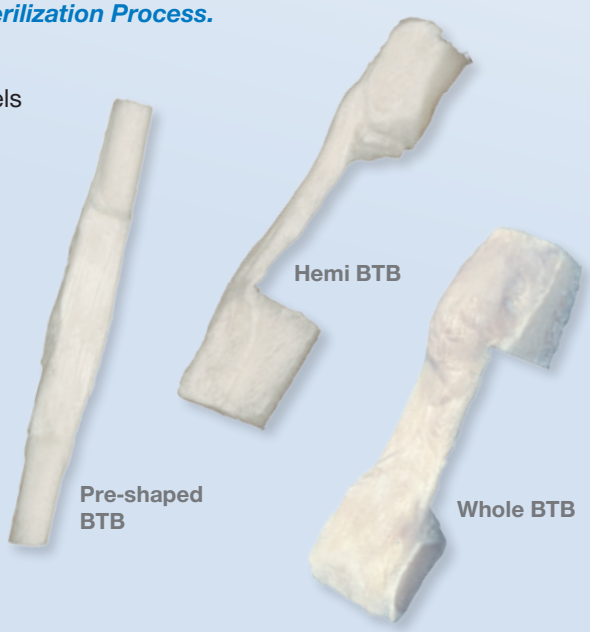
PATELLAR TENDONS

Sterilized without irradiation through the BioCleanse® Tissue Sterilization Process.

Storage: Frozen

- Pre-shaped bone blocks are available to fit 9, 10 and 11mm tunnels
  - Minimizes operating room time by eliminating the need for intraoperative shaping of the bone blocks
- Larger bone blocks are available (hemi, pre-trimmed and whole)
  - Provides additional bone for revision surgery or customized shaping to meet specific patient needs

CODE	DESCRIPTION
453002	Patellar Tendon, Pre-shaped, 10/10mm
453005	Patellar Tendon, Pre-shaped, 11/11mm
453012	Patellar Tendon, Pre-shaped, 9/10mm
453013	Patellar Tendon, Pre-shaped, 10/11mm
453008	Patellar Tendon Hemi
453010	Whole Patellar Tendon



BTB SELECT® ALLOGRAFT

Sterilized without irradiation through the BioCleanse® Tissue Sterilization Process.

Storage: Frozen

- Available in precise intra-articular lengths (33 - 45mm)
  - Allows surgeon to accurately match patient intra-articular length

CODE	DESCRIPTION
455034	BTB Select, 10/10mm

ADJUSTABLE LENGTH BTB ALLOGRAFT

Sterilized without irradiation through the BioCleanse® Tissue Sterilization Process.

Storage: Frozen

- Intra-articular length can be adjusted in the OR
  - Allows surgeon to accurately match patient intra-articular length

CODE	DESCRIPTION
453028	Femoral bone block with eyelet
453029	Adjustable BTB

Please Note: Order both the femoral bone block with eyelet and the tendon with assembled tibial bone block for a complete Adjustable Length BTB graft configuration.

LIGAMENT RECONSTRUCTION

PRE-SHAPED, PRE-TRIMMED AND CONVENTIONAL ACHILLES TENDONS

Sterilized without irradiation through the BioCleanse® Tissue Sterilization Process.

Storage: Frozen

- Pre-shaped bone blocks are available to fit 10 and 11mm tunnels
  - Minimizes operating room time by eliminating the need for intraoperative shaping of the bone blocks
- Larger bone blocks are available (pre-trimmed and conventional)
  - Provides additional bone for revision surgery or customized shaping to meet specific patient needs

CODE	DESCRIPTION
453006	Pre-shaped Achilles Tendon, 10mm
453004	Pre-shaped Achilles Tendon, 11mm
453206	Pre-trimmed Achilles Tendon
453042	Achilles Tendon with Large Calcaneus Block

NON-BONE TENDONS

Sterilized without irradiation through the BioCleanse® Tissue Sterilization Process.

Storage: Frozen

Non-bone tendons are interchangeable as graft options. Literature suggests biomechanical properties are dependent upon diameter of collagen not graft type.[1]

- BioCleanse-processed non-bone tendons are carefully pre-trimmed at proximal and distal ends
  - Results in robust grafts for suturing

CODE	DESCRIPTION	FOLDED DIAMETER Available in .50mm increments
453016	Tibialis Posterior Tendon	6.5mm to 11mm
453017	Tibialis Anterior Tendon	6.5mm to 11mm
453043	Peroneus Tendon	6.5mm to 10mm
453015	Semitendinosus Tendon	4.5mm to 7.5mm
453014	Gracilis Tendon	3mm to 6mm

1. **Pearsall et. al.**, "A Biomecahnical Comparison of Three Lower Extremity Tendons for Ligamentous Reconstruction About the Knee." *Arthroscopy.* 2003.

At the core of RTI's processing facility is the BioCleanse® processing system, featuring fully automated equipment and technology.

UNICORTICAL DOWEL

Sterilized through the BioCleanse® Tissue Sterilization Process

Storage: Freeze-dried

- Often used for ACL revision tunnel back-fill

CODE	DESCRIPTION
D02805	Non-Cannulated, 5mm
D02807	Non-Cannulated, 7mm
D02808	Fully Cannulated, 8mm
D02809	Fully Cannulated, 9mm
D02810	Fully Cannulated, 10mm
D02811	Fully Cannulated, 11mm
D02812	Fully Cannulated, 12mm
D02814	Fully Cannulated, 14mm
D02816	Fully Cannulated, 16mm

MENISCUS

BIOCLEANSE® PROCESSED MENISCUS

Sterilized without irradiation through the BioCleanse® Tissue Sterilization Process.

Storage: Frozen

- Specifically sized to match patient radiographs or MRIs
- Instruments are loaned at no additional cost for use during the allograft procedure

CODE	DESCRIPTION
453101	Meniscus Lateral, Left
453102	Meniscus Lateral, Right
453201	Meniscus Medial, Left
453202	Meniscus Medial, Right

FRESH-STORED OSTEOCHONDRAL GRAFTS

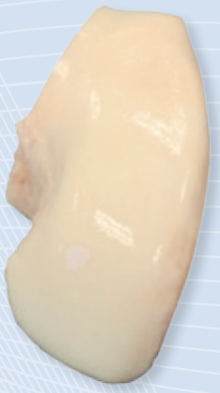
FRESH-STORED OC FEMORAL CONDYLE*

Aseptically Processed

Storage: Refrigerated

- Specifically sized to match patient radiographs or MRIs
- Instruments are loaned at no additional cost for use during the allograft procedure

CODE	DESCRIPTION
002682	Left Lateral Femoral Hemi-Condyle
002683	Left Medial Femoral Hemi-Condyle
002684	Right Lateral Femoral Hemi-Condyle
002685	Right Medial Femoral Hemi-Condyle



FRESH-STORED OC TALUS*

Aseptically Processed

Storage: Refrigerated

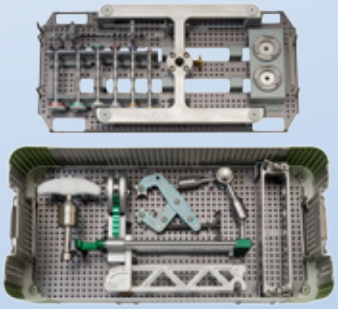
- Specifically sized to match patient radiographs or MRIs
- Instruments are loaned at no additional cost for use during the allograft procedure

CODE	DESCRIPTION
002680	Left Talus
002681	Right Talus

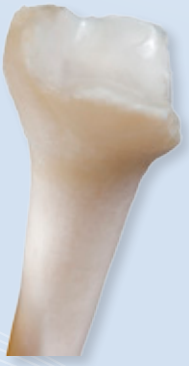
Coring Station

PRECISION ALLOGRAFT CARTILAGE KIT (PACK™)

- Offers an optimized and simplified technique for cartilage restoration
- Minimizes trauma to the allograft
- Provides a clean recipient socket and pristine plug surface



Coring reamers and counter bores are color coded by size.



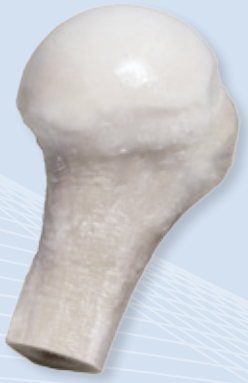
FRESH-STORED OC DISTAL TIBIA*

Aseptically Processed

Storage: Refrigerated

- Specifically sized to match patient radiographs or MRIs
- Instruments are loaned at no additional cost for use during the allograft procedure

CODE	DESCRIPTION
002670	Left Distal Tibia
002671	Right Distal Tibia



FRESH-STORED OC HUMERAL HEAD*

Aseptically Processed

Storage: Refrigerated

- Specifically sized to match patient radiographs or MRIs
- Instruments are loaned at no additional cost for use during the allograft procedure

CODE	DESCRIPTION
002672	Left Osteochondral Humeral Head
002673	Right Osteochondral Humeral Head

FRESH-STORED OC PATELLA*

Aseptically Processed

Storage: Refrigerated

- Specifically sized to match patient radiographs or MRIs

CODE	DESCRIPTION
002676	Left Osteochondral Patella
002677	Right Osteochondral Patella

FRESH-STORED OC TROCHLEA*

Aseptically Processed

Storage: Refrigerated

- Specifically sized to match patient radiographs or MRIs

CODE	DESCRIPTION
002674	Left Osteochondral Trochlea
002675	Right Osteochondral Trochlea

**Fresh-stored osteochondral allografts are cleansed, processed and preserved to maintain chondrocyte viability, and therefore are not sterilized through the BioCleanse®, Tutoplast® or Cancelle® SP DBM sterilization processes.*

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