Sports Medicine Implants

NOVOMEDICS
MODERNE MEDIZINTECHNIK

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The Path from Recovery to Implantation


Donor Screening


Serological & Microbiological Testing


Tissue before processing

BioCleanse® Tissue Sterilization Process


Tissue shaped into final form

Tutoplast® Tissue Sterilization Process


Membrane tissue, soft tissue augmentation grafts, bone particulate

Through its innovations, RTI Biologics, Inc. (RTI) continuously raises the bar of science and safety for biologics – from being the first company to offer precision-tooled bone implants and assembled technology, to inventing fully validated sterilization processes that include viral inactivation steps. Three such processes – the BioCleanse® Tissue Sterilization Process, the Tutoplast® Tissue Sterilization Process and Cancelle® DBM Sterilization Process – have a proven combined record of more than four million implants distributed with zero incidence of implant-associated infection. Validation studies have been performed for each process based on tissue type using appropriate challenge microorganisms.

Serological Testing (for every donor):

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

After consent/authorization for donation is obtained, donor history screening and laboratory testing is performed in accordance with 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, including 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 (autopsy report, when available)
  - Laboratory, pathology and radiology reports

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 serological 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.

Bone and sports medicine soft tissue

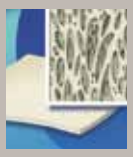
Low temperature chemical process

BIOCLEANSE® TISSUE STERILIZATION PROCESS

Tissue sterilized to SAL 10^{-6}

Bone grafts are terminally sterilized by a validated method. Sports medicine tendons are not terminally irradiated.

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



Tissue undergoes Tutoplast Process

Tissue shaped into final form

Low-dose terminal irradiation

TUTOPLAST® TISSUE STERILIZATION PROCESS

Sterile finished graft

Validated low dose gamma irradiation achieves terminal sterility of SAL 10^{-6}.

BioCleanse® Tissue Sterilization Process

RTI Biologics' allograft constructs/spacers and sports medicine soft tissue implants are sterilized to Sterility Assurance Level 10^{-6} through its patented BioCleanse Tissue Sterilization Process, an automated, pharmaceutical grade process. BioCleanse sterilization is used on grafts that provide a natural biologic scaffold in orthopedic, spine and sports medicine procedures.

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 positive and negative pressure in the presence of the chemical agents (including detergents and sterilants), which gently perfuse the tissue. This combination 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.

Even if other safeguards fail, RTI's BioCleanse technology sterilizes both bone and soft tissue to SAL 10^{-6}. This SAL was established using worst case testing scenarios which included Achilles tendon (because of its dense nature) and spores (because they are the most difficult microorganisms to remove).

Tutoplast® Tissue Sterilization Process

The Tutoplast process is a chemical sterilization methodology originally developed 40 years ago by Tutogen Medical, Inc. (now merged with RTI Biologics, Inc.) to sterilize and preserve tissue for implantation. Membrane and soft tissue augmentation grafts, as well as bone particulate, sterilized through Tutoplast are used in dental, urological, wound covering and other procedures.

How does the Tutoplast process work?

Osmotic, oxidative and alkaline (membranes only) treatments break down cell walls and inactivate or remove pathogens and 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.

Wound Covering and Augmentation

Matrix™ HD Graft

- Sterile room temperature human dermis graft
- Well-suited for reconstructive surgical applications and treatment of chronic skin wounds

Matrix™ HD *Sterilization: Tutoplast®*

Code	Description	Storage
TD2203	2cm X 3cm	RT
TD0405	4cm X 5cm	RT
TD0508	5cm X 8cm	RT
TD0214	2cm X 14cm	RT
TD1010	10cm X 10cm	RT
TD1315	13cm x 15cm	RT

(Stored dehydrated at room temperature for off-the-shelf use)

RT=*Room Temperature*

Ligament Reconstruction

Pre-shaped Bone-Patellar Tendon-Bone (BTB)

Pre-shaped Bone-Patellar Tendon-Bone (BTB) *Sterilization: BioCleanse®*

Code	Description	Storage
453002	Pre-shaped BTB 10mm	FZ
453005	Pre-shaped BTB 11mm	FZ
453012	Pre-shaped BTB 9/10mm	FZ
453013	Pre-shaped BTB 10/11mm	FZ

NON-IRRADIATED

BTB Select® Allograft

- Assembled technology provides precision size-matching relative to the intra-articular length of BTB allografts

BTB Select® Allograft *Sterilization: BioCleanse®*

Code	Description	Storage
455034	BioCleanse® BTB Select® pre-shaped 10/10mm	FZ

RTI maintains an inventory of intra-articular lengths from 35-44mm.

NON-IRRADIATED

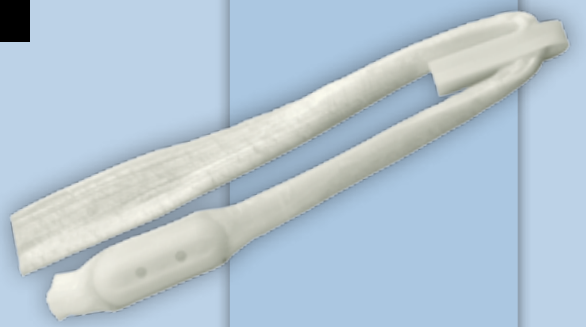
Adjustable Length BTB

- Combines the flexibility of soft tissue grafts with BTB fixation

Adjustable Length BTB *Sterilization: BioCleanse®*

Code	Description	Storage
453028	Femoral bone block with eyelet	FZ
453029	Tendon with assembled tibial bone block	FZ

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.



NON-IRRADIATED

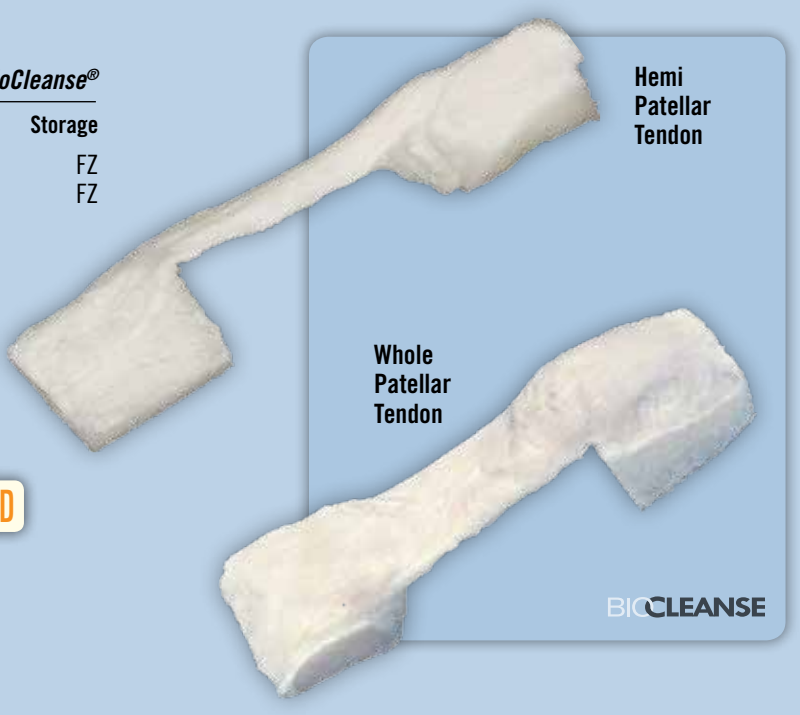
FZ=*Frozen*

Ligament Reconstruction

Hemi and Whole Patellar Tendons

Hemi and Whole Patellar Tendons *Sterilization: BioCleanse®*

Code	Description	Storage
453008	Patellar Tendon Hemi	FZ
453010	Patellar Tendon Whole	FZ



NON-IRRADIATED

Pre-shaped, Pre-trimmed and Conventional Achilles Tendons

Pre-shaped Achilles Tendons *Sterilization: BioCleanse®*

Code	Description	Storage
453006	Pre-shaped Achilles Tendon with Calcaneus 10mm	FZ
453004	Pre-shaped Achilles Tendon with Calcaneus 11mm	FZ

Pre-trimmed Achilles Tendons *Sterilization: BioCleanse®*

453206	Pre-trimmed Achilles Tendon with Calcaneus	FZ

Conventional Achilles Tendons *Sterilization: BioCleanse®*

453042	Achilles Tendon with Large Calcaneus	FZ

NON-IRRADIATED

FZ=*Frozen*

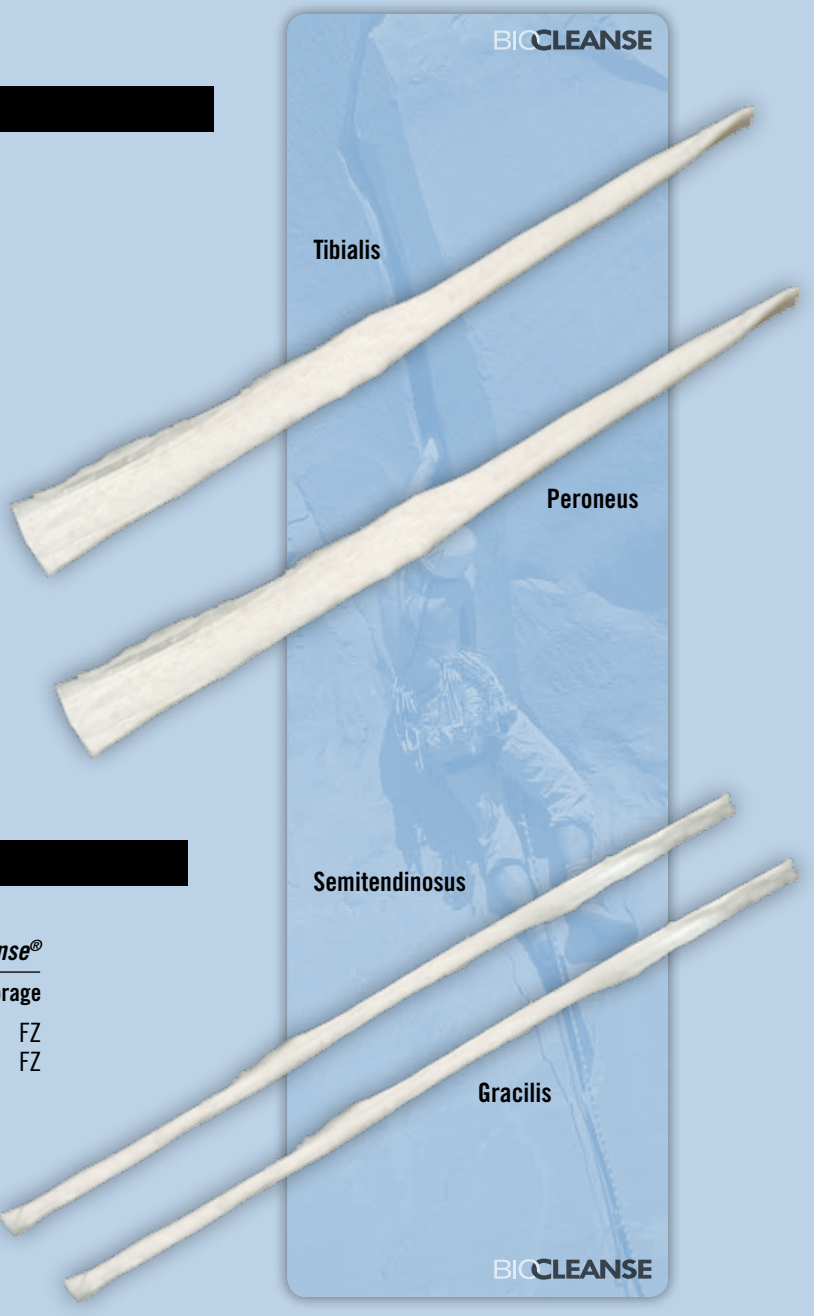
Ligament Reconstruction

Tibialis and Peroneus Tendons

Tibialis and Peroneus Tendons *Sterilization: BioCleanse®*

Code	Description	Storage
453016	Posterior Tibialis Tendon	FZ
453017	Anterior Tibialis Tendon	FZ
453043	Peroneus Longus Tendon	FZ

NON-IRRADIATED



Semitendinosus and Gracilis Tendons

Semitendinosus and Gracilis Tendons *Sterilization: BioCleanse®*

Code	Description	Storage
453015	Semitendinosus Tendon	FZ
453014	Gracilis Tendon	FZ

NON-IRRADIATED

Unicortical Bone Dowel

Unicortical Bone Dowel *Sterilization: BioCleanse®*

Code	Description	H x D	Storage
D02808	Unicortical Dowel	8x30-35mm	FD
D02810	Unicortical Dowel	10x30-35mm	FD
D02812	Unicortical Dowel	12x15-35mm	FD
D02814	Unicortical Dowel	14x15-35mm	FD
D02816	Unicortical Dowel	16x15-35mm	FD
D02818	Unicortical Dowel	18x15-35mm	FD

FZ=*Frozen*
FD=Freeze Dried

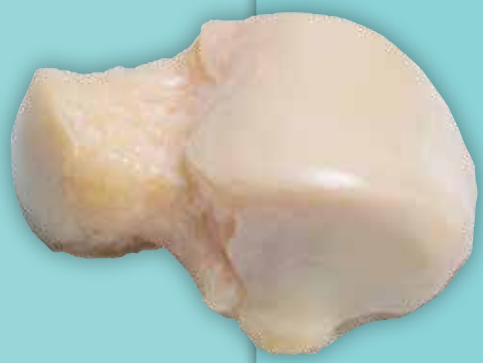
Fresh-stored Osteochondral

Fresh-stored OC Femoral Condyle*

- Specifically sized to match patient radiographs or MRIs

Fresh-stored OC Femoral Condyle		***Aseptically Processed***
Code	**Description**	**Storage**
002682	Left Lateral Condyle	RF
002683	Left Medial Condyle	RF
002684	Right Lateral Condyle	RF
002685	Right Medial Condyle	RF

Fresh-stored OC Talus*



- Specifically sized to match patient radiographs or MRIs

Fresh-stored OC Talus		***Aseptically Processed***
Code	**Description**	**Storage**
002680	Left Talus	RF
002681	Right Talus	RF

RF=*Refrigerated*

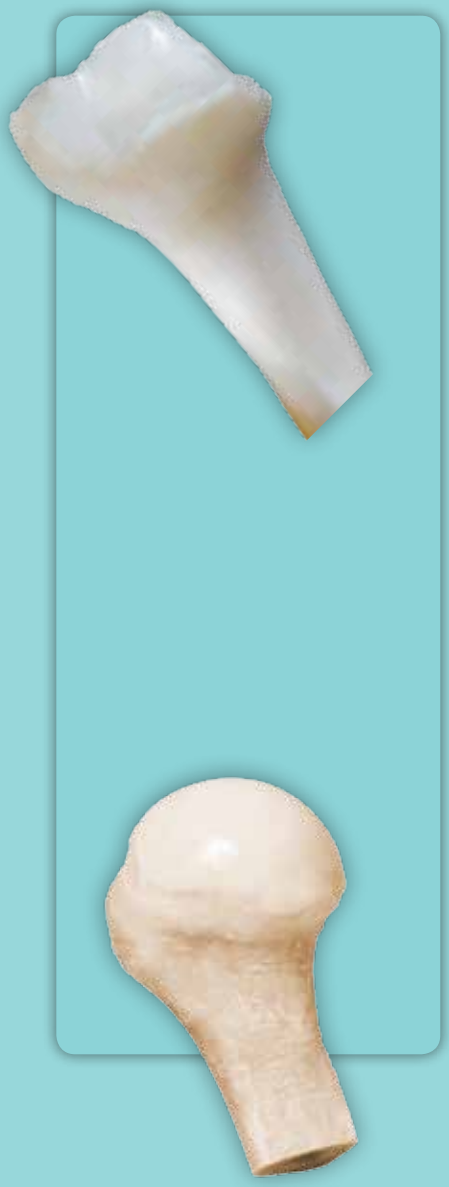
Fresh-stored osteochondral allografts are cleansed, processed and preserved to maintain chondrocyte viability, and therefore are not sterilized through the BioCleanse®, Tutoplast® or Cancelle® SP sterilization processes.

Fresh-stored Osteochondral

Fresh-stored OC Distal Tibia*

- Specifically sized to match patient radiographs or MRIs

Fresh-stored OC Distal Tibia		***Aseptically Processed***
Code	**Description**	**Storage**
002670	Distal Tibia OC Left	RF
002671	Distal Tibia OC Right	RF



Fresh-stored OC Humeral Head*

- Specifically sized to match patient radiographs or MRIs

Fresh-stored OC Humeral Head		***Aseptically Processed***
Code	**Description**	**Storage**
002672	Left Humeral Head	RF
002673	Right Humeral Head	RF

RF=*Refrigerated*

Fresh-stored Osteochondral

Fresh-stored OC Patella*

- Specifically sized to match patient radiographs or MRIs

Fresh-stored OC Patella®		***Aseptically Processed***
Code	**Description**	**Storage**
002676	Left Patella	RF
002677	Right Patella	RF

Fresh-stored OC Trochlea*

- Specifically sized to match patient radiographs or MRIs

Fresh-stored OC Trochlea		***Aseptically Processed***
Code	**Description**	**Storage**
002674	Left Trochlea	RF
002675	Right Trochlea	RF

RF=*Refrigerated*

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 sterilization processes.

Meniscus

BioCleanse® Meniscus

- Specifically sized to match patient radiographs or MRIs

BioCleanse® Meniscus *Sterilization: BioCleanse®*

Code	Description	Storage
453101	Meniscus Lateral with Bone Bridge (Left)	FZ
453102	Meniscus Lateral with Bone Bridge (Right)	FZ
453201	Meniscus Medial with Bone Bridge (Left)	FZ
453202	Meniscus Medial with Bone Bridge (Right)	FZ
453030	Meniscus Lateral without Bone Bridge	FZ

NON-IRRADIATED

FZ=Frozen

About RTI Biologics, Inc.

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

RTI Biologics, Inc. 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 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, are clinically successful and are scientifically proven to address donor-to-recipient disease transmission risk while preserving tissue strength and biocompatibility. They have a proven record of more than four million implants distributed with zero incidence of implant-associated infection.

RTI's worldwide corporate headquarters are located in Alachua, Fla., with international facilities in Neunkirchen, Germany, and Aix-en-Provence, France. The company is accredited in the U.S. by the American Association of Tissue Banks.

Vision

We will be recognized as the world leader in transforming donated and natural tissue into safe and innovative biologic solutions.

Mission

We improve lives by using the body to heal the body to achieve life-restoring results.

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References

[1] Archibald, LA, et al., "Seroprevalence of Bloodborne Viruses Among Cadaveric Donors of Human Tissue: Implications for Tissue Safety." Presented at EATB 2005.

[2] Carr, AS, et. al., "Mechanical Testing of Soft Tissue Allografts Sterilized Through the BioCleanse Process." Unpublished data, 2005.

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