Distributor:
ORTHOFIX®
Lewisville, TX 75056 | Phone: 888-298-5700

Manufacturer:
RTI BIOLOGICS™
386.418.8888 • 800.624.7238 • www.rtix.com

AlloQuent™-S
AlloQuent™ TLIF

DESCRIPTION
This package contains donated human allograft tissue intended for transplantation. This product is restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects by a qualified healthcare professional (i.e., physician).

DONOR SCREENING AND TESTING
The donated human tissue utilized for this implant was recovered from a donor screened for risk factors associated with infectious diseases and medical conditions that rule out donation. The donor's blood was tested for relevant communicable diseases in a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) or equivalent and registered with the U.S. Food and Drug Administration (FDA) for donor testing. The following test criteria were met for this donor:

Required Infectious Disease Testing	
Blood Test	**Acceptable Result**
HIV-1/ HIV-2 Antibody	Negative / Non-Reactive
Hepatitis C Virus Antibody	Negative / Non-Reactive
Hepatitis B Surface Antigen	Negative / Non-Reactive
Hepatitis B Core Antibody (Total)	Negative / Non-Reactive
Treponema Pallidum (Syphilis)	Negative / Non-Reactive
Human T-Cell Lymphotropic Virus I/II Antibody	Negative / Non-Reactive
HIV-1 / HCV/ HBV* NAT-TMA	Negative / Non-Reactive

* For donors received after January 01, 2014.

If additional testing was performed (e.g., West Nile), all available test results were reviewed as part of the donor eligibility determination.

A licensed physician for RTI Biologics determined that the donor met eligibility requirements. The physician utilized available relevant information which may have included, but was not limited to: donor risk assessment interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology reports, death certificate and autopsy report (if performed).

RECOVERY AND PROCESSING
Tissues are processed into their final forms in controlled environments. Microbial testing is performed where appropriate and results meet documented acceptance criteria that are based on AATB and FDA requirements. This tissue has been deemed suitable for transplantation based on the donor eligibility and processing records.

BIOCLEANSE® TISSUE STERILIZATION PROCESS *GRAFTS:*

Tissue labeled with BioCleanse® have been sterilized through the BioCleanse® process, a low temperature chemical sterilization process validated to kill viruses, fungi, bacteria and spores. Grafts that have been through the BioCleanse® process are labeled with the BioCleanse® logo.

STERILIZATION:

STERILE R labeled grafts are terminally sterilized by gamma irradiation with a validated* dose.

STERILE labeled grafts are terminally sterilized by gas plasma through a validated* process.

* All references to "validated" sterilization processes indicate that the tissue meets or exceeds requirements for product sterilization, based on a SAL of 10^{-6} per AAMI and ISO Standards.

ADVERSE REACTIONS
Surgeons should discuss the following potential complications of tissue transplantation with their patients:

- Loss of function and/or integrity of transplanted tissue due to resorption, fragmentation, and/or disintegration including, but not limited to, associated loss of continuity, displacement, bending and/or fracture.
- Transmission of known infectious agents including, but not limited to, HIV, Hepatitis B, Hepatitis C, syphilis and bacteria.
- Immune rejection of transplanted grafts or allergic reactions to residual chemicals.

This product may contain trace amounts of the following processing chemicals: ascorbic acid, detergent, hydrochloric acid, hydrogen peroxide, isopropyl alcohol, phosphate buffered saline, povidone-iodine.

The same medical/surgical conditions that may complicate any surgical procedure may occur during or following the transplantation of an allograft.

Success of treatment with this graft is dependant upon the patient's host tissue response. Resorption of allograft tissue with commensurate substitution of functional host tissue is required to restore function to the graft treated site.

Orthofix and RTI Biologics, Inc. (RTI), their affiliates, distributors and agents disclaim all implied warranties concerning this tissue including any warranty of merchantability or fitness for particular purpose. Please promptly report complaints and possible adverse events as instructed in the Complaints section of this insert.

RECEIPT INSPECTION

Verify the product ordered matches product received. Should you receive an incorrect order or find that the shipping container and/or graft packaging integrity are compromised, immediately notify distributor. Do not use any tissue if the sterile barrier (inner packaging) has been compromised.

STORAGE

Allograft products which do not specifically require refrigerated or frozen storage conditions on the product labeling are intended for storage at "room" or "ambient" temperature. For long-term storage purposes, RTI defines "room" or "ambient" temperature within the range expected to be maintained in a climate controlled environment such as a medical device warehouse or hospital storeroom. See individual product label for specific range.

It is the responsibility of the end-user to maintain grafts intended for transplantation at appropriate storage conditions. It is recommended that storage conditions should be documented and controlled.

SPECIAL INSTRUCTIONS AND WARNINGS

- Once opened, the graft must be used for the current procedure or discarded.
- This graft may not be sterilized or re-sterilized.
- Do not use expired or damaged product.
- Manipulation or alterations made to assembled or pre-shaped graft may cause graft failure.
- Inadequate hydration may result in graft damage upon impaction.
- Adhere to directions and warnings stated in product insert(s).
- Use surgical instrumentation and accessories provided by distributor for use with this product.
- Adhere to any surgical technique guidance provided by distributor.
- Additional grafts of varying types and sizes should be accessible in case of an unexpected need.
- This allograft and all packaging materials used by RTI are latex free.
- Sterile barrier packaging is protected by a dust barrier (e.g. box, sealed plastic pouch).

DIRECTIONS FOR FREEZE-DRIED TISSUE IN PEEL PACKS

1. Remove dust cover or box.
2. Set Tissue Utilization Record (TUR) card aside.
3. Open outer package and pass sterile inner package to sterile field.
4. Save outer package for patient & TUR peel off labels.
5. Open inner package on back table or sterile field.
6. Use sterile water, saline or patient blood to rehydrate graft.
7. Place tissue into sterile bowl containing fluid.
8. Minimum required times are listed in the following table.

Table3: Rehydration Guidelines

Rehydration Time Before Use	Allograft Types
≥ 30 sec	(FD) labeled bone grafts

TISSUE UTILIZATION RECORD (TUR CARD)

The TUR card is designed for tracking implanted grafts. All information provided is kept confidential and used for product tracking only. This card must be completed by the operating room staff or clinician after the surgery. For further instructions please see those listed on the TUR card. Return completed copy to RTI to address or fax provided on TUR card.

CUSTOMER RETURNS & COMPLAINTS

3451 Plano Parkway
Lewisville, TX 75056, USA
Phone: 888-298-5700
FAX: 800-861-9363

ORTHOFIX®

Table 4: Definitions of label symbols:

See instructions for use	**EXP** or Expiration date	Storage temperature limits
STERILE	STERILE R	
Sterile by Gas Plasma	Sterile by Gamma Irradiation	Do not reuse
REF	LOT	SN
Catalogue number	Lot number (Donor number)	Serial Number (Tissue number)
Rx only		
For prescription use only	Manufacturer	

RTI Biologics, Inc.
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