

**QuickGraft® TISSUE INSTRUCTIONS FOR USE**  
**READ BEFORE USING**  
**DONATED HUMAN TISSUE**

**CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.**  
**Aseptically Processed. Passes USP <71> Sterility Tests.**  
**Not Terminally Sterilized. Do Not Sterilize.**

**THIS TISSUE WAS RECOVERED FROM A DECEASED DONOR FROM WHOM LEGAL AUTHORIZATION OR CONSENT HAS BEEN OBTAINED. THIS RECOVERY WAS PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.**

**Description**

MUSCULOSKELETAL TRANSPLANT FOUNDATION (MTF) QuickGraft Pre-Sutured Tendon tissue is frozen human allograft tendon minimally processed to preserve the extracellular matrix of the tendon. The allograft tendon and non-absorbable, Ultra High Molecular Weight Polyethylene (UHMWPE) #2 suture are combined to create a construct. The sutures are inert and elicit only minimal local tissue reaction and there is not any significant change in tensile strength retention known to occur in vivo. The suture braid are uncoated and contain trace filaments of Longwood Black or D&C Blue No. 6 suture for color. The sutures meet all requirements established by the United States Pharmacopeia (USP) for non-absorbable sutures except for diameter. QuickGraft is a single tendon folded and then sutured to secure the fold configuration

**Indication For Use**

QuickGraft is indicated for use as a construct in anterior cruciate ligament and posterior cruciate ligament reconstruction. QuickGraft is for single patient use only.

**Cautions and Warnings**

**ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY. Do not use portions of an allograft from one container on multiple patients. Do not sterilize.** Trace amounts of Gentamicin, Amphotericin B, or Primaxin may be present. Trace amounts of processing solutions may remain. Caution should be exercised if the patient is allergic to any of these substances.

As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation. In handling this suture care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps. Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

This allograft must not be used under any of the following conditions:

- If the container seal is damaged, or not intact.
- If the container has any physical damage.
- If the container label or identifying bar code is severely damaged, not readable or is missing.
- If the frozen allograft has not been used within 24 hours of thawing or has been stored at temperatures that exceed recommended storage temperatures.
- If the expiration date shown on the container label has passed.

Use caution in the following circumstances:

- Fever
- Uncontrolled diabetes
- Pregnancy
- Hypercalcemia
- Renal insufficiency
- History of or active Pott's disease
- Sepsis, or infection in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative instructions

**NOTE: Potential residues of processing agents/solutions may be present.**

**Precautions**

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases may occur despite careful donor

selection and laboratory testing, including serology and nucleic acid testing (NAT). Bacterial infection at the site of grafting may occur. ***Within the United States: Adverse outcomes attributable to the construct must be promptly reported to MTF. Outside of the United States: Adverse outcomes attributable to the construct must be promptly reported to your local representative.***

**Adverse Effects**

Possible adverse effects of using human tissues include but are not limited to:

- Infection of soft tissue and/or bone (osteomyelitis)
- Immune response of non-infectious cause, including fever
- Disease transmission or undesirable immune response
- Device failure that could require additional surgery for implant revision
- Cauculi formation when prolonged contact with salt solutions

**Processing**

Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment.

- Tissue that is aseptically processed with no exposure to gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions" and "Passes USP <71> Sterility Tests".
- Tissue that is aseptically processed and treated with low-dose gamma radiation, prior to processing, is labeled as follows: "Tissue is recovered and processed under aseptic conditions. Treated with gamma radiation" and "Passes USP <71> Sterility Tests".

**Donor Screening and Testing**

Prior to donation, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Board of Trustees.

Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA. The donor blood samples were tested for:

- |   |             |
|---|-------------|
| • Hepatitis B virus (HBV) surface antigen | • Syphilis  |
| • HBV core antibody                       | • HIV-1 NAT |
| • Hepatitis C virus (HCV) antibody        | • HCV NAT   |
| • HIV-1/2 antibody                        | • HBV NAT   |

Additional testing of SARS-CoV-2, HTLV I & II and/or West Nile Virus (as applicable) may have been performed. All infectious disease test results passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, consent, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening, including laboratory testing, meet or exceed current standards established by the American Association of Tissue Banks.

**Storage**

It is recommended that the QuickGraft be stored on dry ice or in a -40°C to -90°C environment until time of surgery. Storage of a package containing allograft at or below -90°C or in liquid nitrogen (vapor or liquid phase) may compromise package integrity. If the thawed QuickGraft is not used within 24 hours of thawing it must be discarded. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

**Preparation for Use**

1. Cut open outer pouch with non-sterile scissors and remove sterile peel pouch.
2. Open peel pouch using proper aseptic technique.
3. Aseptically transfer inner vacuum-sealed pouch into sterile field.
4. Cut open inner vacuum-sealed pouch with sterile scissors and remove QuickGraft

**NOTE: The L dimension measurement of QuickGraft is taken while the graft is under ~ 10-20 lbs. of tension.**

#### Thawing

1. It is recommended that frozen QuickGraft be placed into a sterile stainless steel basin or equivalent containing a warm (39°C± 2°C) sterile irrigant (i.e. normal saline or Lactated Ringers Solution). Antibiotics may be used with the irrigant according to surgeon's preference.
2. The tissue thaw time is per surgeon's preference.
3. The QuickGraft should then be rinsed 3 times in Lactated Ringers Solution or normal saline.

#### Patient Record

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. A TissueTrace® Tracking Form and peel-off stickers have been included with each package of QuickGraft. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off stickers), and comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively, a system for electronic submission may be used and sent to MTF@Sceris.com. **Within the United States:** Once completed, the bottom page of the form should be returned to MTF using the self-addressed mailer. Copies of this information should be retained by the transplant facility for future reference. **Outside of the United States:** Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.

**Reference:** Current MTF policies and procedures are in compliance with current FDA, AATB and other regulatory requirements.

#### Definitions of Label Symbols



Consult instructions for use



Do Not Reuse

For Translation of Instructions for Use



[www.mtfbiologics.org](http://www.mtfbiologics.org)



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All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

**CAUTION: Restricted to use by a physician.**

MTF tissue forms and products are protected by one or more issued or licensed United States patents. A list of patents on available tissues and related technologies may be found on the MTF web site [www.mtfbiologics.org](http://www.mtfbiologics.org).

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