LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

FlexiGRAFT® Tendon Constructs

INSTRUCTIONS FOR USE
ALLOGRAFT BIO-IMPLANT

Read this entire package insert carefully prior to use.

Federal law (USA) restricts this allograft bio-implant for use by a licensed clinician only.

DESCRIPTION

This device was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. The device consists of either a single tendon or combination of tendons that have been cleaned and disinfected through a proprietary process. The tendons are pre-sutured and then terminally sterilized via gamma irradiation. The device may include Achilles, anterior tibialis, posterior tibialis, peroneus longus, semitendinosus, quadriceps and/or gracilis tendons. It may also include bone dowels. The device is pre-sutured with sutures from the Arthrex FiberWire® Suture Family. Please refer to the Arthrex® Suture Family package insert for information regarding the sutures.

INDICATIONS FOR USE

This device is intended for use in soft tissue approximation and/or ligation.

For Canadian Market: FlexiGraft tendon construct devices are indicated for ligament reconstruction. Specifically, they are intended for the following uses:

- GraftLink® is intended for use in anterior cruciate ligament (ACL) reconstruction.
- The pre-sutured lateral ankle tendon construct is intended for use in lateral ankle ligament reconstruction.
- GraftLink® TS is intended for use in anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) reconstruction.

CONTRAINDICATIONS

The contraindications include, but are not limited to:

- Use in any patient who has a known or suspected allergy to any of the antibiotics and/or processing reagents listed in this package insert.

WARNINGS AND PRECAUTIONS

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any allograft bio-implant, the transmission of infectious agents exists.

This device may contain residuals of antibiotics (Bacitracin, Gentamicin, Polymyxin B Sulfate), alcohol and/or surfactants. Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or reagents.

See Arthrex Suture Family package insert for additional precautions.

STORAGE REQUIREMENTS

The distributor, intermediary and/or end-user clinician or facility is responsible for storing this device under appropriate conditions prior to further distribution or implantation. This device must be stored as listed in the table below.

Preservation Method	Storage Temperature	Storage Cautions
Frozen	Refer to the label.	This device may be stored between -20°C to -39°C for no more than six months.
		Do not store in a liquid nitrogen freezer or a refrigerator.

POTENTIAL ADVERSE EVENTS

Potential adverse events or outcomes include, but are not limited to, infection, allograft tissue rejection, allergic reaction to residual processing reagents, reoperation and/or death.

Promptly report any adverse event(s) or outcome(s) potentially attributable to the allograft bio-implant (see COMPLAINTS AND RETURNS section).

DONOR SCREENING AND TESTING

All donors have been screened and tissues recovered, processed, stored, tested and distributed in accordance with current U.S. federal regulations as promulgated in 21 CFR 1270, 1271 and 820, current Standards for Tissue Banking set forth by the American Association of Tissue Banks (AATB) and international laws and regulations as required.

This allograft bio-implant was deemed suitable for implantation by LifeNet Health. A physician medical director evaluated the following donor variables to determine donor suitability: infectious disease test results, current donor medical history, behavioral risk assessment interview, physical assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or coroner reports (if performed).

All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR 493. Test methods that are FDA-licensed, approved, or cleared for donor screening are used as available. The following test criteria were met for the donor of this allograft bio-implant:

Required Infectious Disease Testing	
Test	Acceptance Criteria
HBcAb: Hepatitis B Total Core Antibody	Negative/Non-Reactive
HBsAg: Hepatitis B Surface Antigen	Negative/Non-Reactive
HCV NAT: Hepatitis C Virus Nucleic Acid Test	Negative/Non-Reactive
HCVAb: Hepatitis C Antibody	Negative/Non-Reactive
HBV NAT: Hepatitis B Virus Nucleic Acid Test*	Negative/Non-Reactive
HIV-1 NAT: Human Immunodeficiency Virus Type 1 Nucleic Acid Test	Negative/Non-Reactive
HIV 1/2 Ab: Human Immunodeficiency Virus Types 1/2 Antibody	Negative/Non-Reactive
RPR/STS or Equivalent: Syphilis	Confirmatory Negative/Non-Reactive
HTLV I/II Ab: Human T-Lymphotropic Virus Types I/II Antibody**	Negative/Non-Reactive

*Not required for donors recovered prior to December 16, 2016. Performed as required by international laws and regulations.
**Not required for donors recovered after March 31, 2010. Performed as required by international laws and regulations.

INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties and/or performance.

GENERAL INSTRUCTIONS:

- Use on a single occasion for a single patient only.
- Once the packaging is opened, the device must be used for the current procedure or discarded.
- Inspect the device, inner and outer packaging and labels carefully:
  - Do not use past the expiration date as indicated on the label.
  - Do not use if the device is damaged or the packaging integrity is compromised.
  - Do not use if there are discrepancies in label information.
- Use aseptic technique at all times.
- Do not re-sterilize.
- Keep the device stored according to recommended storage instructions until preparing it for implantation.
- Thaw each device individually.
- Do not remove sutures from the device (See Arthrex Suture Family package insert for additional precautions).

OPENING INSTRUCTIONS:

1. Non-Sterile Team Member: Open the outer peel pack and present inner pouch to the Sterile Team Member.
2. Sterile Team Member: Firmly grasp the inner pouch and remove from outer peel pack. Peel open inner bag and place the device in a sterile basin.

PREPARATIONS FOR USE:

3. Refer to the table below for the recommended thawing time based on thawing technique.
4. If solution soak technique is utilized, the following solutions may be used for thawing: antibiotic solution, saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components.

Once the device is thawed, it must be used during the current procedure or discarded. Do not refreeze or refrigerate the device after thawing has begun.

Thawing Technique	Thawing Time
Room Temperature (Standing Air)	30 minutes
Warm Solution Soak (37°C – 42°C)	5 minutes
Room Temperature Solution Soak	10 minutes

5. Pre-tension the graft after thawed.
6. Measure the length and diameter size of the pre-sutured tendon construct by pulling through a sizing block.

TRACEABILITY

It is the responsibility of the end-user to maintain recipient records for the purpose of tracking tissue post-implantation. As a courtesy to the end-user clinician or facility, LifeNet Health has enclosed a Graft Implant Tracking Card to assist in the post-implantation tracking. Please refer to the enclosed card for additional instructions.

COMPLAINTS AND RETURNS

For further information on returns or to report a complaint or adverse event, please contact your authorized distributor or LifeNet Health Client Services (available 24 hours a day) at 1-888-847-7831 (inside the U.S.) or 00+1-757-464-4761 ext. 2000 (outside the U.S.) and have the bio-implant's identification number available (see label).

WARRANTY STATEMENT

Due to the inherent variability of allograft tissue, biological and biomechanical properties cannot be guaranteed by LifeNet Health.

Manufactured by:
LifeNet Health, 1864 Concert Drive, Virginia Beach, Virginia, 23453 USA
Source Establishment: LifeNet Health CTO #100038
For patent information, please visit: www.lifenethealth.org/patents