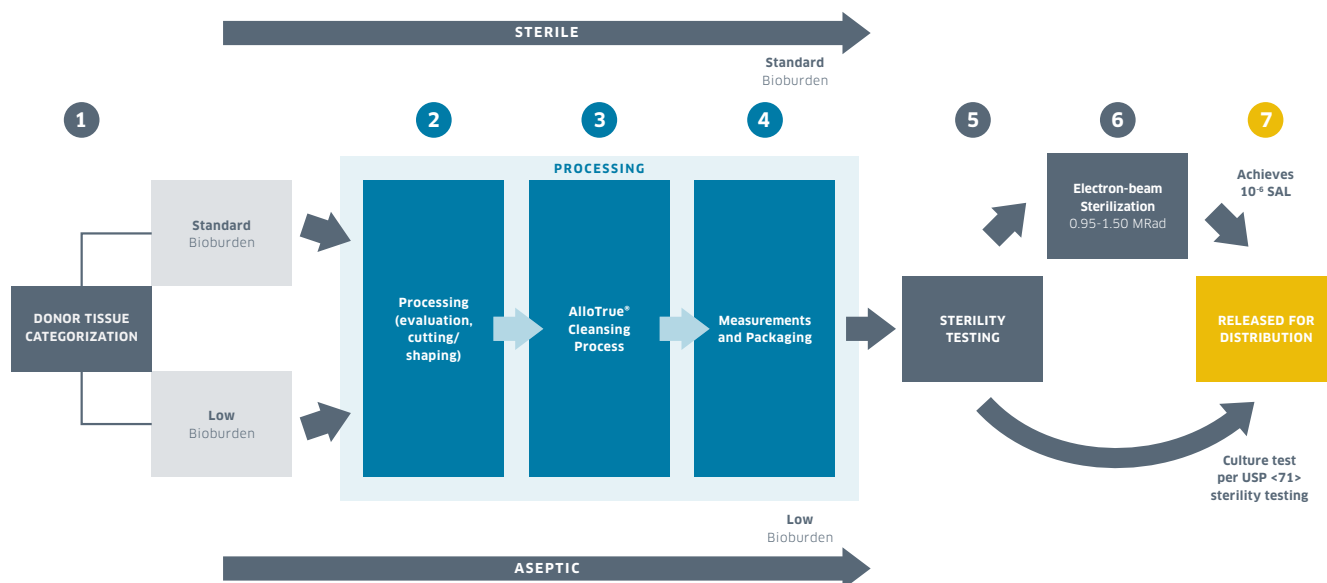


CREATING ALLOCONNEX® TENDONS

Quality and safety are built into every step of the AlloConnex® tendon preparation process. The diagram below outlines the comprehensive methodology used to process AlloConnex® tendons, highlighting the key quality, safety, and sterility measures applied from donor tissue evaluation through final release for distribution.



DEFINITIONS:

Bioburden - number of viable microorganisms on the tissues

ISO Class 5 - highly controlled environment for tissue processing

Electron-beam - high energy stream of electrons used to sterilize materials

Mrad - megarad a conventional unit of absorbed radiation dose

SAL - sterility assurance level is a quantitative, statistical measure of the probability that a single viable microorganism remains on a product after sterilization

USP <71> Sterility Testing - chapter in the United States Pharmacopeia (USP), that establishes quality standards for pharmaceuticals and certain healthcare products in the United States

1 DONOR TISSUE CATEGORIZATION

Based on donor qualification and tissue evaluation, tendons are separated into two groups – standard and low bioburden levels. Standard bioburden categorized tissue undergoes an additional validated post-packaging electron-beam sterilization process due to its higher initial bioburden, providing an additional level of sterility assurance. Low bioburden categorized tissues do not undergo post-packaging sterilization due to low initial bioburden.

2 PROCESSING

Aseptic processing minimizes the chance that donor tissue could be contaminated during tissue processing and takes place in ISO Class 5 processing suites where validated protocols are also followed to ensure consistency and safety throughout tissue processing. Strict tissue evaluation criteria are followed, including the use of sterile equipment and solutions, while technicians wear medical-grade protective equipment throughout processing.

3 ALLOTRUE® CLEANSING PROCESS

Tendons are agitated and cleansed within a closed system, with mild disinfectants and antibiotics to remove blood, lipids and bioburden. This method is designed to effectively clean the tissue, while preserving biomechanical properties and structural integrity of the tendons.¹

4 MEASUREMENTS AND PACKAGING

Tendons are evaluated against strict specifications, measured and cultured for any remaining bioburden, and placed into their final packages. Tendons with an initial low bioburden will skip the sterilization step and remain as aseptically processed tendons. Aseptic tendons are tested via USP <71> sterility testing.² Tendons with standard bioburden levels proceed to the electron-beam sterilization step.^{3,4}

5 STERILITY TESTING

Sterility bacterial cultures, collected during the measuring and packaging step, are incubated for a minimum of 14 days per US Pharmacopeia, Chapter 71, Sterility Testing Guidelines (that outline a standardized method for testing if a product is sterile).² This testing method is used to ensure final sterility cultures show no growth, including slow growing organisms.

6 ELECTRON-BEAM STERILIZATION

Tendons are frozen and then sterilized with low-dose electron-beam irradiation. This sterilization method achieves a SAL level of 10^{-6} .^{3,4} Applied at a low-dose range of 0.95 to 1.50 Mrad (9.5–15.0 kGy), the validated process preserves the biomechanical properties and structural tissue integrity.

7 RELEASE FOR DISTRIBUTION

The following items are included in the tendon packaging for distribution:

- **Label** – contains the tendon description, dimensions, storage conditions, expiration date, and “Sterile R” if sterilized.
- **Package Insert** – provides directions for proper handling, preparation, storage, and clinical use of the allograft tissue.
- **Transplantation Record and Feedback Form** – used to track the final disposition of the allograft tissue.
- **Pathways Card** – allows for patients to write a thank you letter to their tissue donor’s family.

ORDER NOW
800.557.3587

AlloSource, a life sciences organization, helps restore patient functionality by transforming the gift of human tissue donation into enhanced medical products that enable a life of movement, health, and wellbeing. We partner with medical professionals and biomedical companies who share our drive for innovation and quality in the use of human tissue allografts for medical advancements. Headquartered in Centennial, Colorado, we have served a global marketplace since 1994. Learn more at allosource.org.

AlloConnex Tendons, Ligaments and Fascia are regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/PS). AlloSource® is registered with the FDA as a tissue establishment and accredited by the Association for Advancing Tissue and Biologics.

1. Data on file.
2. United States Pharmacopeial Convention. *United States Pharmacopeia–National Formulary (USP–NF), General Chapter <71> Sterility Tests*. Rockville, MD: United States Pharmacopeial Convention; 2025.
3. International Organization for Standardization. ISO 11137-1:2025. *Sterilization of health care products – Radiation – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*. Geneva, Switzerland: International Organization for Standardization; 2025.
4. Association for the Advancement of Medical Instrumentation. *TIR37:2007. Sterilization of health care products – Radiation – Guidance on sterilization of human tissue-based products*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2007.



6278 S Troy Cir
Centennial, CO 80111
USA

MAIN 720. 873. 0213

allosource.org