

THE FACTS

ON ALLOGRAFT TENDON STERILIZATION

FACT 1

STERILIZATION OF ALLOSOURCE'S TISSUE INCLUDES

AlloTrue™, a patented tissue cleansing process, removes blood and lipids and reduces bioburden from allograft tendons without exposing the tissue to harsh chemicals.¹

E-beam irradiation provides a faster method to achieve sterilization than gamma irradiation.

- AlloSource follows ISO standard 11137 for sterilization validation to a Sterility Assurance Level (SAL) of 1×10^{-6} which indicates being free of viable microorganisms.^{2,3}
- Sterile R designation on the label indicates the tendon was sterilized in final packaging.



FACT 2

CONTROLLED LOW DOSE (10-15 KGY), LOW TEMPERATURE IRRADIATION DOES NOT IMPACT BIOMECHANICAL PROPERTIES OF ALLOGRAFT TENDON^{4,5,6}

- Tissues maintain structural and biomechanical properties similar to those of non-irradiated tendon allograft⁶
- AlloSource uses a validated low irradiation dose (< 10-15) kilogray and low temperature which preserves biomechanical properties of tissue.⁷

FACT 3

CONTROLLED LOW DOSE (10-15 KGY), LOW TEMPERATURE IRRADIATION DOES NOT IMPACT CLINICAL RESULTS OF ALLOGRAFT TENDONS.

- Numerous clinical studies support the use of controlled, low dose low temperature irradiation of allograft tendons, and provide optimal clinical results of sterile allografts.⁸

STERILE R

6278 S Troy Cir
Centennial, CO 80111

main 720. 873. 0213
fax 720. 873. 0212

allosource.org



TENDON ALLOGRAFTS SAFE AND EFFECTIVE

DEFINITIONS

E-BEAM IRRADIATION a process that uses beta radiation to sterilize tissue.

BIOMECHANICAL TISSUE PROPERTIES addresses effects on tendon stress, strain, elasticity and elongation.

ALLOTRUE AlloSource's proprietary cleansing process designed to penetrate deep within donor tissue to remove blood and lipids and reduce bioburden, using a variety of cleaning solutions inside a fully automated, closed, rotating canister.

KILOGRAY A kilogray is equal to one thousand gray (1000Gy). Gray is defined as the absorption of one joule of ionizing radiation by one kilogram (1 J/kg) of matter, e.g. human tissue.

STERILE R Symbol for the method of sterilization using irradiation.

REFERENCES

1. Data on file.
2. SO, 11137: Sterilization of Health Care Products- Requirements for Validation and Routine Control: Radiation Sterilization.
3. TIR37: 2007: Sterilization of Health Care Products - Radiation - Guidance on Sterilization of Human Tissue-based Products
4. The effects of ⁶⁰Co gamma radiation doses on initial structural biomechanical properties of ovine bone-patellar tendon-bone allografts. Cell and tissue Bank (2011) 12:89-98.
5. Yankee, AB. The Biomechanical Effects of 1.0 to 1.2 Mrad of Gamma Irradiation on Human Bone-Patellar Bone-Tendon Allografts. The American Journal of Sports medicine Vol. 41, 4: pp 835-840. First published February 6, 2013.
6. Elenes, EY, Hunter SA, Soft-tissue allografts terminally sterilized with an electron beam are biomechanically equivalent to aseptic, nonsterilized tendons J Bone Joint Surg Am. 2014 Aug 20;96(16):1321-6
7. Block, J. The Impact of Irradiation on the Microbiological Safety, Biomechanical Properties, and Clinical Performance of Musculoskeletal Allografts. Orthopedics, Nov;29(11):991-6
8. Brian J Samsell, Mark A. Moore., Use of Controlled Low Dose Gamma Irradiation to Sterilize Allograft Tendons for ACL Reconstruction: Biomechanical and Clinical Perspective. Cell Tissue Bank (2012) 13: 217.