

# 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.<sup>1</sup>

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  $1 \times 10^{-6}$  which indicates being free of viable microorganisms.<sup>2,3</sup>
- 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<sup>4,5,6</sup>

- Tissues maintain structural and biomechanical properties similar to those of non-irradiated tendon allograft<sup>6</sup>
- AlloSource uses a validated low irradiation dose (< 10-15) kilogray and low temperature which preserves biomechanical properties of tissue.<sup>7</sup>

**STERILE R**

### 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.<sup>8</sup>

6278 S Troy Cir  
Centennial, CO 80111

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

[allosource.org](http://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 <sup>60</sup>Co 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.