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 X 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.

STERILE R

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 allograft[6]
- 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]

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AlloSource®
DOING MORE WITH LIFE

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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.

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