Coll-e-Strong™

A Non-Gamma Irradiated Technology Q&A

Q: Are Coll-e-Strong™ tendons and ligaments gamma irradiated?

A: No, Coll-e-Strong™ tendons and ligaments do not undergo any pre-gamma or terminal-gamma irradiation process.

Q: How does a Coll-e-Strong™ tendon and ligament differ from tissues that are gamma irradiated?

A: Coll-E-Strong™ tendons and ligaments undergo sterilization utilizing electrons. These electrons interact with a waveguide in a linear accelerator.

Q: How long does it take to sterilize a Coll-E-Strong™ tendon and ligament using electrons versus a graft that is gamma irradiated?

A: Coll-E-Strong™ tendons and ligaments undergo a validated process that subjects them to electrons for a period of seconds, as opposed to gamma irradiation which normally takes 5 to 6 hours to accomplish the same SAL of 10^{-6}.

Q: Are Coll-E-Strong™ tendons and ligaments labeled STERILE?

A: Yes, a Sterility Assurance Level (SAL) of 10^{-6} has been achieved within the final package.

Q: How does the tensile strength of a Coll-E-Strong™ tendon and ligament compare with aseptic, non-irradiated grafts?

A: Bio-Research has shown that the biomechanical properties of a Coll-E-Strong™ tendon and ligament are statistically equivalent to those of aseptic, non-irradiated tissue. A request for the study can be made through your representative.

Q: What is the expiration date for a Coll-E-Strong™ tendon and ligament?

A: Frozen tissue grafts expire five years from the date of processing. The expiration date is included on the product label and packing slip.

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Q: Do all Coll-E-Strong™ donors meet FDA and American Association of Tissue Banks (AATB) standards?

A: Yes, all Coll-E-Strong™ donors meet or exceed the standards set by the FDA and AATB. All donors are recovered and processed in the United States.

Q: Why is gamma irradiated Sports Medicine tissue still offered?

A: Surgeons should have options to choose from when ordering allografts. Gamma irradiation is still strongly recognized by the industry as an appropriate method to terminally sterilize tissue. Surgeons have asked us to invest time and resources to develop an alternative to gamma irradiation without compromising the Sterility Assurance Level (SAL) of 10^{-6} and graft bio-mechanics.

*Please refer to the package IFU for specific instructions with regard to warnings, precautions, storage, and preparation.

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