

maxxeus SPORTS

A Non-Gamma Irradiated Technology Q&A Overview

Q: Are Maxxeus Sports tendons and ligaments gamma irradiated?

A: No, Maxxeus Sports tendons and ligaments do not undergo any pre gamma or terminal gamma irradiation process.

Q: How does a Maxxeus Sports tendon and ligament differ from tissues that are gamma irradiated?

A: Maxxeus Sports tendons and ligaments undergo sterilization utilizing electrons. These electrons interact with a wave guide in a linear accelerator.

Q: How long does it take to sterilize a Maxxeus Sports tendon and ligament using electrons versus a graft that is gamma irradiated?

A: Maxxeus Sports 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 Maxxeus Sports 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 Maxxeus Sports tendon and ligament compare with aseptic, non-irradiated grafts?

A: Bio-Research has shown that the biomechanical properties of a Maxxeus Sports tendon and ligament are statistically equivalent to those of aseptic, non-irradiated tissue. A request for the study can be made on maxxeussports.com.

Q: What is the expiration date for a Maxxeus Sports 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.

Q: Do all Maxxeus Sports donors meet FDA and American Association of Tissue Banks (AATB) standards?

A: Yes, all Maxxeus Sports 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.

maxxeus
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