



ParametricsMedical

Lo-RAD[®]

Lower Dose Gamma Irradiation

Terminal Sterility and Functionality with Lower Dose Gamma Irradiation

Lower Dose Gamma Irradiation represents the latest example of the Parametrics Medical Commitment to Technology and Safety. The low dose process allows allografts to be irradiated at doses of 14kGy (1.4 MRad), while maintaining a sterility assurance level (SAL) of 10^{-6} . The low dose process is validated using ISO 11137 Method 2B, and is used in conjunction with the patented technology, to provide an excellent combination of safety and functionality.

- A recent study showed that low-dose gamma irradiation had no effect on the strength and elastic modulus of any allograft.¹
- Parametrics Medical's lower dose gamma irradiation was validated using ISO 11137 Method 2B.
- ISO 11137 Method 2B is used to determine the lowest dose of gamma irradiation needed to sterilize tissue. Initially, multiple lots of tissue are irradiated with incremental doses. The results of sterility tests from those lots are used in additional tests upon which the final production dose is determined. Parametrics Medical and our partner chose this methodology and employed a two media test approach because it is best suited to the variations in bioburden inherent in human tissue.
- Standard was executed twice - Trypticase Soy Broth and thioglycollate media were used to detect both aerobic and anaerobic microorganisms.
- SAL of 10^{-6} was maintained at a greatly reduced irradiation dose, providing a better combination of safety and functionality.
- Whole allografts were utilized for validation as opposed to representative samples.
- All Parametrics Medical allografts are irradiated in final sterile packaging, assuring sterility of tissue.

 **DePuy Synthes**

MITEK SPORTS MEDICINE

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Treatment

Allografts are cleaned and disinfected using a proprietary process involving chemical and antibiotic exposure and then terminally irradiated to reduce the potential of disease transmission. This process, along with rigorous donor screening, has been designed and validated to increase the safety of our Lo-Rad line of allografts.

Parametrics Medical allografts treated with lower dose gamma irradiation process

- Achilles Tendon
- Tibialis Tendon (anterior, posterior)
- Patellar Ligament (bone-tendon-bone)
- Patellar Ligament with Extensor
- Semitendinosus
- Gracilis
- Peroneus Tendon (longus)

Serologic Testing Panel

- RPR
- HIV 1/2Ab
- HBsAg
- HTLV I/IIAb
- HBcAb
- HIV NAT
- HCVAbs
- HCV NAT

Independent Testing

Lower Dose Gamma Irradiation validation testing provided by Nelson Laboratories, an independent laboratory.



Achilles Tendon



Tibialis Tendon



Patellar Ligament

1. Balsly CR, Cotter AT, Williams LA, Gaskins BD, Moore MA, Wolfenbarger L Jr. Effect of low dose and moderate dose gamma irradiation on the mechanical properties of bone and soft tissue allografts. Cell Tissue Banking. 2008;9:289-298.



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