AlloSource®

6278 S Troy Cir
Centennial, CO 80111

MAIN 720. 873. 0213
FAX 720. 873. 4703

allosource.org

March 14, 2016

AlloSource Gamma Irradiation Statement

All AlloSource tissue products are processed and packaged using aseptic techniques in certified cleanrooms. Tissues such as Bone and Tendons are subjected to a rigorous validated cleansing process (AlloTrue) which is designed to remove blood and lipids from the grafts and significantly reduce bioburden associated with this tissue. The cleansing process does not impact the biomechanical or physical aspects of the graft and has demonstrated Human Tissue bioburden reduction capability.

Aseptic Tissue:
Tissue products may be labeled as "aseptic", meaning they have not undergone a terminal sterilization process after being aseptically processed and cleansed as described above.

Terminal Sterilization:

Other tissue products may be labeled with the symbol STERILE R or as "Irradiated", meaning they have been terminally sterilized after being aseptically processed and cleansed as described above.

For sterilized bone and tendon allografts, AlloSource utilizes a low temperature (on dry ice) low dose gamma irradiation process to ensure tissue sterility as described below.

Gamma Irradiation Certified Dosage Limits:

Gamma irradiated terminally sterilized AlloSource tissue products labeled as STERILE R or "Irradiated" are exposed to the radionuclide Cobalt-60 (^{60}Co) using a standard batch process validated to provide a Sterility Assurance Level (SAL) of 10^{-6}. The validation of this allograft sterilization method followed ISO Standard 11137:1995 "Sterilization of Health Care Products — Requirements for Validation and Routine Control— Radiation Sterilization" Method 2B. The validated absorbed dose range used in the terminal gamma irradiation process is 0.95 MRad (9.5 kGy) to 1.4 MRad (14.0 kGy). This dose is reviewed for each batch of tissue subjected to the irradiation process.

In addition, this dose is audited quarterly as required by ISO 11137:2006, "Sterilization of Health Care Products—Radiation" to a SAL of 10^{-6} is maintained.

Trevor Wright
Regulatory Affairs Manager