

Frequently Asked Questions

QUALITY CONTROL & POST-PROCESSING TESTING

Post-processing quality control at LifeNet Health is a multi-faceted systems approach, designed to assure the safest and most efficacious allograft bio-implants possible. All Quality Control & Post Processing testing is completed by well-trained qualified personnel meeting and exceeding LifeNet Health and Industry Standards and required regulations.

The Analytical Team:

Verifies graft acceptability for “lot release.” Approximately 35,000 grafts are released per month. Not all grafts receive the same post-processing testing, but all must meet the stringent requirements related to their individual final testing needs.

- Residual Moisture Content for freeze dried grafts
- Residual Calcium Content for PAD® demineralized grafts
- Residual DNA Content for MATRACELL®-decellularized cardiac patches
- Cell viability for ViviGen® products using a lactate dehydrogenase assay (LDH)

The Microbiology Team:

- Tests processing facilities to ensure that appropriate environmental controls for processing were met
- Performs post-processing cultures on grafts not subjected to the Allowash XG® sterilization protocol to ensure culture negative

The Quality Systems Post-Production Team:

- Verifies production records adhere to all applicable production SOPs
- Verifies donor suitability as a cross-check
- Reviews dosimetry results and irradiation facility Certificate of Conformance to assure final package sterility meets LifeNet Health standards and that irradiated grafts have a Sterility Assurance Level of 10⁻⁶
- Releases allograft bio-implants from quarantine to distribution

The Distribution Team:

- Prints final packaging labels (all elements of quality must be approved in computer system for labels to print)
- Performs a Final Article Inspection to assure that all parameters were met, and that final packaging and distribution can proceed
- Proceeds with Final packaging (label, instructions for use, additional materials based on allograft type) with cross-check
- Provides a 100% visual inspection of all grafts prior to distribution

Since 1995, LifeNet Health has provided over 5 million grafts processed using Allowash XG® Technology to the surgical community to restore the health of patients, with no incidence of disease transmission.