LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

FREQUENTLY ASKED QUESTIONS

Validated Musculoskeletal Processes
Allowash XG®: Safety with Confidence

LifeNet Health's Allowash XG technology encompasses a comprehensive patented and validated process, during which greater than 99% of bone marrow and blood elements are removed from the internal bone matrix. This step, along with subsequent chemical treatment and sterilization steps, have been shown to render tissue sterile to a Sterility Assurance Level (SAL) of 10^{-6}. They also inactivate enveloped and non-enveloped viruses, without compromising the biomechanical or biochemical properties of the tissue needed for its intended surgical application.

Six Steps for Tissue Safety and Sterilization

Step One – Bioburden Control: All donors accepted for tissue recovery are subjected to a meticulous and rigorous screening routine that exceeds the requirements set forth by the Food and Drug Administration (FDA) and American Association of Tissue Banks (AATB). Donors are then recovered in strict aseptic conditions. This first step allows for a stringent control of bioburden on incoming tissue, even before it enters our processing facilities.

Step Two – Bioburden Assessment: All recovered tissue is sampled for microbiological contamination at the time of recovery. Standard microbiological methods utilizing both aerobic and anaerobic media are employed to culture and identify bacteria and fungi. Donor blood samples are also used for required infectious disease testing, and evaluated for potential hemodilution that may impact acceptability. This extensive serological testing exceeds industry standards and utilizes the latest NAT advanced testing techniques, allowing LifeNet Health to further control and eliminate incoming bioburden.

Step Three – Minimized Contamination: LifeNet Health's state-of-the-art processing facilities contribute to maintaining a low bioburden on tissues. Designed for the processing and preservation of musculoskeletal and cardiovascular tissue allograft, all processing areas have been designed to allow compliance with FDA, state and federal requirements, including GMP for medical devices. Our facilities maintain cleanliness levels that minimize or eliminate environmentally induced graft contamination.

Step Four – Rigorous Cleaning: Through treatment with hypotonic solutions and antimicrobial reagents, and/or use of processes such as ultrasonication and centrifugation, blood elements (including marrow and lipids) are solubilized and removed from the tissue. Key solutions are forced into and through the bone matrix and then directed to waste, resulting in the lysis of cells and cleaning of the tissues.

Step Five – Disinfection and Rinsing: The tissue, freed from over 99% of marrow and lipids, is subjected to an intensive decontamination, disinfection and cleaning regimen, designed to remove and eliminate viruses and bacteria. Tissue then undergoes water soak mediation to remove processing reagents, followed by centrifugation and/or micro- absorption to remove excess water and any remaining processing residuals.

Step Six – Terminal Sterilization: The Allowash XG process concludes with a controlled and validated dose of gamma irradiation, administered at low temperatures after the tissue is packaged. This final step produces a Sterilization Assurance Level (SAL) of 10^{-6} without compromising the biomechanical or biochemical properties of the tissue needed for its intended surgical application.

Validated to Provide Effective Bacterial Log Kill
The Allowash XG process has been designed to provide bactericidal effectiveness, and key validation studies have proven this effectiveness.

Validated to Provide Effective Viral Inactivation
Through its cleaning, disinfection and rinsing regimens, Allowash XG removes greater than 99% of bone marrow and blood elements from the internal matrix of bone, the environment in which viruses usually occur.

Validated to Achieve Sterility with Confidence
Based on a modified ISO/AAMI Method 2B Protocol Sterilization Validation Study (modified ISO/AAMI Method 1 Protocol for all soak and intercalary grafts), LifeNet Health has validated sterility of its allograft tissue to the Sterility Assurance Level (SAL) of 10^{-6}.

Validated to Maintain Biomechanical Integrity
Studies performed clearly show that tissue processed with Allowash XG maintains its biomechanical or biochemical properties suitable for the tissue's intended clinical applications.

Validated to Maintain Osteoinductivity
Studies performed clearly show that demineralized tissue processed with Allowash XG maintains its osteoinductive potential.

Allowash XG renders tissue sterile, without compromising the biomechanical or biochemical properties of allograft tissue for their intended surgical applications. This is achieved by:

- Removing greater than 99% of cellular elements from the bone matrix
- Ensuring a Sterility Assurance Level (SAL) of 10^{-6} through chemical treatment and sterilization steps
- Inactivating enveloped and non-enveloped viruses

That's sterility without compromise, from the provider that gives you allograft access with confidence.

Since 1995, over 6 million bio-implants processed using Allowash® Technology have been distributed by LifeNet Health, with no disease transmission.