

VALIDATED TO PROVIDE EFFECTIVE ORGANISM LOG KILL

The Allowash[®] process has been designed to provide bactericidal and virucidal effectiveness and key validation studies have proven this effectiveness. Through its cleaning, disinfection and rinsing regimens, Allowash[®] removes greater than 99% of bone marrow and blood elements from the internal matrix of bone, the environment where viruses usually thrive.

Studies were performed to validate the effectiveness and bacterial and viral log reduction of Allowash[™] chemicals used in the process. These studies clearly indicate that the chemicals used are bactericidal and virucidal. Coupled with a removal of bone marrow, lipids, and proteins, Allowash[®] is effective in reducing the risk of viral transmission of processed tissues.

Two additional studies were performed to characterize the bioburden reduction capabilities of the Allowash[®] processing steps on soft tissues and cut grafts. Microorganisms were seeded in a known volume of bone marrow, then the seeded bone marrow was injected into cancellous cubes. The cancellous cubes were subjected to Allowash[®] processing. All samples tested passed a 14-day sterility test as specified by the USP (71) standard and all media passed a growth promotion test as specified by the USP (71) standard. In addition, bacteriostasis/fungistasis testing on cancellous cubes and positive controls served to demonstrate that no residual chemicals remained that would prevent the detection of microorganisms.

BETTER CLEANING WILL NOT MEAN MORE LENIENT SCREENING

The Allowash[®] technology will never act as a substitute for the strict donor screening and testing guidelines employed by LifeLink. Allowash[®] will add an ever-greater measure of assurance to physicians and patients.

As one of the largest full-service tissue banks in the country, we're proud of our safety record; and we're committed to maintaining these high standards for the future. Our goal is to improve tissue-banking technologies for all patients in need of a transplant.

To find out more about Allowash[®] or to obtain related information, call LifeLink at 1-800-683-2400. We want you to see that there can be no compromises.



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Allowash[®] is a registered trademark of LifeNet Health. The process is protected by one or more of U.S. patent numbers 6,024,735, 5,977,432, 5,977,034, 5,976,104, 5,820,581, 5,797,871, 5,556,379. The validations mentioned in this brochure were performed by LifeNet Health.

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Allowash[®] Technology No Compromises



ALLOWASH[®] TECHNOLOGY

NO COMPROMISES

It took years of research and development. This revolutionary process has proven its significance in the processing of human allograft tissue. LifeLink is pleased to use Allowash[®], a processing and cleaning treatment that takes cleanliness to a new level.



VALIDATED TO MAINTAIN BIOMECHANICAL INTEGRITY

Pre-clinical and clinical studies performed clearly show that tissues processed with Allowash[®] maintain their appropriate biomechanical and biochemical properties for that tissue's intended clinical applications.

VALIDATED TO MAINTAIN OSTEOINDUCTIVITY

Studies performed clearly show that demineralized bone produced from bone processed with Allowash[®] technology maintains its osteoinductive potential.

A BREAKTHROUGH PROCESS WITH VISIBLE RESULTS

Through flushing, centrifugation, hypotonic processes and ultrasonication, blood elements (including marrow and lipids) are solubilized and removed from the tissue. Key solutions are forced into and through the bone matrix, resulting in the lysis of cells and cleaning of the tissues.

Tissue is subjected to an intensive debridement, decontamination, and disinfection regimen designed to kill and eliminate viruses and bacteria by removing over 99% of the marrow and lipids from the tissue. Tissue then

undergoes a series of water rinses to remove processing reagents, followed by centrifugation to aid in removing excess water and processing residuals.

TOXICITY TO HUMAN CELLS

Allowash[™] Solution is not toxic to human dermal fibroblasts, does not significantly reduce the number of growing human dermal fibroblasts in culture, and is not toxic to human dermal fibroblasts when exposed to demineralized freeze-dried bone allografts (DFDBA).

