

Which LifeNet Health allograft bio-implants are processed using Allowash XG[®] technology?

All musculoskeletal tissue processed by LifeNet Health undergoes the validated Allowash process that encompasses a comprehensive 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 a subsequent chemical sterilant treatment have been shown to substantially reduce bacterial and fungal bioburden and inactivate enveloped and non-enveloped viruses. The Allowash XG process concludes with a controlled terminal sterilization step that results in a Sterility Assurance Level (SAL) of 10^{-6} without compromising the biomechanical or biochemical properties of the tissue as needed for its intended surgical application. Not all tissue undergoes a terminal sterilization step after final packaging due to the properties of the tissue material; this tissue must demonstrate culture negativity to be deemed suitable for clinical implantation.

The following table provides an overview of which allografts provided by LifeNet Health are processed using Allowash XG technology.

Tissue Type / Family	Cleaning / Sterilization System	
	Allowash [®] (without terminal sterilization)	Allowash XG [®] (with terminal sterilization)
Validation Method	Based on U.S. Pharmacopeia <UPS> 26	Based on ANSI/AAMI/ISO Method 2B and Method 1 Protocol Sterilization Validation modified for human tissue
Sterilization Level	Culture negative	Sterility Assurance Level (SAL) of 10^{-6}
FlexiGraft[®] <u>Exception</u> : Meniscus		√
	√	
MatriGraft[®]		√
OraGraft[®]		√
ReadiGraft[®]		√
VertiGraft[®]		√
OsteoBiologics		√
Optium DBM [®]		√
I/C Graft Chamber [®]		√

Since 1995, over 4 million bio-implants processed using Allowash Technology have been distributed by LifeNet Health, with no disease transmission.