

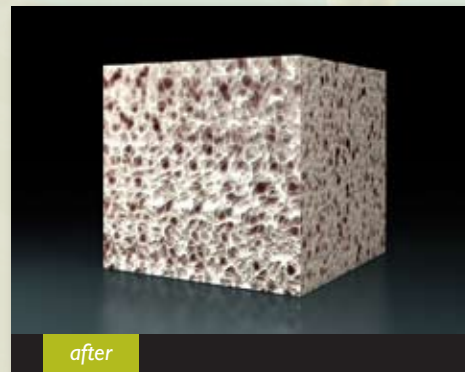


ALLOWASH XG[®] Allograft Bio-Implant Sterilization Technology

Sterility Without
Compromise.

Why Choose ALLOWASH XG® Sterilized Allograft Bio-Implants?

Your patients receive allograft bio-implants that are **sterile**. With the introduction of Allowash® in 1995, LifeNet Health pioneered a revolution in allograft bio-implant cleaning and disinfection. Today, **ALLOWASH XG®** extends this technological leadership and ensures the utmost allograft bio-implant safety. With this technology, LifeNet Health has proudly delivered over 2 million allograft bio-implants with no incident of disease transmission to date.



What is sterility?

ster•ile (stēr'əl, -īl') ▶adj. **Free from microorganisms.**

LifeNet Health demonstrates sterility of its allograft tissue processed with Allowash XG® to a 10⁻⁶ Sterility Assurance Level (SAL).¹

That's no more than a single viable particle in a million units. Other providers offer an SAL of just 10⁻³, which means there are as many as one in a thousand implants that could be infected. In contrast, a 10⁻⁶ SAL is the same sterility level of medical devices.

And, it's been shown that Allowash XG gives you sterility without compromising the **biomechanical** or **biochemical** properties of LifeNet Health bio-implants needed for surgical applications. So you can be **assured** that you and your patients are receiving **safe, healthy, effective** allograft bio-implants.

Please contact your LifeNet Health representative for more information about our comprehensive offering of allograft bio-implant products and services or call 888-847-7831.

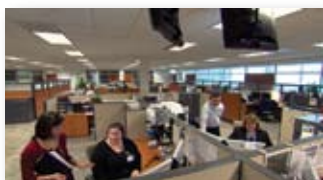
¹ Moore M, Linthurst Jones A, Gaskins B, et al. Adaptation of ANSI/AAMI/ISO 11137 method 2B sterilization validation for medical devices to tissue banking. Presented at: American Association of Tissue Banks Annual Meeting; Chicago, IL; August 2004.



Setting the Standard

ALLOWASH XG® is a patented and proprietary sterilization process that removes greater than 99% of bone marrow and blood elements from the internal bone matrix. Allowash XG renders allograft bio-implants sterile without compromising their biomechanical or biochemical properties.

How does ALLOWASH XG work? Six Steps To Sterilization



Step 1 – 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 2 – 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 any 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 Nucleic Acid Test (NAT) advanced testing techniques, allowing LifeNet Health to further control and eliminate incoming bioburden.



Step 3 – 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 allografts, 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 4 – 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 5 – 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 6 – Terminal Sterilization

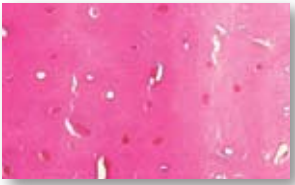
The Allowash XG process concludes with a controlled and validated dose of gamma irradiation administered at low temperatures after the allograft bio-implants are packaged. This final step produces a Sterilization Assurance Level (SAL) of 10^{-6} without compromising the biomechanical or biochemical properties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

What does the data say?

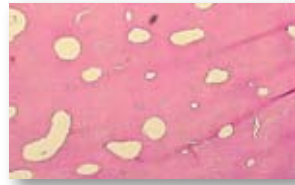
Safety with no change in biomechanical or biochemical properties

✓ Thoroughly Penetrates Tissue.

More than 99% of extractable elements are removed from the bone matrix.



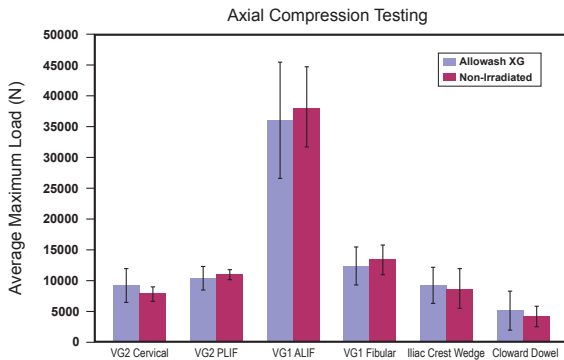
H&E stained histology section of cortical bone retaining blood vessels and blood.



H&E stained histology section of cortical bone cleaned of blood vessels and blood.

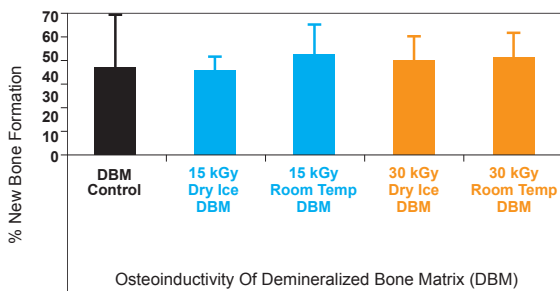
✓ Maintains Biomechanical Properties.

Allowash XG preserves structural integrity.



✓ Maintains Biochemical Properties.

Allowash XG allows for bone growth in Demineralized Bone Matrix (DBM).



✓ Eliminates Viruses and Bacteria.

Allowash XG is shown to inactivate enveloped and non-enveloped viruses, and it is validated to provide an effective bacterial log kill.

Viral Inactivation Log Reduction		
Virus	Type	Log Reduction
HIV	RNA, enveloped	12.4
BVDV	RNA, enveloped	10.4
PrV	DNA, enveloped	12.1
PPV	DNA, nonenveloped	3.8
HAV	RNA, nonenveloped	5.7
PV-I	RNA, nonenveloped	12.4 (w/o gamma)

Bacterial Inactivation Log Reduction					
Organism	Allowash	3% H ₂ O ₂	Antibiotics	70% IPA	Additive Log Kill
<i>C.sordelli</i>	2.3	5.87	1.14	1.96	11.27
<i>E.faecalis</i>	0.14	4.98	1.15	5.9	12.17
<i>E.coli</i>	0.32	6.78	6.23	5.96	19.29
<i>P.aeruginosa</i>	0.56	6.66	5.78	5.24	18.24
<i>A.niger</i>	0.03	6.49	0.28	5.59	12.39
<i>S.aureus</i>	0.44	4.09	0.94	6.45	11.92
<i>B.subtilis</i>	3.48	2.68	2	1.34	9.5
<i>C.albicans</i>	0.96	5.57	4.43	5.56	16.52





LIFENET HEALTH SUITE OF ALLOGRAFT TECHNOLOGIES

ALLOWASH XG® Tissue Sterilization

Renders allograft bio-implants sterile without compromising their biomechanical or biochemical properties.

MATRACELL™ Allograft Decellularization

Safely removes donor cells and DNA without sacrificing the biomechanical strength of the allograft bio-implant.

PRESERVON® Allograft Bio-implant Preservation

Allows allograft bio-implants to be stored fully hydrated at ambient temperature.

PAD® Allograft Demineralization

Precisely manages demineralization to optimize osteoinductivity.

LifeNet Health, a non-profit global leader in regenerative medicine, is the world's largest provider of bio-implants and organs for transplantation whose mission is saving lives and restoring health by advancing the field of tissue engineering. Please contact your LifeNet Health representative for more information about our comprehensive offering of allograft products and services.



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www.AccessLifeNetHealth.org

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