

OrACELL[®] Overview

for Value Analysis Committee Review

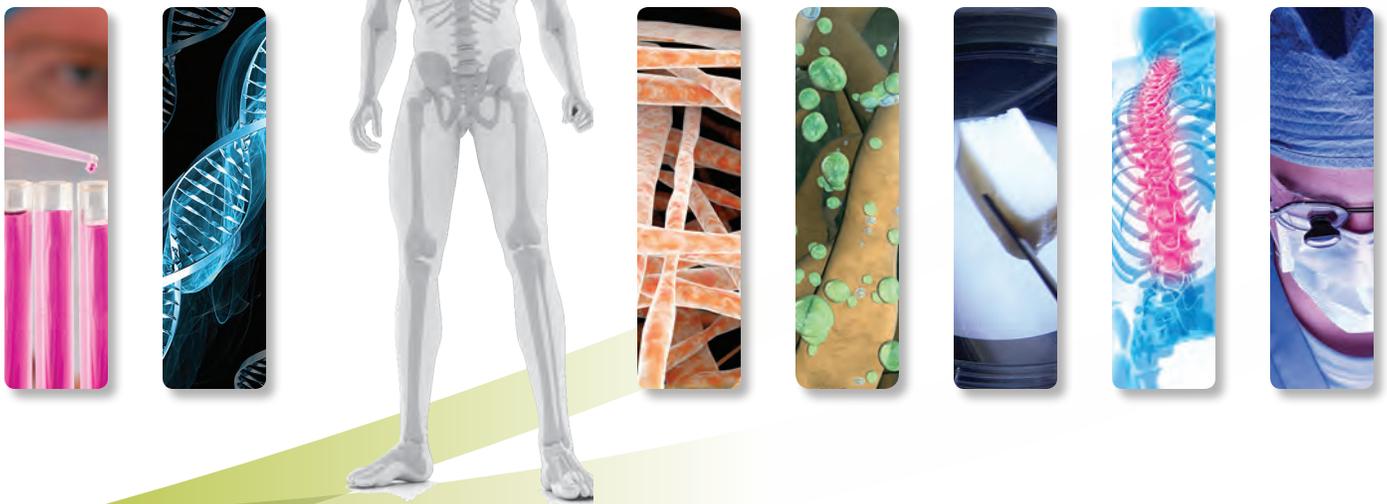


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OrACELL® Information

Description of Product:

OrACELL bio-implants are manufactured by LifeNet Health, a leader in regenerative medicine that excels in safety, innovation, quality, and service. OrACELL is an acellular dermal matrix intended for soft tissue repair and reconstruction. OrACELL bio-implants are decellularized using MatrACELL®, a proprietary and patented technology that removes $\geq 97\%$ of the DNA without compromising the desired biomechanical or biochemical properties. This allows the matrix to retain its growth factors, native collagen scaffold, and elastin required for healing. OrACELL bio-implants are packaged using PRESERVON®, which allows the graft to be stored fully hydrated at ambient temperature. This eliminates the need for refrigeration, and lengthy thawing and rehydrating processes. Finally, all OrACELL bio-implants undergo terminal sterilization, which renders the allograft sterile to medical device grade standards with a Sterility Assurance Level (SAL) of 10^{-6} .

Value Proposition:

LifeNet Health is the world's most trusted provider of allograft tissues. The OrACELL bio-implants are sterile, ambient temperature stored, and ready to use. All grafts have a sterility assurance level of 10^{-6} , and are backed by the quality reputation of LifeNet Health.

Key Product Benefits:

- **Biocompatible.** Acellular dermis grafts are comprised of 100% natural human material which is remodeled naturally during the healing process.
- **DNA Removal.** OrACELL bio-implants decellularized with the MatrACELL technology, achieve $\geq 97\%$ of the DNA removed without compromising the desired biomechanical or biochemical properties
- **Ready to Use.** OrACELL bio-implants are stored at ambient temperature and ready to use out of the package without rehydration.
- **Medical Device Grade Sterility.** OrACELL bio-implants are terminally sterilized to an SAL of 10^{-6} offering 1,000 times greater sterility assurance than other providers that have an SAL of 10^{-3} .

OrACELL® Information

Key Impact on Patient Care:

- LifeNet Health's stringent donor selection, coupled with validated work processes ensure safe, consistent final product.
- Reduced cellular and DNA levels allow for cellular infiltration and revascularization.

Key Impact on Surgical Costs/OR Time:

- OrACELL bio-implants are available in a wide variety of configurations to provide the surgeon with the best treatment options for the patient.
- Decreased OR time since product is stored at ambient temperature and is ready to use.

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. LifeNet Health does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of LifeNet Health product offerings. A surgeon must always refer to the package insert, product label, and/or instructions for use before using any LifeNet Health product. Products may not be available in all markets because product availability is subject to regulatory and/or medical practices in individual markets. Please contact your LifeNet Health representative if you have any questions about the availability of LifeNet Health products in your area. LifeNet Health, its divisions, or other wholly-owned subsidiaries own, use or have applied for the following trademarks or service marks: LifeNet Health, DermACELL, MatrACELL, Preservon. All other trademarks are trademarks of their respective owners or holders. Copyright © 2014 LifeNet Health.

The Value of Working with LifeNet Health

Safety:

For over 30 years, we have refined and defined safety in the allograft industry. Our processes, quality systems, and proprietary cleaning and sterilization technologies are designed to ensure the utmost safety for your patient - **reducing the probability of infection that could be caused by an allograft implant, and saving your facility unexpected costs.** Infections erode profits and hold legal ramifications if hospitals fail to implement best practices in infection control. Since 1995, over four million bio-implants processed using Allowash technology have been distributed by LifeNet Health with no disease transmission.

The thread of safety is woven through every step of the donation proces, including:

▪ Nationwide Recovery Network	▪ Stringent Donor Screening and Review
▪ Physical Examination & Recovery Protocols	▪ Bacteria & Serology Testing
▪ Controlled Processing & Terminal Sterilization	▪ Final MD Review & Release

Quality:

LifeNet Health's controlled tissue processing environment is designed to ensure bio-implant quality and safety. Through the consistent application of quality systems, quality control, and design control processes, LifeNet Health is both a medical device company and a tissue bank and our bio-implants are designed and manufactured to ensure the highest possible quality. **LifeNet Health grafts consistently perform as they should, allowing medical professionals to focus on the procedure, and patients to focus on healing.** Year after year, this dedication to quality is validated internally, and vetted by your peers, as well as government and industry regulators.

▪ Extraordinary Design Control Processes	▪ A product complaint rate of approximately 0.1%
▪ Validated Processes	▪ ISO, AATB, FDA, CLIA accreditations, registrations and certifications
▪ Quality Control Post-Processing Testing	

Innovation:

Because LifeNet Health leads the industry, and our innovations bring both clinicians and patients the most up-to-date technologies, **choosing LifeNet Health means choosing a partner able to consistently provide you with products, technologies, and services designed to improve safety, clinical effectiveness, ease of use and, ultimately, cost for the facility.** Since opening its doors in 2012, the LNH Institute of Regenerative Medicine has been a hub of research and development activity, and can **supply you with the products to meet your needs now - and in the future.**

The Value of Working with LifeNet Health

Service:

Healing never takes a vacation, and neither do we. We offer strategic inventory alternatives, and have a team of product managers and service specialists dedicated to meet your needs to save you valuable time. LifeNet Health supports the CE needs of your staff through award-winning training programs to complement the continuing education needs of your staff.

▪ Global Network of Partners	▪ Sales & Consulting Support
▪ Continuing Education Programs (on and off-site)	▪ Flexible Return Policies
▪ Consignment Options	▪ 24/7 Order Support

Clinical Effectiveness:

Our extensive portfolio of implants consistently performs at the highest level because LifeNet Health has invested considerable resources performing multiple clinical studies to ensure your patients' outcomes are positive.

Supply Chain Reliability:

LifeNet Health offers you a partner with bi-coastal production facilities - ensuring a dedicated supply of much needed allograft products to your facility. And we are working towards being able to produce and process our entire extensive portfolio at each facility, which supports nearly every surgical discipline.

▪ Multiple Distribution Centers	▪ World's 2nd Largest Access to Donor Tissue
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Experience:

Many of the world's largest orthopedics companies partner with and rely on LifeNet Health's expertise and experience. As a non-profit organization, LifeNet Health is able to focus our energies and passion to our mission of saving lives and restoring health -- not shareholders' concerns for the bottom line.

▪ Over 30 years of tissue banking experience	▪ Longest-running AATB certification
▪ First of its kind to become ISO certified	▪ Trusted partner of leading orthopedics companies
▪ Preferred allograft provider to 6 of US News & World Report's top 10 hospitals	▪ Global distribution

Product Attributes - OrACELL		
Product Type:	Allograft Decellularized Dermis	
Product Indication/Example Clinical Use:	Soft Tissue Repair and Reconstruction	
Regulatory Classification	HCT/P	
Shelf Life (in years):	18 months – 1x1, 1x4, 1.5x2 3 years – 2x4	
Storage Options:	Preservon (Fully hydrated, ambient temperature)	
Packaging Options:	Double Peel Pouch	
Product in Use Since:	2010	
Bio-Implant Attributes (check all that apply):	Biocompatible	Yes
	Decellularized	Yes
	Pre-sutured	
	Sterile	Yes
	Anti-Viral Claim	Yes
	Osteoinductive	
	Osteoconductive	
	Osteogenic	
	Resistance to infection	Yes
Product Ability to Save OR/Surgical Time: (explain)	Stored at ambient temperature and ready to use out of package with no rehydration necessary	
Product Ability to Save vs. Current Options (explain)	Ready-to-use, sterile, and fully hydrated grafts	

Effectiveness	
In vitro/Bench Data:	Yes
Animal Clinical Data:	Yes
Human Clinical Case:	Yes
Human Clinical Series:	Yes
Human Clinical Study:	Yes

Supply Chain Reliability	
Processing Facilities Redundancy	Yes. Three facilities in VA, one in WA.
Lab Processing Redundancy	Yes. One in VA, one in WA.
Distribution Centers	Yes: VA and WA.

Supply Service Attributes:		
Ordering	(US) Phone: 1-888-847-7831 (US) Fax: 1-888-847-7832 email: orders@lifenethealth.org	(OUS) Phone: 1-757-464-4761 x2000 (OUS) Fax: 1-757-301-6579 email: lnhinternational@lifenethealth.org
Customer Service Availability:	12 hours a day, 7 days a week - with 24 hour on-call support for emergencies	
Out of Stock/Backorder Notification:	Provided within 24 hours at time of order	
Subscribe to an outside supplier credentialing agency? (US Only)	Yes. Subscribed to Reptrax and other credentialing agencies that local hospitals require to be used.	
Educational offerings:	Continuing Education units (CEs) and in-house conference/seminars available upon request.	
LNH Facility Tours	Yes. Available upon request.	

Surgical Applications	Bio-Implants Available
General Orthopedics	ReadiGRAFT, ReadiGRAFT BLX, Optium, MatriGRAFT
Spine	ReadiGRAFT, ReadiGRAFT BLX, Optium, MatriGRAFT, VertiGRAFT
Orthopedics Trauma/Fracture	ReadiGRAFT, ReadiGRAFT BLX, Optium, MatriGRAFT
Sports Medicine	FlexiGRAFT, ArthroFLEX, Fresh Grafts
Oncology Orthopedics	Osteoarticular Grafts
Cranialmaxillofacial	OraGRAFT, OrACELL
Urology/General Surgery	ReadiGRAFT, MatriGRAFT
Wound Management	SWAI - Soft Tissue, DermACELL
Cartilage Repair	Fresh Grafts
Cardiac	CardioGRAFT
Vascular	AngioGRAFT

LifeNet Health Summary of Accreditation and Certifications			
American Association of Tissue Bank (AATB) Registration	✓	ISO 13485	✓
FDA registration	✓	CLIA Lab certified	✓
UNOS member	✓	Health Canada CTO registration	✓
Association of Organ Procurement Organizations (AOPO) accreditation	✓		

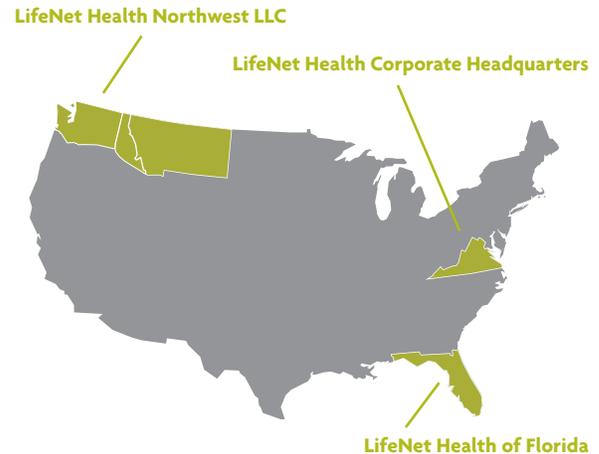
About LifeNet Health

Saving Lives and Restoring Health is Our Business.

Since 1982, LifeNet Health has helped to save lives and restore health for thousands of patients each year. It is the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

Our full line of allograft bio-implants provides surgeons with the tools they need to improve the lives of patients. Furthermore, we provide exemplary service to clinicians and hospitals by making the finest quality allograft implants easily accessible. With LifeNet Health as your primary bio-implant supplier, you are investing in the best possible value to ensure the well being of your patients and the reputation of your hospital.

Every year LifeNet Health distributes over 400,000 allograft bio-implants to meet the urgent needs of hospitals and patients around the world. Our record of safety is unmatched. And our philosophy is simple: When partnering with a bio-implant supplier, your decision should not be based solely on fee, but rather on the overall value you and your patients expect and deserve.



LifeNet Health Timeline

- 1982 Eastern Virginia Tissue Bank established.
- 1989 Eastern Virginia Tissue Bank becomes LifeNet.
- 1995 Allowash® cleaning technology introduced by LifeNet.
- PAD® Demineralization technology introduced by LifeNet.
- 2000 LifeNet merges with Virginia's Organ Procurement Agency.
- 2001 First VertiGraft® VG2® Cervical spine allograft bio-implant is implanted.
- 2006 LifeNet Health merges with Florida Tissue Services, Inc. to become LifeNet Health of Florida.
- 2007 LifeNet becomes LifeNet Health.
- Preservon® ambient storage, fully-hydrated preservation technology introduced by LifeNet Health.
- 2008 CardioGraft® Cardiac Patch with Matracell® receives Food & Drug Administration (FDA) clearance.
- Skin & Wound Allograft Institute is established.
- OsteoCleanse® Autograft Cleaning System launched.
- 2009 LifeNet Health Regenerative Medicine Institute established.
- 2010 Record year in LifeNet Health allograft bio-implant distribution (over 300,000).
- ArthroFlex®, DermACELL® and Oracell® decellularized dermis is launched.
- 2012 LifeNet Health merges with Northwest Tissue Services and establishes LifeNet Health Northwest.

Safety

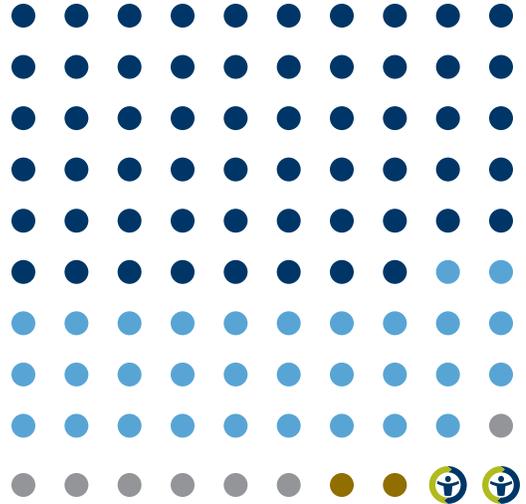
For over 30 years, we have refined and defined safety in the allograft industry. Our processes, quality systems, and proprietary cleaning and sterilization technologies are designed to ensure the utmost safety for your patient - **reducing the probability of infection that could be caused by an allograft implant, and saving your facility unexpected costs.** Infections erode profits and hold legal ramifications if hospitals fail to implement best practices in infection control. Since 1995, over four million bio-implants processed using Allowash technology have been distributed by LifeNet Health with no disease transmission.

Cleaning and Sterilization with Allowash XG®

- A patented and validated process that removes greater than 99 percent of bone marrow and blood elements from the internal bone matrix.
- Allowash XG has been shown to render a Sterility Assurance Level (SAL) of 10^{-6} and to inactivate viruses without compromising the biomechanical or biochemical properties of the tissue.
- An Extensive Network of Qualified Recovery Partners
- LifeNet Health only accepts donors from federally designated Organ Procurement Organizations (OPOs) or qualified tissue recovery partners.

ONLY
2%

of total donors screened for transplantation are accepted by LifeNet Health.



- 58% Age
- 31% Medical History and/or High Risk Behavior
- 7% Lack of Consent
- 2% Other + Post-Recovery Rejections
- 2% Accepted Donors



- Each partner is audited to ensure that their recovery process meets current FDA regulations, AATB standards and LifeNet Health's own stringent guidelines.

LifeNet Health's rigorous screening process meets or exceeds FDA requirements and guidelines and AATB standards.

- A complete donor report obtained from the next of kin and/or person most qualified to provide accurate information on the donor, including any autopsy results.
- Reviewed and signed by LifeNet Health medical director.
- Comprehensive recovery protocol
- A specialized team is dispatched to recover the tissue under strict LifeNet Health guidelines, including a physical assessment and thorough review of all medical records.
- Donor tissue is recovered using the safest recovery techniques and sterile equipment to minimize any bioburden contamination.
- Recovered tissue is sampled and tested for microbiological contamination. Blood is obtained for serological testing.
- Abnormal skin lesions are biopsied to rule out cancers—a practice unique to the industry.



Since 1995,
Over 4 Million
 BIO-IMPLANTS PROCESSED
 using **Allowash** technology
 have been distributed by
 LifeNet Health with no
 disease transmission.



Quality

LifeNet Health's controlled tissue processing environment is designed to ensure bio-implant quality and safety. Through the consistent application of quality systems, quality control, and design control processes, LifeNet Health bio-implants are designed and manufactured to ensure the highest possible quality. **LifeNet Health grafts consistently perform as they should, allowing medical professionals to focus on the procedure, and patients to focus on healing.** Year after year, this dedication to quality is validated internally, and vetted by your peers, as well as government and industry regulators.

Controlled Tissue Environment

- State-of-the-art facilities engineered to eliminate the possibility of cross-contamination.
- Strict attention to hygiene and cleanliness.
- LifeNet Health exceeds regulatory requirements.
- Focused Product Development and Quality Control.
- A comprehensive design process, including computer-aided drawings (CAD), focused engineering and meticulous product testing.
- No bio-implant can be released until going through a multidisciplinary review.
- Analytic testing is performed on demineralized tissue to ensure that residual calcium levels are within AATB guidelines.
- Freeze-dried tissue is tested to be certain residual moisture levels are below six percent as measured by gravimetric analyses.

- 100% visual inspection on all bio-implants prior to release.
- All records are reviewed and signed by the LifeNet Health Medical Director.

Flexibility and Selection

- Wide selection of bio-implants for surgeons according to specific criteria and graft sizes.
- Validated Storage and Shipping Methods
- Precise storage, packaging and shipping requirements in line with specific bio-implant type.
- Shipped products include specific instructions for safe storage and preservation at facility.

Registrations, Accreditations & Certifications

- American Association of Tissue Banks (AATB) accreditation.
- Food and Drug Administration (FDA) registration.
- United Network for Organ Sharing (UNOS) member.
- Association of Organ Procurement Organizations (AOPO) member.
- Licensed in required states.
- International Organization for Standardization (ISO) 13485: 2003 certified.
- Health Canada CTO Registered.

OVER
400,000

grafts are distributed by LifeNet Health each year with a product **complaint rate of less than 0.1%.**

FROM **Screening**
TO **Packaging**

LifeNet Health's Quality Control processes include **hundreds of steps to ensure quality and safety.** In many cases, our requirements are even more stringent than those required by organizations including the AATB and FDA.

OVER
45 U.S. Patents
IN THE FOLLOWING
AREAS:

Decellularization, Plasticized Grafts, Textured and Composite Bone Grafts, Tissue Sterilization Process, Demineralization, Osteoinductive Bone

Innovation

Choosing LifeNet Health means choosing a partner able to consistently provide you with products, technologies, and services designed to improve safety, clinical effectiveness, ease of use and, ultimately, cost for the facility. Since opening its doors in 2012, the LNH Institute of Regenerative Medicine has been a hub of research and development activity, and can **supply you with the products to meet your needs now - and in the future.**

Innovation in Sterilization Processes

Our patented Allowash XG sterilization process renders allograft bio-implants sterile, without compromising biomechanical or biochemical properties.

Innovation in Preservation Technology

Our proprietary Preservon® technology allows bio-implants to be stored in a fully hydrated state at ambient temperature. This eliminates the need for lengthy rehydration and saves valuable OR time.

Innovation in Demineralization Technology

Patented PAD® Demineralization technology provides precise bone demineralization to target the ideal residual calcium level of 1–4 percent. This controlled process protects bone morphogenetic proteins (BMPs) while ensuring optimal osteoinductivity.

Innovation in Decellularization Technology

MatrACELL decellularization renders allograft bio-implants acellular, without compromising the biomechanical or desired biochemical properties of an allograft bio-implant for its intended surgical application.

Innovation in Cell Technology

Our Institute of Regenerative Medicine is dedicated to the development of new cell-based technologies, designed to improve tissue and bone repair procedures.



Experience

With 30 years of experience, millions of allograft bio-implants provided and top-rated technology to back it all up, LifeNet Health proudly takes the industry lead. In fact, our allograft bio-implants are proven in more applications than any other.

LifeNet Health Bio-Implants Division is a leader in the engineering and processing of dental, cardiovascular, spinal and orthopedic bio-implants and distributes more than 400,000 bio-implants every year to restore health to patients around the world.

LifeNet Health Foundation is dedicated to raising and directing funds to support the donation process in the communities we serve.

LifeNet Health Transplant Services Division is a leading, federally designated Organ Procurement Organization that coordinates the recovery and transplant of organs in Virginia, offers a comprehensive program of bereavement support for donor families, and educates the public about donation.

LifeNet Health Tissue Services Division is dedicated to training, educating and maintaining relationships with more than 55 partners in order to promote donation in their respective communities.

LifeNet Health International Division is dedicated to the development and management of international partners and customers.

LifeNet Health of Florida is a division dedicated to the recovery of tissue in Northern Florida, improving the awareness of tissue donation and educating the public about donation in the Northern Florida Community.

LifeNet Health Northwest is a full-service tissue recovery, processing and distribution division of LifeNet Health based in Renton, Washington.

Skin and Wound Allograft Institute (SWAI) was established to ensure the processing and delivery of skin allograft bio-implants for U.S. burn centers.

LifeNet Health Institute of Regenerative Medicine (IRM) Regenerative medicine embodies a convergence of stem cell therapies, tissue engineering, drug delivery, and existing tissue reconstruction and replacement methods. The IRM develops novel regenerative approaches and products derived from donor tissues and organs and strives to reduce morbidity and complications in surgical procedures.



In addition to our
**30 years OF
Experience,**

LifeNet Health:

- Has the longest-running AATB certification.
- Is the first organization of its kind to be ISO certified.
- Has strategic partnerships with leading healthcare organizations.



Performance/Clinical Effectiveness

LifeNet Health provides the only allograft bio-implants backed by an entire body of published clinical data.

In fact, our allograft bio-implants are proven in more applications than any other. The result? The kind of confidence that only comes with the world's most trusted provider of transplant solutions.

We have become the largest non-profit organ and tissue provider in the United States and have grown to distribute over 400,000 bio-implants annually.

More than 40 clinical studies document the clinical effectiveness and performance of LifeNet Health allograft bio-implants in the following applications:



Spine



More than 50,000 bio-implants distributed annually



Sports Medicine



More than 20,000 distributed annually



General Orthopedics & Trauma



More than 40,000 distributed annually



Craniomaxillofacial



More than 200, 000 distributed annually

Supply Chain Reliability

LifeNet Health offers you a partner with bi-coastal production facilities - ensuring a dedicated supply of much needed allograft products to your facility.

And we are working towards being able to produce and process our entire extensive portfolio at each facility, which supports nearly every surgical discipline.



Clinical Efficacy Supporting Documentation

Human Clinical Case Reports:

1. Wallace SC. Guided bone regeneration for socket preservation in molar extraction sites: histomorphometric and 3D computerized tomography analysis. J Oral Implantol. 2013 Aug;39(4):503-9
2. Holtzclaw D. Guided bone regeneration in the maxillary anterior. Case on file; LifeNet Health
3. Rosen PS. Congenitally missing maxillary lateral incisors – Preparation for implants (one-stage therapy). Case on file; LifeNet Health
4. Holtzclaw D. Combined extraction socket grafting and horizontal augmentation of resorbed ridge. Case on file; LifeNet Health
5. Orlando M. Augmentation of alveolar ridge with acellular dermis. Case on file; LifeNet Health
6. Wan Lou C. Vestibuloplasty using acellular dermis. Case on file; LifeNet Health
7. Chou-Lin K. Vestibuloplasty using a human acellular dermal matrix (ADM) Case on file; LifeNet Health

Human Clinical Case Series:

1. Sindler, A. Treatment of gingival recession using OrACELL decellularized dermis. Case on file; LifeNet Health

Ordering LifeNet Health Allograft Bio-Implants

Health care facilities, approved distributors and authorized tissue dispensing intermediaries are permitted to order allograft bio-implants from LifeNet Health. Only licensed clinical professionals may actually transplant tissue.

Orders may be placed by e-mail, phone and/or fax or e-mail at lnhinternational@lifenethealth.org. A valid purchase order number must be provided for all orders. All phone calls to LifeNet Health's Client Services department are recorded for quality control purposes.

Title to LifeNet Health products passes from LifeNet Health to the customer once the shipment leaves our facility.

Transportation of LifeNet Health Allograft Bio-Implants

All LifeNet Health Bio-Implants (except CardioGraft and AngioGraft cryopreserved) will be shipped either Fed Ex Priority or UPS Worldwide Express and customer will be charged for each shipment.

Cryopreserved CardioGraft and AngioGraft allograft bio-implants will be shipped by special courier services and a courier fee will be charge for each cryoshipper. Return of the empty cryoshipper will be handled and coordinated by LifeNet Health.

Return Policy

LifeNet Health does not allow for the return of unused allograft bio-implants. For information about returning damaged allograft tissue, please contact LifeNet Client Health Services at 1-757-464-4761 ext 2000.

Payment Terms and Conditions

Payments are due prior to shipment unless otherwise stated. Payments are due in US dollar only. Allowable forms of payment are: Visa/Master Card, or wire transfer. Account statements are sent monthly to all accounts as a reminder of outstanding payments due. For any payment questions or information please call 1-757-464-4761 ext. 4444 or e-mail at: accountsreceivable@lifenethealth.org

This reference manual should not be considered as an approval of products in every country. It is recommended that you verify product approval or registration status for your country with Client Services prior to placing an order.

Please Mail All Payments To:

LifeNet Health
P.O. Box 79636
Baltimore, MD 21279-0636

LifeNet Health Vendor Information

Company:
LifeNet Health, Inc.
Address: 1864 Concert Drive Virginia Beach, VA 23453
Phone: 757-464-4761 ext. 2000
Fax: 757-301-6579
Email: lnhinternational@lifenethealth.org

Summary Of LifeNet Health Accreditations/ Certifications

- ✓ AATB ACCREDITATION
- ✓ FDA REGISTRATION
- ✓ UNOS MEMBER
- ✓ AOPO MEMBER
- ✓ ISO 13485 CERTIFIED
- ✓ CLIA CERTIFIED
- ✓ LICENSED IN REQUIRED STATES
- ✓ HEALTH CANADA CTO 10038



LifeNet Health helps to save lives and restore health for thousands of patients each year. We are the world's most trusted provider of transplant solutions, from organ procurement to new innovations in bio-implant technologies and cellular therapies—a leader in the field of regenerative medicine, while always honoring the donors and healthcare professionals that allow the healing process.

1864 Concert Drive
Virginia Beach, VA 23453
1-888-847-7831

www.AccessLifeNetHealth.org

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