Pliafx[®] Prime

Optimized Handling. Uncompromised Performance.

FIBER SURFACE TECHNOLOGY

LifeNet Health's fiber technology is an innovation that provides a solution to fusion by harnessing nature's time-tested patterns and strategies.





Hospitable Scaffold with Unique Fiber Technology

• LifeNet Health has developed a unique demineralized bone matrix (DBM) that is comprised of interlocking fibers. The long, rough cortical fiber surface of PliaFX Prime provides many contact points for cellular attachment, and the interconnected fibers allow the cells to spread out and make cell-to-cell connections. PliaFX Prime contains interconnected, optimally demineralized bone fibers which provide the osteoconductive and osteoinductive properties necessary to support cellular proliferation and bone formation.^{13,4}



PliaFX Prime encourages cellular attachment, migration and infiltration^{3,4}



Attachment was evident at 30 minutes, with the BM-MSCs presenting a spherical morphology.



On Day 1, the BM-MSCs migrated and transformed to a flattened morphology **indicative of cellular health.** The cells also began secreting extracellular matrix (ECM), which provides a scaffold for **cell growth and attachment.**



On Day 7, the BM-MSCs infiltrated between fibers and demonstrated **cellto-cell interactions** which allow cells to communicate with each other and are critical to the development and function of tissues.

Provides Enhanced Surgical Flexibility

• These interlocking fibers become moldable upon rehydration, conform to the surgical site, and resist migration. PliaFX Prime offers flexibility in rehydration, even allowing the option to use soluble antibiotic solution.²⁻⁴

Precise Demineralization Process for Regeneration

- PliaFx Prime is optimally demineralized using LifeNet Health's proprietary technology to expose growth factors such as bone morphogenic proteins (BMPs), which can recruit host cells to the implant site and stimulate bone-forming activity.^{13,4}
- Literature has shown that BMPs including BMP-2 & BMP-7 are important for bone healing as they are known for their ability to stimulate differentiation of MSCs to osteochondroblastic lineage and are important factors necessary for bone healing and regeneration.³
- Angiogenic growth factors, VEGF and angiogenin, were detected in PliaFX Prime samples (see table). These results demonstrate that PliaFX Prime retains osteinductive and agniogenic growth factors.^{13,4}

Growth Factor	Concentration		
BMP-2	85.78 ± 6.84 ng∕g DBM		
BMP-7	11.24 ± 1.49 ng⁄g DBM		
Osteopontin	101.49 ± 36.71 ng/mL		
VEGF	377.49 ± 196.99 pg∕mL		
Angiogenin	285.50 ± 171.57 pg∕mL		

Pre-clinical test data/results may not necessarily be indicative of human clinical performance (or outcomes).

Safety Profile

LifeNet Health prides itself on our safety record over the last 40+ years. We hold the longest continuous accreditation from the American Association of Tissue Banks (AATB) and have a comprehensive range of measures in place to validate the safety of our allograft bio-implants; this includes stringent donor screening methods and release criteria. To obtain suitable donors, we maintain an extensive network of recovery partners. Additionally, we are a leading, federally designated Organ Procurement Organization. We only accept donors from federally designated Organ Procurement Organizations and qualified tissue recovery partners. These partners are regularly audited to document that their recovery process meets current FDA regulations, AATB standards, and our own stringent guidelines. It is important to KNOW your tissue provider.



Allowash XG°

Since 1995, more than 10 million implants processed using Allowash technology have been distributed by LifeNet Health without any reports of disease transmission.

Ordering, Shipping and Storage Information

Ordering

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

Orders may be placed by phone, fax and/or email at orders@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.

Return Policy

LifeNet Health allows for the return of most unused allografts within 90 days from the date of purchase as long as specific criteria have been met. For information about returning allograft tissue, please contact LifeNet Health Client Services at 1-888-847-7831 or refer to LifeNet Health's Return Policy for specific guidelines. As with all donated tissue, we request that the gifts be treated with respect.

Payment Terms and Conditions

Payments are due 30 days from the invoice date unless otherwise stated. Payments are due in US dollars only. Allowable forms of payment are: American Express, Company Check, Visa/Master Card, ACH, 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 accountsreceivable@lifenethealth.org

Please Mail All Payments To: LifeNet Health Vendor Information

LifeNet Health P.O. Box 79636 Baltimore, MD 21279-0636 LifeNet Health 1864 Concert Drive Virginia Beach, VA 23453 Toll Free Phone: 1-888-847-7831 1-757-464-4761 ext. 2000 (OUS) Toll Free Fax: 1-888-847-7832 1-757-301-6579 (OUS) orders@lifenethealth.org

Moldable Demineralized Fibers | PliaFX®

Freeze-Dried Ambient Storage

	Description	Size/Volume	Order Code	Shelf Life
		0.5 cc	BL-1800-00	4 Years
		1.0 cc	BL-1800-01	4 Years
	Prime	2.5 cc	BL-1800-02	5 Years
		5.0 cc	BL-1800-05	5 Years
		10 сс	BL-1800-10	5 Years

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References

- 1. Data on file LifeNet Health EX-0403.00.
- 2. Data on file LifeNet Health 63-0252-03.03.
- McLean JB, Carter N, Sohoni P, Moore MA. Cell Attachment and Osteoinductive Properties of Tissue Engineered, Demineralized Bone Fibers for Bone Void Filling Applications. Clinical Implementation of Bone Regeneration and Maintenance. 2019.
- DePuy Synthes. PliaFX® Prime Moldable Demineralized Fibers White Paper. 2022. AMP Document #US_DPS_SPNE_170825.

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