



PliaFX® Pak

Packable Demineralized Fibers with Chips

Clinical Overview

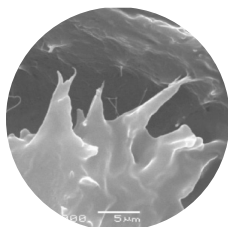
PliaFX Pak is a proprietary mix of 100% bone, moldable demineralized cortical fibers with bone chips, providing optimized handling, hemostatic and osteoconductive^{1,2,3,7} properties. The demineralized fibers interlock with the chips, allowing the graft to become moldable upon rehydration without the use of a carrier.^{1,3,4,7}

Applications

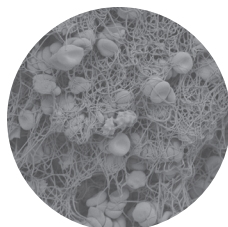
ACDF, ALIF, scoliosis correction and fusion, or other surgical procedures that require bone void filler.

Features & Benefits

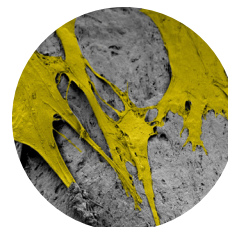
- **Optimized Handling:** Fibers interlock with bone chips to provide a moldable, intact graft that easily transfers to the surgical site, conforms to the surgical site and resists migration.^{1,3,4,7}
- **Hemostatic:** Fibers and chips facilitate coagulation and stop bleeding.^{1,7}
- **Osteoconductive:** Large surface area and interconnected network of fibers and chips provide a scaffold that promotes cell attachment and cell spreading.^{1,2,3,7}
- **100% Bone:** Demineralized fibers and bone chips facilitate natural remodeling during the bone healing process (no human, xenograft or synthetic carriers).^{1,2,3,7}
- **New Bone Formation Potential:** Fibers demineralized by PAD® technology retain osteoinductive and angiogenic growth factors and thus retain the potential to induce new bone and blood vessel formation *in vivo*.^{1,3,7}
- **Safety:** Sterilized using proprietary Allowash XG® technology, providing a sterility assurance level of 10⁻⁶ to reduce the risk of disease transmission without compromising the graft's osteoconductive properties or osteoinductive potential.^{3,5,7}
- **Customizable:** Easily mixes with autograft, allograft and/or fluid of surgeon's choice.
- **Convenient:** Ambient storage and rapid rehydration.



Interlocking fiber microhooks provide moldable handling



Hemostatic fibers facilitate coagulation and stop bleeding



Osteoconductive scaffold promotes cell spreading at 7 days

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PliaFX Pak

Ambient Storage*

Volume	Order Code	Shelf Life
1 cc	BL-2100-01	4 years
2.5 cc	BL-2100-02	4 years
5 cc	BL-2100-05	5 years
10 cc	BL-2100-10	5 years
20 cc	BL-2100-20	5 years
30 cc	BL-2100-30	5 years

*While ambient room temperature has not been defined by regulatory bodies, LifeNet Health would recommend storage at 2°C to 37°C with excursions of less than 24 hours up to 40°C. If an excursion outside this range occurs, please contact LifeNet Health.



100% bone chips with precision-machined demineralized fibers



Fibers interlock with bone chips to provide moldable handling



Conforms to the surgical site and resists migration

Instructions for use available at [LifeNetHealth.org/IFU](https://www.lifenethealth.org/IFU)

References:

1. LifeNet Health, PliaFX® Pak – Moldable Demineralized Fibers White Paper.2022. 68-20-369.00.
2. Murphy MB, Suzuki RK, Sand TT, et al. Short term culture of mesenchymal stem cells with commercial osteoconductive carriers provides unique insights into biocompatibility. J Clin. Med. 2013; 2,49-66; doi:10.3390/jcm2030049
3. J. B. McLean, N. Carter, P. Sohoni, and M. A. Moore, 'Cell Attachment and Osteoinductive Properties of Tissue Engineered, Demineralized Bone Fibers for Bone Void Filling Applications', Clinical Implementation of Bone Regeneration and Maintenance. Intech Open, Feb. 10, 2021.
4. Brydone AS, Meek D, MacLaine S. Bone grafting, orthopaedic biomaterials, and the clinical need for bone engineering. Proc Inst Mech Eng H. 2010;224(12):1329-1343.
5. Eisenlohr LM. Allograft Tissue Sterilization Using Allowash XG® Bio-Implants Brief. 2007. 68-0089.

†Pre-clinical test data/results may not necessarily be indicative of human clinical performance (or outcomes). Important Information: Prior to use, refer to the instructions for use supplied with the device(s) for indications, contraindications, side effects, warnings and precautions.

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