



PliaFX[®] Pak

Moldable Demineralized Fibers with Cancellous

Clinical Overview

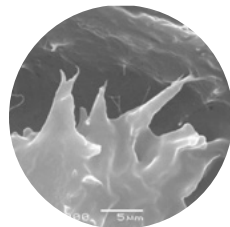
PliaFX Pak is a proprietary mix of 100% bone, moldable demineralized cortical fibers with cancellous chips, providing optimized handling, hemostatic¹ and osteoconductive^{2,3} properties. The demineralized fibers interlock with the cancellous chips, allowing the graft to become moldable upon rehydration without the use of a carrier.⁴

Applications

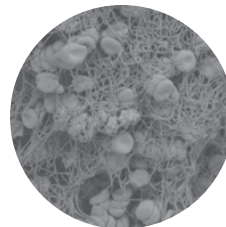
Orthopedic fracture, fusion, osteotomy and/or other procedures requiring filling of large bone defects to promote healing.

Features & Benefits

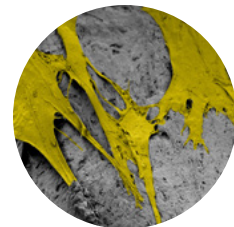
- **Optimized Handling:** Fibers interlock with cancellous chips to provide a moldable, intact graft that easily transfers to the surgical site, conforms to the surgical site and resists migration.⁴
- **Hemostatic:** Fibers and cancellous chips facilitate coagulation and stop bleeding.¹
- **Osteoconductive:** Large surface area and interconnected network of fibers and cancellous chips provides a scaffold that promotes cell attachment and cell spreading.^{2,3}
- **100% Bone:** Demineralized fibers and cancellous chips facilitate natural remodeling during the bone healing process (no human, xenograft or synthetic carriers).
- **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*.^{3,5,6,1}
- **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.^{7,8,9}
- **Customizable:** Easily mixes with autograft, allograft and/or fluid of surgeon's choice.⁴
- **Convenient:** Ambient storage and rapid rehydration.⁴



Interlocking fiber microhooks provide moldable handling



Hemostatic fibers facilitate coagulation and stop bleeding¹



Osteoconductive scaffold promotes cell spreading at 7 days³



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PliaFX Pak

Ambient Storage*

Volume	Order Code	Shelf Life
10 cc	BL-2000-10	5 years
20 cc	BL-2000-20	5 years
30 cc	BL-2000-30	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. Precision-machined cortical fibers with cancellous chips



Moldable upon rehydration and easily transfers to the surgical site⁴



Conforms to the surgical site and resists migration⁴

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

References

1. Data on file LifeNet Health CC#68143
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. Data on file LifeNet Health ES-17-111-02
4. Data on file LifeNet Health ES-21-049
5. Data on file LifeNet Health ES-17-110
6. Data on file LifeNet Health TR-19-0446
7. Data on file LifeNet Health 68-60-037 Sterilization Process Validation
8. Weintroub S, Reddi AH. Influence of irradiation on the Osteoinductive potential of demineralized bone matrix. Calcif Tissue Int. 1988; 42(4):255-60
9. Eisenlohr LM. "Allograft Tissue Sterilization Using Allowash XG®" 2007 Biolmplants Brief

[†]Results in an animal model may not be representative of performance in humans.

