PliaFX® Flo

Flowable Demineralized Fibers

Clinical Overview

PliaFX Flo is a demineralized bone matrix (DBM) comprised of optimally demineralized[1-3,†] fibers with surface characteristics that set the standard[4-6,†] for osseointegration, combined with a glycerol carrier.[7] The graft flows directly from the syringe for precise delivery with no intraoperative preparation required.[7]

Applications

Bony voids or gaps of the skeletal system (e.g., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure; Surgically created osseous defects or osseous defects from traumatic injury to the bone.[7]

Features & Benefits

- **Precise Delivery:** Packaged in a sterile syringe, allowing delivery directly to the surgical site.[7]
- **Optimized Handling:** Fibers interlock to provide a moldable, intact graft that easily transfers to the surgical site, conforms to the surgical site and resists migration.[4,†]
- **Osteoconductive:** Large surface area and interconnected network of fibers provide a scaffold that promotes cell attachment and spreading.[4,8,†]
- **New Bone Formation Potential:** Fibers were readily mineralized as early as 6 weeks when cultured *in vitro* indicating that the growth factors in the graft can promote bone-forming cells to mineralize the graft given the appropriate microenvironment.[9,†]
- **Safety:** Sterilized using proprietary Allowash XG® technology which provides the security of medical device-grade sterility without compromising the biochemical or biomechanical properties of the graft.[4,7,10,†]
- **Customizable:** Easily mixes with biomaterials such as autograft or allograft.[11,12,†]
- **Convenient:** Ambient storage and no rehydration required.[7]

Interlocking fibers provide moldable, cohesive graft that resists migration.[4,†]

Osteoconductive scaffold promotes cell spreading at 7 days.[4,†]

Graft easily mixes with biomaterials such as autograft or allograft.[11,12,†]

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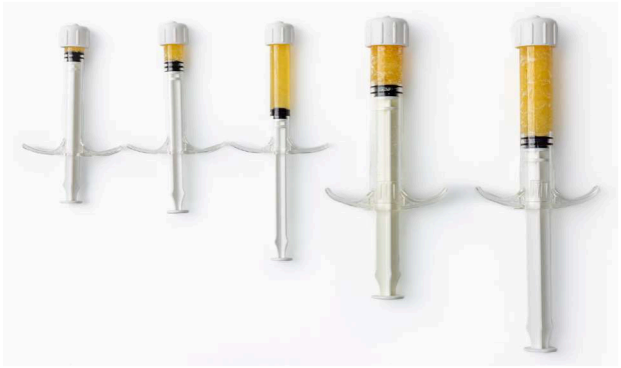

PliaFX Flo		
Ambient Storage*		
Volume	**Order Code**	**Shelf Life**
0.5 cc	BL-2200-00	3 years
1 cc	BL-2200-01	3 years
2.5 cc	BL-2200-02	3 years
5 cc	BL-2200-05	3 years
10 cc	BL-2200-10	3 years

*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.

Instructions for use available at **LifeNetHealth.org/IFU**

References:

1. Zhang M, Powers RM Jr, Wolfinbarger L Jr. Effect(s) of the Demineralization Process on the Osteoinductivity of Demineralized Bone Matrix. J Periodontol. 1997;68(11):1085-92. doi: 10.1902/jop.1997.68.11.1085.
2. Herold RW, Pashley DH, Camuenin MF, Niagro F, Hokett SD, Peacock ME, Mailhot J, Borke J. The Effects of Varying Degrees of Allograft Decalcification on Cultured Porcine Osteoclast Cells. J Periodontol. 2002;73(2):213-9.
3. Mott DA, Mailhot J, Cuenin MF, Sharawy M, Borke J. Enhancement of Osteoblast Proliferation In Vitro by Selective Enrichment of Demineralized Freeze-Dried Bone Allograft With Specific Growth Factors. J Oral Implantol. 2002;28(2):57-66.
4. 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.
5. Rodriguez RU, Kemper N, Breathwaite E, et al. Demineralized Bone Matrix Fibers Formable as General and Custom 3D Printed Mold-based Implants for Promoting Bone Regeneration. Biofabrication. 2016;8(3):03500.
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7. LifeNet Health. Instructions for Use. 63-0411.
8. 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
9. LifeNet Health. PliaFX Prime White Paper. 68-20-232.
10. Wolfinbarger L, Eisenlohr LM, Ruth K. (2008). Demineralized Bone Matrix: Maximizing New Bone Formation for Successful Bone Implantation. Musculoskeletal Tissue Regeneration: Biological Materials and Methods, 93-117.
11. LifeNet Health. Clinician Perspective Video, Dr. Branch, PliaFX. EX-2104.
12. LifeNet Health. Clinician Perspective Video, Dr. Yoon, PliaFX. EX-2039.

†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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