

# PliaFX<sup>®</sup> Prime

Optimized Handling. Uncompromised Performance.



Supporting Literature for the Advantages of a 100% Bone,  
Moldable Demineralized Fiber Allograft

## Supporting Literature for the Advantages of 100% Bone

Demineralized bone matrices (DBMs) are used in a wide variety of clinical applications for bone repair. An ideal DBM provides both osteoinductive and osteoconductive properties while offering versatile handling. Many commercial DBMs are composed of demineralized bone combined with an inert carrier that is used to improve handling. The proportion of the osteoinductive element of the graft – the demineralized bone – varies widely by manufacturer. PliaFX Prime is an advanced demineralized bone graft that is comprised of 100% bone fibers which provide the osteoconductive and osteoinductive properties necessary to support bone formation. The interlocking fibers allow the graft to become moldable upon rehydration without the use of a carrier. PliaFX Prime conforms to the surgical site and remains both intact and in place.

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The following is a review of literature that explore the relationship between demineralized bone content and osteoconductive and osteoinductive properties.

## Peer-Reviewed Publications

### Quantitative and sensitive in vitro assay for osteoinductive activity of demineralized bone matrix

**Summary:** Researchers tested the osteoinductive potential of DBMs from different bone banks using alkaline phosphatase (ALP) assays and a nude rat muscle pouch model. Varied amounts of active DBM were mixed with inactive DBM to test dose response. “When different amounts of active and inactive DBM were implanted, the 100% active DBM group gave a denser image of calcific deposits.” Explants of 100% active DBM induced higher ALP activity compared to explants with inactive DBM. Implants with 100% active DBM showed large amounts of new bone. The present study also “provides data indicating that this induction is dose dependent, associated with the quantity of active molecules available to the cells and unique to BMP-2 and BMP-7, since other growth factors showed no such effects.”

**100% active demineralized bone resulted in a denser image of calcific deposits, induced higher ALP activity, and showed larger amounts of new bone.**

Han B, Tang B, Nimni ME. Quantitative and sensitive in vitro assay for osteoinductive activity of demineralized bone matrix. *J Ortho Res.* 2003;4:648–54.

### The Effect of Poloxamer 407-Based Hydrogel on the Osteoinductivity of Demineralized Bone Matrix

**Summary:** Investigators used alkaline phosphatase (ALP) assays and an athymic rat model (n=6) to determine the effects of DBM formulations. Two formulations of DBM were used: DBM consisting 27% weight (wt) DBM bone content with 73% wt sterile water (DBM-W), and DBM consisting 25% wt DBM bone content and 75% wt poloxamer 407-based hydrogel (DBM-H). ALP activity was significantly higher in the DBM-W group at days 7 and 14 of treatment ( $p < 0.001$  DBM-W;  $p = 0.0003$  DBM-H). The DBM-W group also showed higher bone volume and a significantly higher percentage of bone volume compared to the DBM-H group,  $2.9 \pm 2.2$  and  $0.92 \pm 0.50$ , respectively. “This implies that the poloxamer 407-based hydrogel itself has no toxicity, but it may inhibit the MSC osteoblastic differentiation by filling up the spaces between the DBM powders, which negatively affects the release of growth factors.”

**Poloxamer-based carriers in commercially available DBM putties may negatively impact the release of growth factors and their ability to promote new bone formation.**

Lee JH, Baek HR, Lee KM, Lee HK, Im SB, Kim YS, Lee JH, Chang BS, Lee CK. The Effect of Poloxamer 407-Based Hydrogel on the Osteoinductivity of Demineralized Bone Matrix. *Clin Orthop Surg.* 2014;6(4):455-61.

### Short Term Culture of Human Mesenchymal Stem Cells with Commercial Osteoconductive Carriers Provides Unique Insights into Biocompatibility

**Summary:** Investigators cultured bone marrow mesenchymal stem cells (BMSCs) with several commercially available bone substitutes (allograft bone chips, bone powder, DBM strip, DBM injectables, collagen sponge, and various forms of calcium phosphates) to determine their effects on osteoprogenitor cell function in vitro. A subset of experiments within the study focused on three injectable putty preparations— Accell Connexus® (Integra, Plainsboro, NJ, USA), OsteoSurge® (Integra, Plainsboro, NJ, USA), and OrthoBlast® II (Citagenix, Laval, QC, Canada). Investigators found that Accell Connexus and OsteoSurge caused a change in media (from red to yellow), indicating a drop in pH of the solution. The investigators concluded that, “rapid resorption and the acidity associated with [DBM putties] fabrication proved incapable of maintaining cell growth in vitro.”

**Poloxamer-based carriers in commercially available DBM putties may negatively impact the functionality of native cells.**

Murphy MB, Suzuki RK, Sand TT, Chaput CD, Gregory CA. Short Term Culture of Human Mesenchymal Stem Cells with Commercial Osteoconductive Carriers Provides Unique Insights into Biocompatibility. *J Clin Med.* 2013;2(3):49-66.

## Posters

### High resolution X-ray computed tomography as a technique to study osteoinductivity of demineralized bone matrix

**Summary:** Investigators used micro-computed tomography to assess osteoinductive potential of human DBM in an athymic rat model. The implant material consisted of different quantities of DBM fibers in a glycerol carrier. DBM samples (100, 200, or 300 mg) were implanted into muscular pouch of rats and were explanted 28 days post-operative. Explants showed an increase of mineralized tissue volume as the quantity of DBM increased. Investigators noted a direct correlation between the volume of DBM implanted and the volume of mineralized tissue formed. “The more material present allowed for greater surface area and cell migration.”

**In this study, a direct correlation was observed between the volume of DBM implanted and the volume of mineralized tissue formed.**

Atti E, Abjornson C, Diegmann M, et al. High resolution X-ray computed tomography as a technique to study osteoinductivity of demineralized bone matrix. *Proceedings of the NASS 18th annual meeting. Spine J* 2003;3:120S.



## PliaFX Prime

| Order Code | Volume  | Shelf Life |
|------------|---------|------------|
| BL-1800-00 | 0.5 cc  | 4 years    |
| BL-1800-01 | 1.0 cc  | 4 years    |
| BL-1800-02 | 2.5 cc  | 5 years    |
| BL-1800-05 | 5.0 cc  | 5 years    |
| BL-1800-10 | 10.0 cc | 5 years    |



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