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StaGraft™ DBM
Biomet...
Shaping the Future of DBM

To learn more about this product,
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References

1. Biomet Internal Test Report (TR-0894)
2. "Combined effects of phosphatidylcholine and demineralized bone matrix on bone induction". Han B, Tang B, Nimni ME. Connect Tissue Res. 2003; 44(3-4):160-6.
3. "Lipids closely associated with bone morphogenetic protein (BMP) and induced heterotopic bone formation". Urist M, Behnam K, Kerendi F, Raskin K, Nuygen T, Shamie A, Malinin T. Connect Tissue Res. 1997;36(1):9-20.
4. "Dose-dependent toxicity of a commercially available demineralized bone matrix material". Wang J, Kanim L, Nagakawa I, Yamane B, Vinters H, Dawson E. Spine 2001; 26(13):1429-36.
5. "Quantitative and sensitive *in vitro* assay for osteoinductive activity of demineralized bone matrix." Han B, Tang B, Nimni ME. J Orthop Res. 2003; Jul;21(4): 648-54.

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Animal studies are not necessarily indicative of human clinical outcomes.

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StaGraft™
Demineralized Bone Matrix

BIOMET®

StaGraft™ DBM: Shaping the Future of DBM. Giving You The Proper Tools To Do That Is Ours.

StaGraft™ DBM is a osteoinductive demineralized bone matrix in a natural lecithin carrier, and is available as a 40% DBM putty, or 35% DBM Plus pre-mixed with resorbable coralline hydroxyapatite granules.

The natural quality of the carrier and its outstanding containment and handling characteristics enable the surgeon to mold it to surgical sites, even in the presence of excessive fluids and under lavage.

StaGraft™ DBM Family

Each lot is verified for osteoinductivity via the validated “C2C12” assay.

- DBM is resistant to wash-out during implantation – formulated with a natural lipid carrier that is resistant to breakdown by bodily fluids or temperature
- Excellent handling and performance characteristics – tolerates lavage/irrigation
- DBM-to-carrier ratio engineered for optimized osteoinductivity
- Every lot is bioassayed to demonstrate osteoinductive capabilities
- Off-the-shelf, moldable tissue graft; no mixing required – use with your preferred technique
- StaGraft™ Plus with Pro Osteon® 500R Resorbable Granules has excellent handling properties
- Easy to use – pre-loaded in a syringe; stored at room temperature
- Donor testing – all tissue undergoes extensive viral, microbiological and serological testing; HIV/PCR testing is done on every donor
- Comes in an array of convenient delivery sizes for a range of uses



StaGraft™ DBM Putty is simple to use and can be formed into any desired shape



StaGraft™ DBM is also available as an injectable, with Pro Osteon® 500R Resorbable Granules (2cc, 5cc, and 10cc)

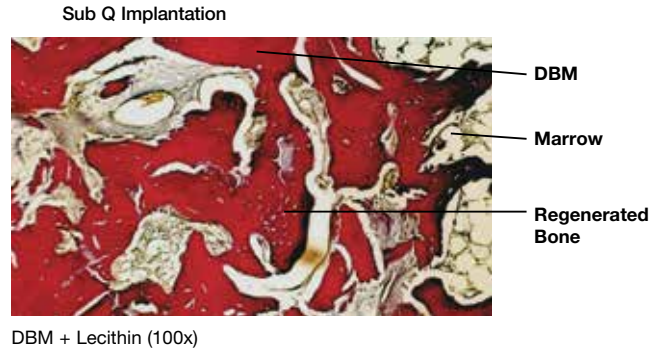
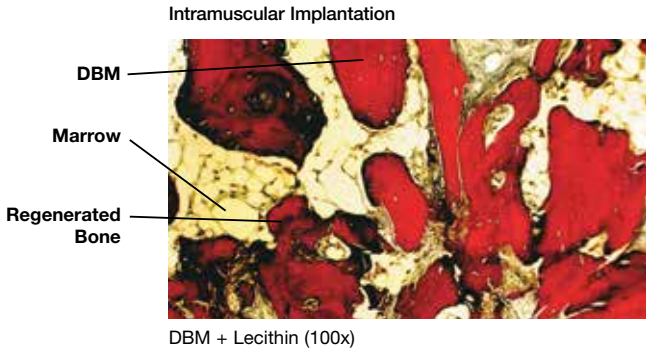


DBM used in the StaGraft™ products is processed and screened according to strict industry standards



The lipid carrier is resistant to bodily fluids, rendering StaGraft™ DBM Putty resistant to migration

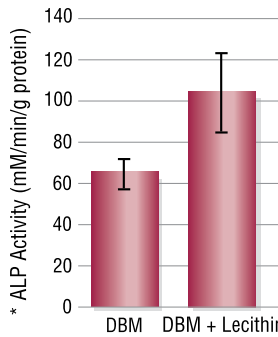
Histology of DBM + Lecithin Implant



4 Weeks Post-Op

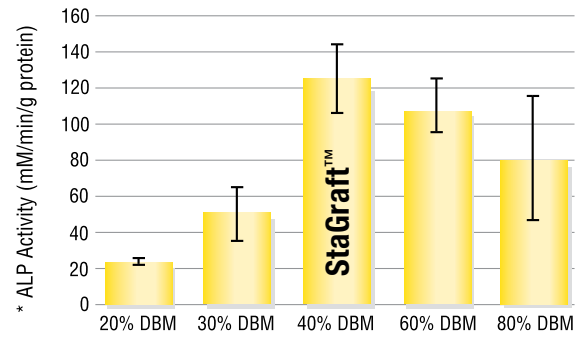
- Intramuscular and subcutaneous implantation sites
- Abundant bone growth is shown in the DBM + Lecithin implant
- Total bone and tissue volume increased in the DBM + Lecithin implant¹

Osteoinductivity



Alkaline phosphatase activity (ALP) is a measurement of osteoinductivity²

Percent DBM



StaGraft™ DBM -to-carrier ratio engineered for optimized osteoinductivity. This was achieved by optimizing the lecithin/DBM ratio at 60/40, as demonstrated in the Nimni study.⁵

- Urist found that endogenous lipids are closely associated with BMP and facilitate heterotopic bone formation³
- 27 Fisher rats, sub-Q and IM 28 day implantation. H&E staining

Non-Toxicity of Lecithin^{1,4}

Lecithin Grafts

Dosage (per 100g rat)	Outcome
.8g	100% Alive and Asymptomatic
1.6g	100% Alive and Asymptomatic
2.0g	100% Alive and Asymptomatic

In an animal model, rats were implanted with lecithin grafts to determine the overall level of toxicity.

All the rats exposed to the lecithin grafts lived and remained asymptomatic.