



ProteiOS®

THE CLEAR CHOICE FOR BONE REGENERATION

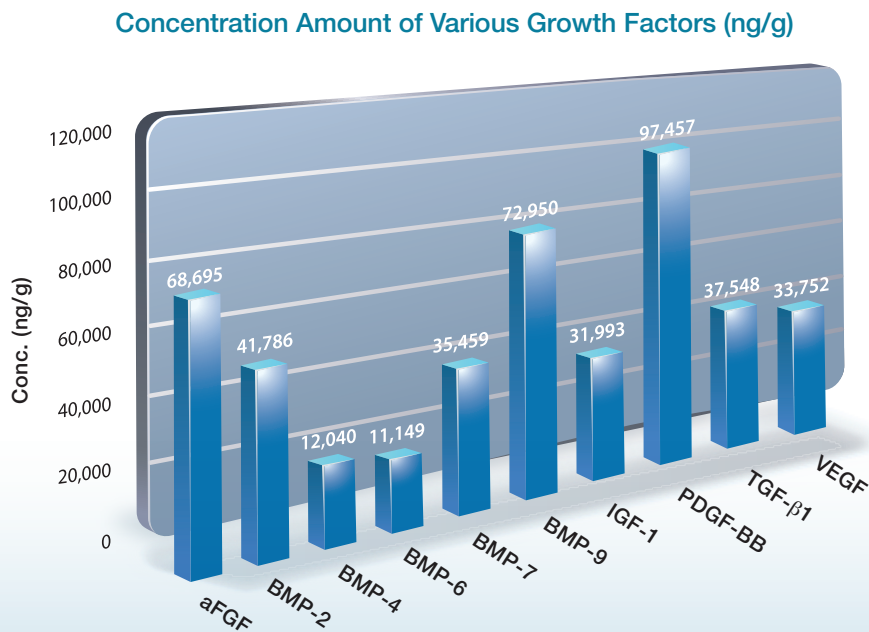
PROCESSING

ProteiOS® provides a clear choice for your bone regeneration needs. Through Biologica's proprietary processing methods, we are able to harness the relevant intracellular growth factors found within the endosteum layer of allograft bone. This layer is found lining the trabecular space and is comprised of mesenchymal stem cells (MSCs), osteoprogenitors, osteoblasts and pericytes.^[1]



GROWTH FACTORS

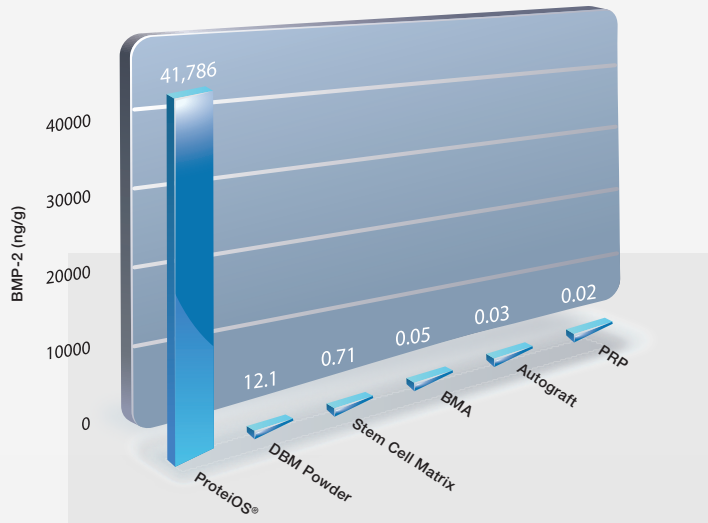
Unlike the various recombinant growth factors (GFs) on the market today (i.e. rhBMP-2, rhPDGF-BB) ProteiOS is not limited to a single growth factor, but contains a whole cascade of naturally occurring GFs and peptides that support bone formation and remodeling. The graph below displays a small sampling of GFs found within ProteiOS.



Osteoinductive, angiogenic, chemotactic and proliferative growth factor proteins found in ProteiOS.^[2]

BMP-2

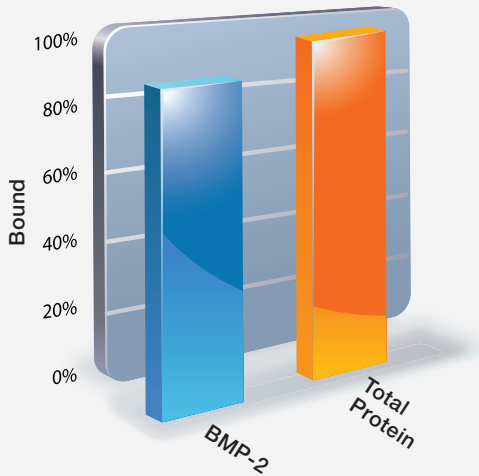
BMP-2 Amount in Various Biologics (ng/g)



BMP-2 is well known to play a critical role in bone formation.^[3] ProteiOS exhibits the highest level of non-recombinant BMP-2 on the market.^[4-8]

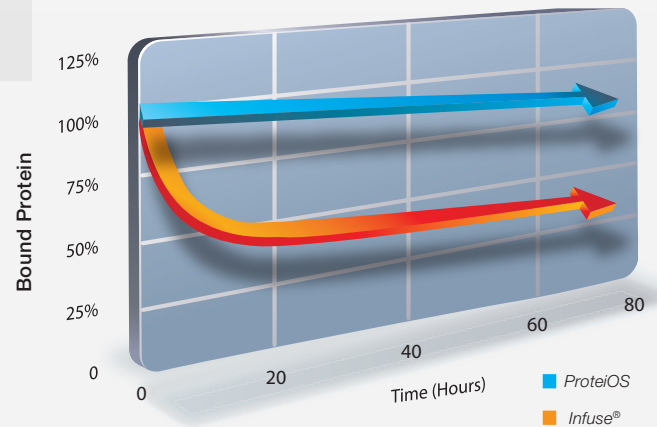
BMP-2 is one of the, if not the, most studied growth factors in orthopaedics today. As seen in the graph below, when the non-recombinant BMP-2 amounts in ProteiOS are compared to other products in the market, there truly is no comparison, as ProteiOS exhibits the highest amount in the market.

ProteiOS Binding Efficiency



ProteiOS when added to a synthetic scaffold displays high growth factor binding when measured at 15 minutes.^[9]

ProteiOS Elution Characteristics



When bound to a synthetic scaffold, ProteiOS exhibits a long-term sustained release versus the high initial "burst release" of rhBMP-2 (Infuse®, Medtronic).^{[9][10]} A continuous long-term release has shown to be a more effective delivery system than an initial burst release.^[11]

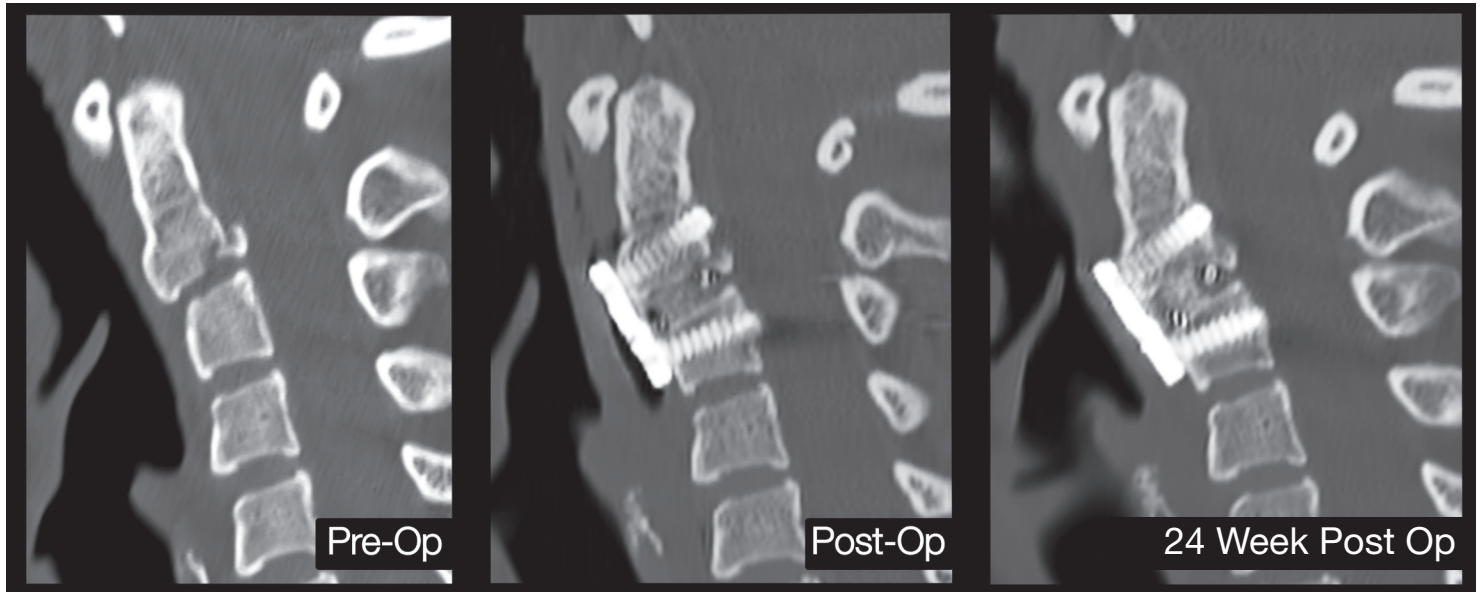
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CLINICAL USE

ProteiOS provides great flexibility across multiple areas of orthopaedics and neurosurgery. Below you will find two examples of its usage in the spine and also in the foot.

USE IN AN ACDF

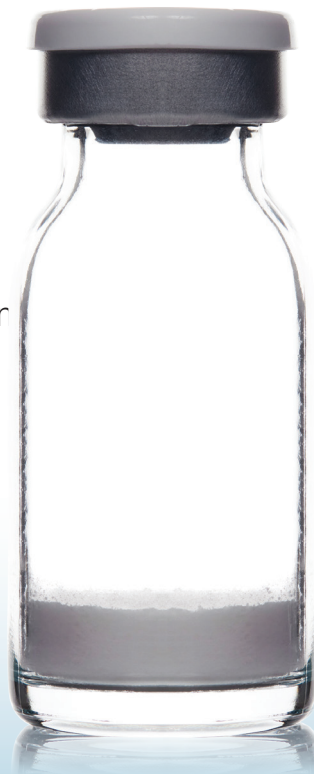


USE IN A JONES FRACTURE, NON-UNION



THE ADVANTAGES

- Possesses the highest concentration of non-recombinant BMP-2 on the market.^[4-8]
- Delivers a full array of growth factors with osteoinductive, angiogenic, chemotactic and mitogenic properties (including but not limited to: BMP-2, BMP-4, BMP-6, BMP-7, BMP-9, TGF- β 1, VEGF, aFGF, bFGF and PDGF-BB).^[2]
- Long-term sustained release of growth factors.^[9]
- High growth factor binding to a synthetic scaffold when measured at 15 minutes.^[9]
- Cost effective solution compared to rhBMP-2 and stem cell products.
- Non-immunogenic response (tested via Mixed Lymphocyte Reaction).^[12]
- Can be utilized with any scaffold approved with bone graft.
- No refrigeration or special storage requirements.
- Off the shelf and ready to use with short preparation time.
- Terminal sterilization via low-dose gamma irradiation.



SAFETY

- Terminally sterilized via gamma irradiation.
 - Donor serology testing by CLIA certified laboratories for:
 - HBsAg: Hepatitis B Surface Antigen
 - HBcAb: Hepatitis B Core Antibody
 - HCVAb: Hepatitis C Antibody
 - HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
 - HCV NAT: Hepatitis C Virus
 - HIV NAT: Human Immunodeficiency Virus
 - HBV NAT: Hepatitis B Virus
 - RPR/STS or Equivalent: Syphilis
- * HTLV I/II testing may have been performed. If testing was performed, results were found to be negative/nonreactive.
- Strict donor screening through an accredited tissue bank for risk factors associated with infectious diseases and medical conditions that would rule out donation.
 - Validated, double sterile barrier packaging.
 - Donor and lot traceability on each label.
 - Every lot tested for protein content.
 - Packaged under nitrogen backfill to mitigate free radical formation.

ORDERING INFORMATION

Part Number	ProteiOS Sizes (reconstituted volume)	Part Number	ProteiOS Sizes (reconstituted volume)
60100010	Small (1cc)	60100050	Large (5cc)
60100025	Medium (2.5cc)	60100100	X-Large (10cc)

REFERENCES

- [1] Clarke B. "Normal bone anatomy and physiology". Clin J Am Soc Nephrol. 2008;3(Suppl 3):S131-9.
- [2] Data on File, Biologica Technologies.
- [3] Lieberman J., et al. "The Role of Growth Factors in the Repair of Bone". J Bone Joint Surg Am, Jun 2002, 84 (6) 1032-1044.
- [4] Data on File, Biologica Technologies.
- [5] Chnari E., et al. "Bone Morphogenetic Protein 2 (BMP-2) Levels are Predictive of the Osteoinductive Potential of Demineralized Bone Matrix," in 56th Annual Meeting of the Orthopaedic Research Society, 2010. Poster 485.
- [6] Data on File, Biologica Technologies.
- [7] Schmidmaier G., et al. "Quantitative assessment of growth factors in reaming aspirate, iliac crest and platelet preparation," Bone, vol.39 pp. 1156-1163, 2006.
- [8] Data on File, Biologica Technologies.
- [9] Data on File, Biologica Technologies.
- [10] Podium Presentation - EORS 2014 NANTES, 22nd Annual Meeting, 2-4 July 2014, Nantes, France.
- [11] Blackwood K., et al. "Scaffolds for Growth Factor Delivery as Applied to Bone Tissue Engineering," International Journal of Polymer Science, vol. 2012, Article ID 174942, 25 pages, 2012.
- [12] Data on File, Biologica Technologies.



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