OrthoBlast® II

DBM and Cancellous Bone in a Reverse Phase Medium

From the Makers of Accell

ORDERING INFORMATION

Description	Catalog No.	Volume
Putty	02-2110-050 02-2110-100	5 cc vial 10 cc vial
Paste	02-2100-010 02-2100-030 02-2100-080	1 cc syringe 2 cc syringe 8 cc syringe

Consult the package insert for information on any indications, contraindications, warnings, cautions and use.

Contact IsoTis Customer Service (800) 550-7155 or (949) 595-8710

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OrthoBlast® II

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Easy-To-Use Bone Graft Substitute

OrthoBlast® II combines demineralized allograft bone with cancellous bone and a reverse phase medium (RPM) to provide an osteoconductive allograft with ideal handling qualities.

Proven Osteoinductive Potential. IsoTis uses a validated in vitro assay to confirm the osteoinductive potential of each lot of DBM it receives from AATB-accredited tissue banks, thus ensuring bone-forming potential.[1-4]

Osteoconductivity from Cancellous Bone. Cancellous bone provides osteoconductive scaffold, rapid bone regeneration, and open spaces for easy cellular penetration and biodegradation.

The RPM Carrier. OrthoBlast II contains a reverse-phase medium that thickens at body temperature, for exceptional handling, graft containment, and resistance to irrigation. It also provides for a slow release of naturally present growth factors.[5]

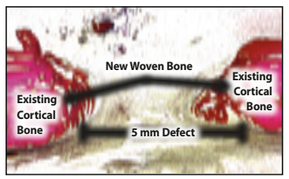
Ready-to-use. OrthoBlast II is available for immediate use with no refrigeration, thawing, mixing or other preparation required. It mixes well with autograft, allograft, and other bone grafting materials.

E-Beam Sterilization. IsoTis treats every lot of product with a low-dose electron beam – a sterilizing process that has been demonstrated to preserve the osteoinductivity of bone growth factors.[6,7]

Proven bone formation in a large, load-bearing animal model.

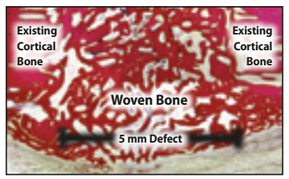
OrthoBlast II was evaluated in a skeletally mature sheep model. Cylindrical 5 mm transcortical defects were created in the tibial diaphysis and grafted with OrthoBlast II. The animals healed for 8 or 16 weeks prior to histological analysis of the regenerated tissue. Sections were stained with a modified Van Gieson stain for assessment of bone regeneration and graft incorporation.

Complete osseous bridging of the 5 mm defect with prolific woven bone was evident by 8 weeks. Active remodeling of the regenerated woven bone to new cortical bone was evident by 16 weeks. Excellent biocompatibility was observed with no evidence of inflammatory response.



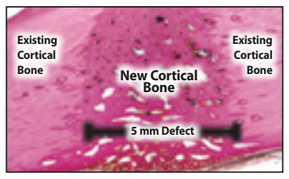
Empty control at 8 weeks (20x)

A 5 mm empty tibial defect with no added graft material served as the negative control. Minimal bone regeneration was observed within the defect at 8 weeks with healing limited to the area adjacent to the existing cortical bone.



8-week tibial defect (20x)

Prolific woven bone was seen bridging the defect by 8 weeks. Active remodeling was evident with no adverse inflammatory response to OrthoBlast II.



16-week tibial defect (20x)

Healing of the defect was near completion as demonstrated by the transformation of woven bone to new cortical bone.

Clinically Proven

OrthoBlast II has enjoyed clinical success in a variety of surgical applications including periarticular defects and long-bone defects. An independent study of two DBM allografts, in cases of metaphyseal and periarticular fractures, concluded that the OrthoBlast success rate was over 30% higher than the alternative allograft product.[8]

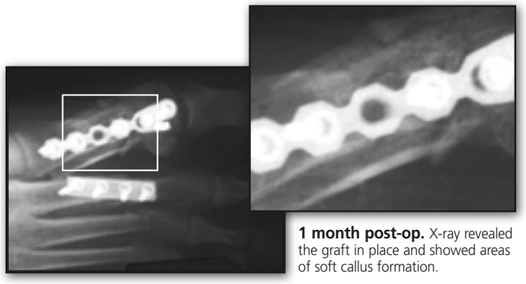
In another independent study of the use of DBM allograft products in ankle/hindfoot fusion, 14% of patients with a glycerol-based allograft developed a nonunion, versus only 8% for the OrthoBlast patients.[9]

Clinical case study

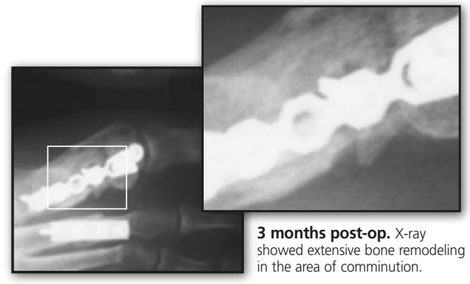
Use of OrthoBlast II and internal fixation in the treatment of a comminuted metatarsal fracture.

A 41-year-old male presented with a secondary crush injury of the right foot. Length of the first metatarsal was re-established with a 6-hole condylar plate by securing it to the most distal and most proximal bone fragments with bone screws. Three cc of OrthoBlast II was injected about the area of extreme comminution to augment bone healing.

Union was achieved with robust bone formation observed around the third screw hole.



1 month post-op. X-ray revealed the graft in place and showed areas of soft callus formation.



3 months post-op. X-ray showed extensive bone remodeling in the area of comminution.

References

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5. Clokie ML, Urist MR: Bone morphogenic protein excipients: Comparative observations on poloxamer. Plastic & Reconstructive Surgery 2000; 105(2):628-637.
6. Weintroub S, Reddi AH: Influence of irradiation on the osteoinductive potential of demineralized bone matrix. Calcif Tissue Int 1988; 42: 255-260.
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