DynaGraft® II Demineralized Bone Matrix

Reference	Description	Size
02-2010-010	Putty (vial)	1cc
02-2010-025	Putty (vial)	2.5cc
02-2010-050	Putty (vial)	5cc
02-2010-100	Putty (vial)	10cc
02-2000-005	Gel (syringe)	0.5cc
02-2000-010	Gel (syringe)	1cc
02-2000-050	Gel (syringe)	5cc
02-2000-100	Gel (syringe)	10cc

OrthoBlast® II Demineralized Bone

Reference	Description	Size
02-2110-050	Putty (vial)	5cc
02-2110-100	Putty (vial)	10cc
02-2100-005	Paste (syringe)	0.5cc
02-2100-010	Paste (syringe)	1cc
02-2100-030	Paste (syringe)	3cc
02-2100-080	Paste (syringe)	8cc

References
[1] Data on file.

Indications for Use

DynaGraft® II is indicated for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. DynaGraft II is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender (extremities, spine and pelvis) and as bony void filler of the extremities and pelvis. These defects may be surgically created or from the result of traumatic injury to the bone.

For orthopedic use, the OrthoBlast® II Paste and Putty are intended for use as an autograft extender (extremities, spine and pelvis) and as a bone void filler (extremities and pelvis) for bony voids or gaps that are not intrinsic to the stability of the bony structure. The OrthoBlast II products are indicated to be packed gently into bony defects of the skeletal system. These defects may be surgically created or from the result of traumatic injury to the bone.

Warnings

- The product must be used prior to the expiration date.
- For single use only.
- Do not re-sterilize.
- Do not use if the packaging has been damaged and/or the product has been compromised. In the event packaging has been compromised, discard the product. Damaged packaging should be returned to the manufacturer.
- Do not use to support reduction of a defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. Screws must gain purchase in the host bone as opposed to the DynaGraft II/OrthoBlast II.
- Do not use to repair bone defects where soft tissue coverage cannot be achieved as complete post-operative wound closure is necessary.
- Do not overfill the graft site.

Precautions

- DynaGraft II and OrthoBlast II are sterile for the duration of the product's shelf life, provided that the package is in its original sealed condition and that it is unopened and undamaged.
- As with all biological products, the tissue in DynaGraft II and OrthoBlast II has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissue selection and laboratory testing. To date, there have been no reports of experimental or clinical viral seroconversion attributed to the use of demineralized bone.
- As with any surgical procedure, the possibility of infection exists.
- Although the production technique is designed to eliminate antigenic properties of the product, the possibility of such a reaction is present.
- Once the container seal has been compromised, the tissue product shall be either transplanted, if appropriate, or otherwise discarded.
- Use caution when filling a closed defect. Resistance during extrusion may be an indication of over pressurization. Excessive pressurization of the device could result in fat embolization and/or embolization of the material into the bloodstream.
- When introducing DynaGraft II or OrthoBlast II, care must be taken to avoid excessive compaction.
- Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects.
- Overfilling the implantation site should be avoided to achieve a tension-free closure of the wound.

SeaSpine

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IsoTis OrthoBiologics, Inc. is a member of the SeaSpine Orthopedics Corporation family of companies.
Made in the U.S.A.

Warning: Applicable laws restrict these products to sale by or on the order of a physician.

IsoTis

DynaGraft® II OrthoBlast® II

Demineralized Bone Matrix

DynaGraft® II / OrthoBlast® II

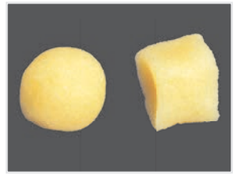
DynaGraft® II / OrthoBlast® II

DESIGN RATIONALE

DynaGraft® II and OrthoBlast® II DBMs are formulated with a unique thermoreversible carrier to meet surgical applications where robust handling is essential.

A Demineralized Bone Matrix (DBM) featuring a poloxamer Reverse Phase Medium (RPM) carrier

FEATURES



Multiple Configurations for Surgical Flexibility

DynaGraft II DBM is a bone graft substitute composed of demineralized bone matrix (DBM) and a poloxamer Reverse Phase Medium (RPM), a biocompatible carrier.

- Available in gel or putty forms for surgeon convenience

OrthoBlast II DBM is a bone graft substitute composed of demineralized bone matrix (DBM) and a poloxamer Reverse Phase Medium (RPM) carrier with the additional benefit of cancellous bone.

- Cancellous bone chips provide a naturally porous structure that supports tissue and vascular growth
- Available in putty and paste forms for surgeon convenience

IsoTis DBM: An Expert Approach to DBM Processing

IsoTis controls the processing of its DBM from start to finish in its state-of-the-art facility. Each lot is tested in a validated in vitro assay to verify osteoinductive potential.[1]

Convenient – Ready to Use

DynaGraft II and OrthoBlast II DBM products are stable and ready for implantation directly from the syringe or vial. No cumbersome or time-consuming preoperative preparation such as thawing or mixing is required.

Safety Through E-Beam Sterilization

IsoTis utilizes electron beam (e-beam) sterilization to ensure product sterility. IsoTis's sterilization process has not been shown to impact the osteoinductive potential of DBM.[1] All products are e-beam sterilized as the last step in manufacturing prior to being shipped.

Superior Handling[1]

DynaGraft II and OrthoBlast II DBM products contain DBM combined with a polaxamer Reverse Phase Medium (RPM). The result is a graft material with robust handling and irrigation resistance.

The unique RPM carrier becomes more viscous at body temperatures and less viscous at room temperature. Because of the RPM's unique thermoreversible property, DynaGraft II and OrthoBlast II are:

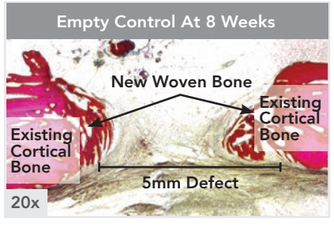
- Moldable at the time of application
- Packable into virtually any size or shape defect

Pre-Clinical Performance[1]

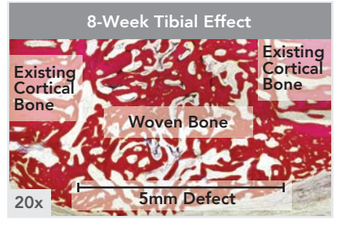
Demonstrated bone formation in a large, load-bearing animal model

OrthoBlast II DBM was evaluated in a skeletally mature sheep model. Cylindrical 5mm transcortical defects were created in the tibial diaphysis and grafted with OrthoBlast II DBM. The animals healed for 8 to 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.

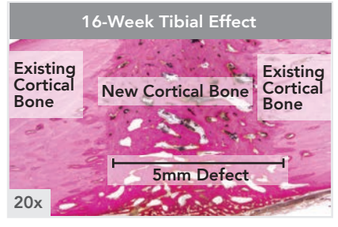
Complete osseous bridging of the 5mm defect with prolific woven bone was evident by 8 weeks. Active remodeling of the regenerated woven bone to new cortical bone was evident by 16 weeks. No evidence of inflammatory response was observed.



A 5mm 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.



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



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