IsoTis

Accell TBM®

Advanced Demineralized Bone Matrix
Powered by Accell® Technology

Accell TBM®

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Accell Total Bone Matrix®

Isotis' patented* Accell® process converts particulate DBM into a dispersed form, which offers early accessibility to naturally occurring inductive bone proteins.[1]

FEATURES

100% Allograft Bone Void Filler

Accell TBM is composed of 100% demineralized bone, with no added carrier. Provided as a pre-formed, dry matrix, it can be easily cut to fit any size or defect.

Accell® Bone Matrix

This patented, dispersed form of DBM offers significantly increased surface area, which provides access to the naturally occurring bone proteins contained in DBM.

IsoTis DBM: An Expert Approach to DBM Processing

IsoTis controls the processing of DBM and ABM 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.[2]

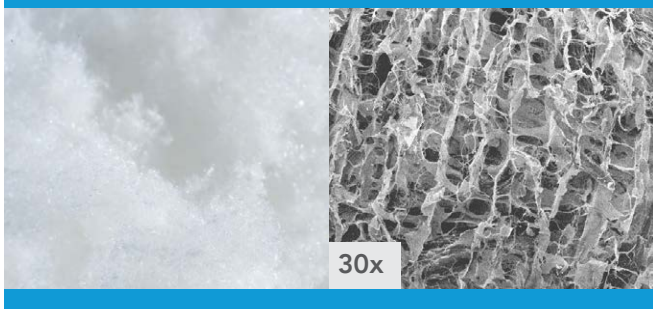
Safety Through E-Beam Sterilization

IsoTis utilizes electron beam (e-beam) sterilization to ensure product sterility. IsoTis' sterilization process has not been shown to impact the osteoinductive potential of DBM.[2] All products are e-beam sterilized as the last step in manufacturing prior to being shipped.

Advanced Demineralized Bone Matrix — Powered by Accell® Technology

The Accell® Advantage

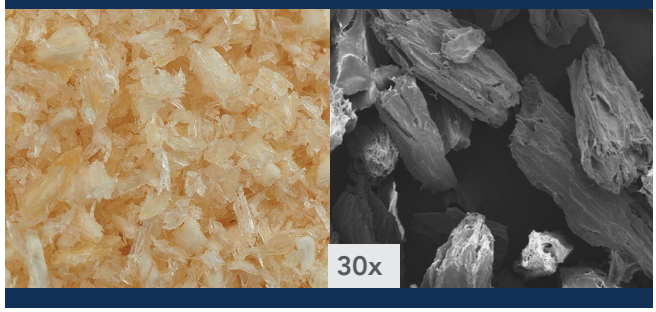
Accell Bone Matrix (ABM)



Open structure, dispersed DBM

- Transformed from particulate DBM
- Highly porous matrix with greater surface area
- Greater exposure to bone proteins compared to DBM

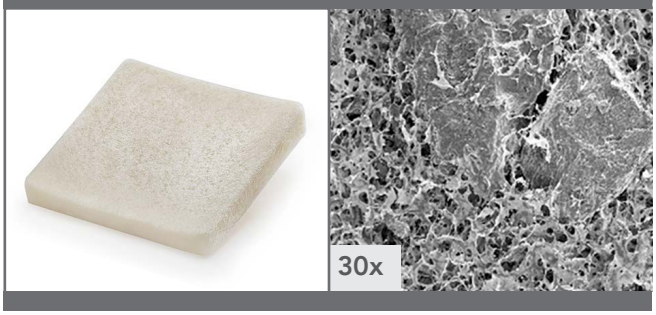
Demineralized Bone Matrix (DBM)



Standard, particulate DBM

- Formed by removing mineral component of cortical bone
- Dense matrix of Type-1 collagen
- Gradual access to naturally occurring bone proteins

ABM + DBM



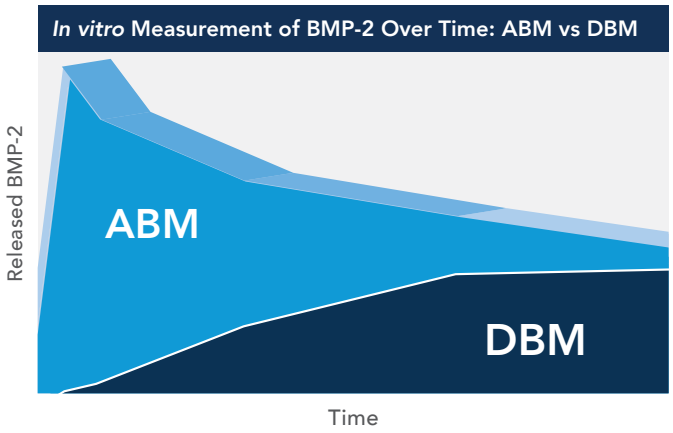
The combination of ABM and particulate DBM provides for both immediate and sustained accessibility to naturally occurring bone proteins which are important for osteogenesis.[1]

Isotis' Patented Accell Bone Matrix

The process of demineralization retains the naturally osteoinductive elements in bone. These osteoinductive elements, including BMPs, play a critical role in the bone forming process. Isotis manufactures both standard DBM and a proprietary dispersed form of DBM, known as ABM which has also been shown to exhibit osteoinductive potential.

Evaluation of Osteoinductive Potential

An *in vitro* study was conducted to examine accessibility to bioactive proteins in ABM and DBM.[1] The content of BMP-2, which has been shown to be strongly correlated with osteoinductive potential *in vivo*[3], was measured over time using an Enzyme Linked Immunosorbent Assay (ELISA). The results are shown graphically below.



Study Results

- Soluble BMP-2 was detected in ABM at an earlier time compared to particulate DBM.
- ABM's open pore structure provides earlier accessibility to bone proteins.
- DBM provides accessibility to bone proteins at later time points.

Accell Total Bone Matrix®

Reference	Description	Size
02-4000-520	Matrix (strip)	5 x 2 x 0.5cm
02-4000-550	Matrix (square)	5 x 5 x 0.5cm
02-4000-760	Matrix (round)	7 x 0.6cm

Indications for Use

Accell TBM is intended for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. Accell TBM is indicated for use as a bone graft extender in the spine, extremities and pelvis, or as a bone void filler in the extremities and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone.

Warnings and Precautions

- Accell TBM is sterile during the stated shelf life in an unopened and undamaged package. The product must be used prior to the expiration date.
- Do not use if the packaging has been damaged and/or the product has been contaminated. In the event of contamination, discard the product.
- Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects.
- As with all biological products, the tissue in Accell TBM has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissue selection and laboratory tests. To date, there have been no reports of experimental or clinical viral seroconversion using demineralized bone powder.
- 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.
- Adverse outcomes potentially attributable to the product must be reported promptly to the manufacturer.
- When introducing Accell TBM, it must be taken care to avoid excessive compaction.
- Overfilling the implantation site must be avoided to achieve a tension-free closure of the wound.

References

1. Khaliq S, Lollis R, Bell D, Oliver R, Walsh WR, and Ingram R, Evaluation of a Next Generation DBM Putty in a Posterlateral Spinal Fusion Model, (2009) Integra LifeSciences Corporation.
2. Data on file
3. Chnari, E; Javoroncov, M; Gertzman AA; Sunwoo MH; Dunn, MG, Bone Morphogenetic Protein 2 (BMP-2) Levels are Predictive of the Osteoinductive Potential of Demineralized Bone. Matrix, 56th Annual Meeting of the Orthopaedic Research Society Poster No. 485.

* U.S. Patent Nos. 7,132,110; 7,811,608

SeaSpine

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