SeaSpine™

OsteoSurge® 300

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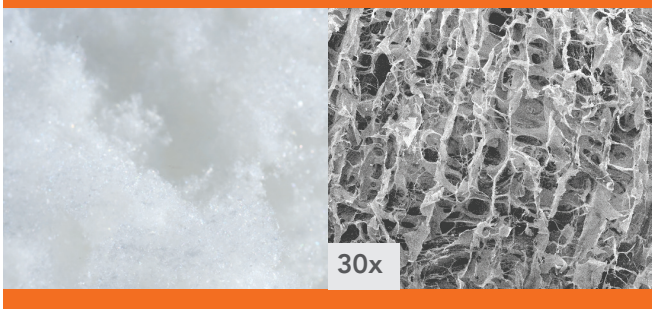
Advanced Demineralized Bone Matrix
Powered by Accell® Technology

OsteoSurge® 300

OsteoSurge® 300 combines patented ABM and particulate DBM with a Reverse Phase Medium (RPM) carrier.

The Accell® Advantage

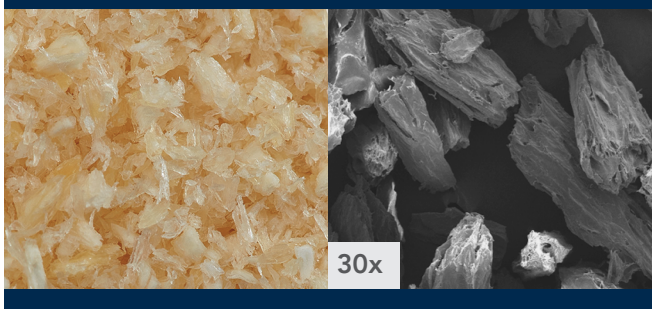
Accell Bone Matrix (ABM)



Open structure, dispersed DBM

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

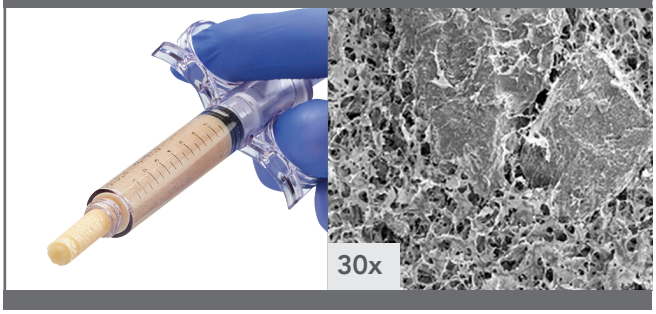
Demineralized Bone Matrix (DBM)



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.[2]

SeaSpine's 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. SeaSpine manufactures both standard DBM and a proprietary dispersed form of DBM, known as ABM which has also been shown to exhibit osteoinductive potential.

OsteoSurge 300 is designed to provide both immediate and sustained access to naturally occurring inductive bone proteins to facilitate fusion.

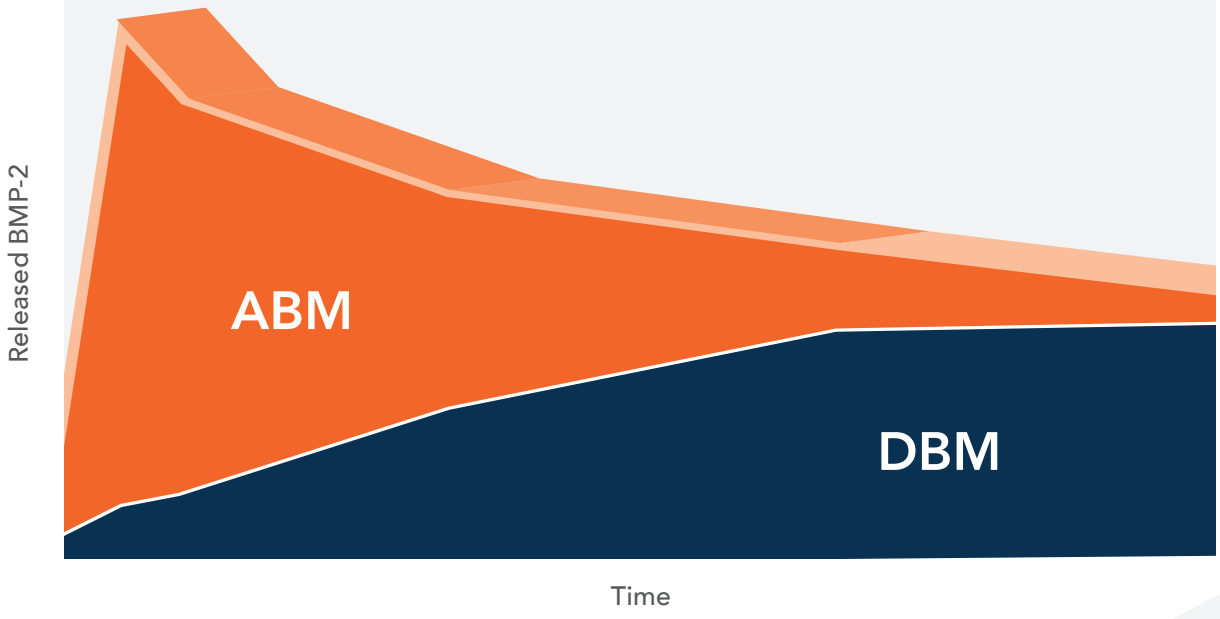
Evaluation of Osteoinductive Potential

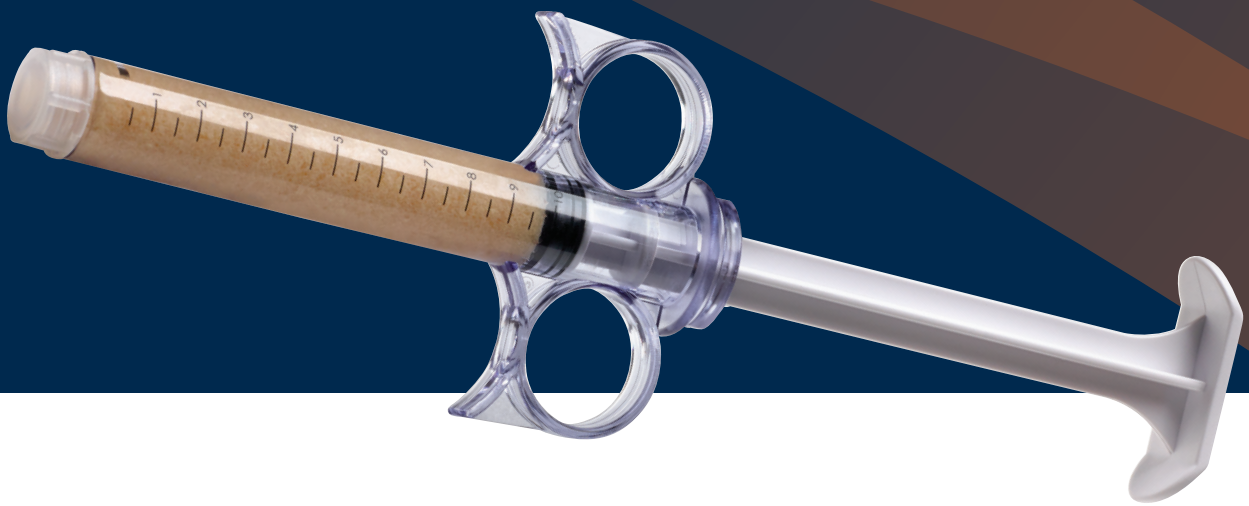
An *in-vitro* study was conducted to examine accessibility to bioactive proteins in ABM and DBM.[2] The content of BMP-2, which has been shown to be strongly correlated with osteoinductive potential *in-vivo*[3], was measured over time using an Enzyme Linked Immunosorbent Assay (ELISA). The results are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

***In-vitro* Measurement of BMP-2 Over Time: ABM vs DBM**





Superior Handling[1]

The optimized formulation of OsteoSurge® 300 contains ABM and DBM combined with a unique poloxamer RPM. The result is a graft material with exceptional handling and containment characteristics.

The unique RPM carrier becomes more viscous at body temperatures, while it is less viscous at room temperature. Because of the RPM's thermoreversible property, OsteoSurge 300 is:

- Moldable at the time of application
- Packable into virtually any size or shape defect
- Mixable with other grafting materials
- Irrigation-resistant

The unique thermoreversible RPM carrier allows OsteoSurge 300 to resist irrigation and graft migration.

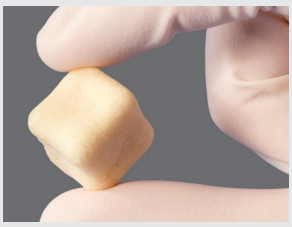
The optimized formulation of OsteoSurge 300 results in a robust, moldable putty that does not stick to surgical gloves.

FEATURES

OsteoSurge® 300 combines patented Accell® Bone Matrix (ABM) and particulate Demineralized Bone Matrix (DBM).

Accell® Bone Matrix x 3

- OsteoSurge 300 contains three times more ABM than the previous generation of Accell Demineralized Bone Matrix products.*
- This patented, dispersed form of DBM offers significantly increased surface area, which provides access to the naturally occurring bone proteins contained in DBM.



Superior Handling

OsteoSurge 300 incorporates a poloxamer Reverse Phase Medium, a biocompatible carrier. This unique thermoreversible carrier allows OsteoSurge 300 to meet the needs of challenging surgical applications where robust handling is essential.

- At room temperature, OsteoSurge 300 is malleable and easily extruded from the syringe.
- At body temperature, OsteoSurge 300 is more viscous, resists irrigation and minimizes graft migration.

Custom, Ready-to-Use Syringe

The ergonomic syringe design and large diameter opening facilitates easy handling and extrusion of the graft. OsteoSurge 300 is ready for implantation directly from the syringe. They do not require any cumbersome or time-consuming preoperative preparation, such as thawing or mixing.

SeaSpine DBM: An Expert Approach to DBM Processing

SeaSpine 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.[1]

Safety Through E-Beam Sterilization

SeaSpine utilizes electron beam (e-beam) sterilization to ensure product sterility. SeaSpine'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.

*Compared to OsteoSurge 100

Evolution of DBM to OsteoSurge® 300

1st Generation: DBM

Early 1990s – First-generation DBM formulations combined standard processed particulate DBM with an inert carrier for easy handling and graft containment.

2nd Generation: DBM + ABM

2002 – A patented process was developed to transform particulate DBM into a dispersed form of DBM. This patented ABM is blended with traditional particulate DBM and an inert carrier to create our second-generation products.

3rd Generation: OsteoSurge 300

2008 – With OsteoSurge® 300, SeaSpine optimized the formulation of ABM, DBM, and RPM. This third-generation product includes three times the amount of ABM as compared to second-generation products with even better handling.

OsteoSurge 300

Reference	Description	Size
56500010	Putty (syringe)	1cc
56500025	Putty (syringe)	2.5cc
56500050	Putty (syringe)	5cc
56500100	Putty (syringe)	10cc

References

1. Data on file.
2. Khaliq S, Lollis R, Bell D, Oliver R, Walsh WR, and Ingram R, Evaluation of a next-generation DBM putty in a posterolateral spinal fusion model, (2009) Integra LifeSciences Corporation.
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.

Indications for Use

OsteoSurge 300 is intended for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The product is indicated for use as a bone graft extender in the spine, extremities and pelvis. OsteoSurge 300 may also be used as a bone void filler in the posterolateral spine, extremities and pelvis. The voids or gaps may be surgically created defects or 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 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 OsteoSurge 300.
- 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

- OsteoSurge 300 is 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 OsteoSurge 300 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 with 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 OsteoSurge 300, 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

For more information or to place an order, please contact:
Phone 866.942.8698 | Fax 800.471.3248
Irvine.customerservice@SeaSpine.com | **SeaSpine.com**

Manufactured by:
IsoTis OrthoBiologics, Inc.
2 Goodyear, Irvine CA 92618
Phone 800.550.7155 | Fax 800.471.3248 | **SeaSpine.com**
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