OsteoSparx® Demineralized Bone Matrix

Reference	Description	Size
56210010	Putty (vial)	1cc
56210025	Putty (vial)	2.5cc
56210050	Putty (vial)	5cc
56210100	Putty (vial)	10cc
56200010	Gel (syringe)	1cc
56200050	Gel (syringe)	5cc
56200100	Gel (syringe)	10cc

OsteoSparx® C Demineralized Bone Matrix

Reference	Description	Size
56230050	Putty (vial)	5cc
56230100	Putty (vial)	10cc
56220010	Paste (syringe)	1cc
56220030	Paste (syringe)	3cc
56220080	Paste (syringe)	8cc

References
1. Data on file.

Indications for Use

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

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

Warnings and Precautions

OsteoSparx
OsteoSparx 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. Damaged packaging should be returned to SeaSpine. Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects.

As with all biological products, the tissue in the OsteoSparx 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.

When filling a closed defect, care must be taken while extruding OsteoSparx from the syringe as possible pressurization of the device could result in fat embolization and/or embolization of the material into the bloodstream. 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. If any dissatisfaction with the product performance or packaging occurs, notify SeaSpine immediately and promptly return the product and/or packaging.

OsteoSparx C
OsteoSparx C is sterile during the stated shelf life in an unopened and undamaged package. The product must be used prior to the expiration date.

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As with all biological products, the tissue in the OsteoSparx C has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissueselection and laboratory tests. To date there have been no reports of experimental or clinical viral seroconversion using demineralized bone powder.

When filling a closed defect, care must be taken while extruding OsteoSparx C from the syringe as possible pressurization of the device could result in fat embolization and/or embolization of the material into the bloodstream. 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. If any dissatisfaction with the product performance or packaging occurs, notify SeaSpine immediately and promptly return the product and/or packaging. When introducing OsteoSparx C, 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. Sites grafted with OsteoSparx C should be allowed to heal approximately 6 months prior to implant placement. OsteoSparx C Putty contains cancellous particles up to 4mm in size. Do not use for periodontal applications.

For further information refer to each product's package insert.

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, Suite A, Irvine CA 92618
Phone 800.550.7155 | Fax 800.471.3248 | **SeaSpine.com**
IsoTis OrthoBiologics, Inc. is a member of the SeaSpine Orthopedics Corporation family of companies.
Made in the U.S.A.

SeaSpine

OsteoSparx® / OsteoSparx® C

OsteoSparx®
OsteoSparx® C

Demineralized Bone Matrix

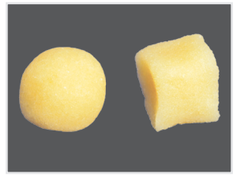
OsteoSparx® / OsteoSparx® C

DESIGN RATIONALE

OsteoSparx® and OsteoSparx® C 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

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

- Available in gel or putty forms for surgeon convenience

OsteoSparx C DBM is a bone graft substitute composed of demineralized bone matrix featuring (DBM) 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

SeaSpine DBM: An Expert Approach to DBM Processing

SeaSpine 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

OsteoSparx and OsteoSparx C 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

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.

Superior Handling[1]

OsteoSparx and OsteoSparx C DBM products contain DBM combined with 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, while it is less viscous at room temperature. Because of the RPM's unique thermoreversible property, OsteoSparx and OsteoSparx C DBM are:

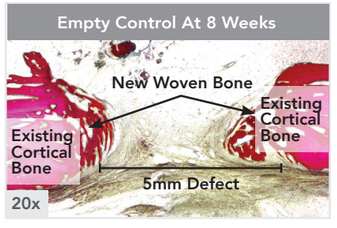
- Moldable at the time of application
- Packable into virtually any size or shape defect

Pre-Clinical Performance[1]

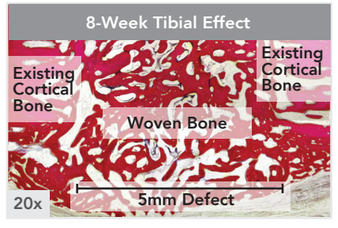
Demonstrated bone formation in a large, load-bearing animal model

OsteoSparx C putty DBM was evaluated in a skeletally mature sheep model. Cylindrical 5mm trans-cortical defects were created in the tibial diaphysis and grafted with OsteoSparx C putty 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.

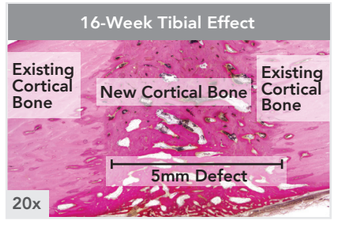
Complete osseous bridging of the 5mm defect with prolific woven bone was evident by 8 weeks. Active remodeling of the regenerated woven bone to new cortical bone was evident by 16 weeks. No evidence of inflammatory response was observed.



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.