SeaSpine

**DIRECTIONS FOR USE**

# OsteoSurge® 300

Demineralized Bone Matrix

**CAUTION**: Federal (U.S.) Law restricts the use of this device to sale by or on the order of a physician.

The Inner Package and its Contents are Sterile
For Single Patient Use on a Single Occasion Only
The demineralized bone matrix (DBM) in this product is derived from voluntarily donated human tissue.

## 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.

## DESCRIPTION

OsteoSurge 300 is made using demineralized human bone mixed with poloxamer resorbable reverse phase medium. OsteoSurge 300 is formulated into a putty form and is provided in a sterile, single use package. As a biological material, some variations in the product should be expected, such as in appearance and handling.

OsteoSurge 300 is packaged in a standard syringe.

## CONTRAINDICATIONS

OsteoSurge 300 is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing contraindications include:

- Significant vascular or neurological impairment proximal to the graft site
- Severe vascular or neurological disease
- Metabolic or systemic bone disorders that affect bone or wound healing
- Uncontrolled diabetes
- Situations where graft site stabilization is not possible
- Cases where intraoperative soft tissue coverage is not planned or possible
- Infected or contaminated wounds
- Severe degenerative bone disease
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Renal impairment
- Active or latent infection in or around the surgical site
- Polymyxin B Sulfate, Bacitracin, Gentamicin and Iodine are used in the processing of the DBM used in OsteoSurge 300 and trace amounts may remain. Since it is impossible to quantify the levels at which any individual may have an allergic response, this product is contraindicated in patients with known sensitivity to these compounds.

## PATIENT SELECTION FACTORS

Procedures involving bone grafting can produce highly variable results. Factors to be considered in selecting the bone grafting material and the surgical technique to be utilized are as follows:

- Age of the patient
- Quality of the patient's bone
- Location of the defect or graft site
- Anticipated loading conditions
- Proximity of the graft to a suitable blood supply
- Ability to achieve direct apposition of the graft to viable host bone
- Presence/addition of autogenous bone or bone marrow at the graft site
- Elimination of gaps in the graft site
- Ability to suitably stabilize the graft site
- Complete coverage of the graft material to prevent migration

## INSTRUCTIONS FOR USE

These instructions are intended as guidelines for the use of OsteoSurge 300 as a part of established surgical techniques. They are not intended to replace or change standard procedures for treatment of bone defects involving bone grafting and fixation. For best results, extreme care should be exercised to assure the correct graft material is selected for the intended application.

## PREOPERATIVE PREPARATION

- Aseptic techniques must be adhered to at all times in order to minimize the risk of post-operative complications. The amount of product needed is based on the type of procedure and size of the defect being treated. When OsteoSurge 300 is being mixed with autograft, a ratio of 1:1 should be used. OsteoSurge 300 does not require rehydration prior to use.
- Radiographic evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of OsteoSurge 300 and fixation devices.
- OsteoSurge 300 does not possess sufficient mechanical strength to support the reduction of a graft site prior to tissue in-growth. Therefore, anatomical reduction and rigid fixation, in all planes, should be obtained independent of OsteoSurge 300.
- For best results, OsteoSurge 300 must fill the defect and contact as much viable bone as possible.
- OsteoSurge 300 must not be used to repair bone defects where complete soft tissue coverage cannot be achieved.
- Only experienced surgeons, who have had appropriate training and experience in the field of bone graft implant materials and surgery, should use OsteoSurge 300.

## REMOVING THE PRODUCT FROM PACKAGING

1. Peel open package.
2. Using aseptic technique, transfer contents to a sterile field.
3. Remove protective cap from syringe tip.
4. Depress the plunger to extrude the implant material.
5. Discard any unused portion.

## POSTOPERATIVE CARE

Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices. The patient should be cautioned against early weight bearing and premature ambulation that could lead to loosening and/or failure of the fixators or loss of reduction.

The length of time a defect should remain in a reduced state of loading is determined by the complexity of the defect site and the overall physical condition of the patient. Hardware should not be removed until the defect is healed.

## 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.

## POTENTIAL ADVERSE EVENTS

Surgical procedures involving implantation of bone grafts are associated with the following risks:

- Superficial wound infection
- Deep wound infection with or without osteomyelitis
- Nonunion, delayed union and/or malunion
- Wound dehiscence
- Loss of reduction
- Refracture
- Cyst recurrence
- Hematoma
- Cellulitis

Adverse outcomes attributable to the product must be reported promptly to the manufacturer. If any dissatisfaction with the product performance or packaging occurs, notify IsoTis OrthoBiologics, Inc. immediately and promptly return product and/or packaging.

## 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 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 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.

**HUMAN TISSUE DONOR SELECTION**
All tissue used in OsteoSurge 300 is recovered from donors and by tissue banks in the United States in accordance with regulations and standards established by the U.S. Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). The tissue bank (as identified on the product's outer packaging) has evaluated the tissue donor and determined that the donor met eligibility criteria for transplant that were current at the time. The tissue bank's evaluation included review of the tissue donor's infectious disease test results, consent documents, medical and social interview, assessment of the donor's body, available relevant medical records including previous medical history, laboratory test results, review of postmortem examination results (if applicable) and information from other sources or records which may pertain to donor eligibility including tissue procurement test results. The review did not reveal risk factors for, conditions indicating clinical and/or physical evidence of infectious disease, or communicable disease agents or diseases, including HIV (human immunodeficiency virus) or hepatitis, or risk factors for viral or prion-associated disease transmission as specified in 21 CFR 1271 Subpart C and Appendix II of the AATB standards.

**SEROLOGICAL TESTING OF HUMAN TISSUE**
All donated human tissue is tested per current FDA and AATB requirements at the time the donor is recovered. Donor blood samples taken at the time of recovery were tested by laboratories registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS) and were found negative or non-reactive using FDA licensed, cleared or approved, tests for:
- HIV antibodies type 1 and type 2 (anti-HIV-1 and anti-HIV-2)
- HIV-1 Nucleic Acid testing (HIV NAT)
- Hepatitis B Surface antigen (HBsAg)
- Hepatitis B Core Antigen [anti-HBc (IgG and IgM)]
- Hepatitis C Virus Nucleic Acid Test (HCV NAT)
- Hepatitis C Virus Antibody (anti-HCV)
- *Treponema pallidium* (Syphilis)

Additional testing may or may not include the following as applicable:
- Hepatitis B Virus Nucleic Acid Tests (HBV NAT or HIV-1/HCV/HBV NAT])
- Cytomegalovirus (CMV) [IgM anti-CMV and/or IgG anti-CMV]
- Epstein-Barr Virus (EBV) [IgM anti-VCA and/or IgG anti-VCA]
- Human T-Lymphotropic Virus type 1 and type 2 [anti-HTLV-I/II]
- West Nile Virus Nucleic Acid Test (WNV NAT)

The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of this human tissue are on file at the tissue bank and are available upon request. This tissue has been determined to be suitable for transplantation based on the results of screening and testing.

**VIRAL INACTIVATION**
The methods for processing of the DBM contained in OsteoSurge 300 were evaluated for their viral inactivation potential. A selected panel of viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable inactivation potential of the processing methods for a wide range of potential viruses.

**OSTEOINDUCTIVE POTENTIAL**
The osteoinductive potential of the Demineralized Bone Matrix (DBM) used in OsteoSurge 300 is determined via an in vitro assay. Results from the assay were correlated with results from implantation of DBM into an athymic mouse muscle pouch. Analysis of these results shows that the in vitro assay has been validated against the in vivo athymic mouse model and predicts with at least 95% confidence the in vivo osteoinductivity of the test material.

Each lot of DBM incorporated in OsteoSurge 300 is evaluated for osteoinductive potential using an in vitro assay. Testing each lot of DBM assures that only DBM with osteoinductive potential is used in OsteoSurge 300. It is unknown how osteoinductive potential of the DBM component, measured via the in vitro assay, will correlate with clinical performance of OsteoSurge 300.

**STERILIZATION**
OsteoSurge 300 has been sterilized by electron beam irradiation. The inner package and its contents are sterile. The package should be inspected prior to use to ensure the sterility barrier has not been compromised. This product is for single use only and must not be re-sterilized. The product must not be used beyond the stated expiration date.

**DO NOT RE-STERILIZE**

**STORAGE**
- Store at ambient temperature (15°C to 30°C) in a clean, dry place. The product has been validated to withstand temperatures between -10°C to 35°C during transit .
- Do not refrigerate or freeze.
- Do not expose to extreme heat.
- It is the responsibility of the tissue dispensing service and user (facility/clinician) to maintain the product under appropriate conditions prior to use.
- Discard any unused product.

**RECIPIENT TRACING**
The FDA requires that allograft tissue be traceable from the donor to the recipient. The tissue bank is responsible for traceability from the donor to the consignee (transplantation facility, clinician or hospital), and the transplantation facility is responsible for traceability to the recipient. A Graft Tracing Record and pre-printed peel-off labels are included with each package of tissue. Record the patient name or ID number, the transplantation facility name and address, the allograft tissue identification information (using the peel-off stickers) and comments regarding the use of the tissue on the Graft Tracing Record. Return the completed form to IsoTis OrthoBiologics and retain a copy in the patient medical record. If the tissue has been discarded, please return the Graft Tracing Record to IsoTis OrthoBiologics with the graft identification information and reason for discard.

**PRODUCT INFORMATION DISCLOSURE**
IsoTis OrthoBiologics, Inc ("IsoTis") HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. IsoTis EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IsoTis SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. IsoTis NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. IsoTis INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS HAVING RECEIVED PROPER TRAINING IN THE USE OF THE DEVICE.

An explanation of the symbols used on product labeling is provided below.

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| STERILE R | Sterilized using irradiation |
| | Consult Instructions for Use<br>www.seaspine.com/eifu |
| | Expiration date (YYYY-MM-DD) |
| | Do not re-use |
| +°C<br>+°C | Temperature limitation |
| **Rx ONLY** | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner |
| REF | Catalog number |
| LOT | Lot number |
| | Manufacturer |

Do not use if package is damaged

Not made with natural rubber latex

Do not re-sterilize

IsoTis OrthoBiologics, Inc. is a member of the SeaSpine Orthopedics Corporation family of companies.



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