Biomet Trauma
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LD33-1028
Revision B
Date: 2012-08

READ BEFORE USING

The tissue was recovered from deceased donor whose legal next-of-kin has given permission for the bone to be donated. Recovery was performed using aseptic procedures. Processing and packaging were performed using aseptic techniques in controlled clean room environments.

StaGraft™ DBM

ATTENTION OPERATING SURGEON

DESCRIPTION

StaGraft™ DBM products (StaGraft DBM Putty and StaGraft DBM Plus) contain human tissue (allograft bone) and are intended for transplantation. The allograft bone has been granulated, demineralized and provided in a lipid carrier. The lipid carrier used in the manufacture of StaGraft DBM products is extracted from soybean. The StaGraft DBM Plus products contain porous ceramic granules that are a composite of highly resorbable calcium carbonate with a slower resorbing 2 µm to 10 µm outer layer of calcium phosphate.

MATERIALS

Syringe Barrel	Polycarbonate
Plunger	Acrylonitrile Butadiene Styrene (ABS)
Plunger Tip	Silicone Rubber
StaGraft DBM Putty	Lipid carrier and Demineralized Bone Matrix (DBM)
StaGraft DBM Plus	Lipid carrier, DBM and calcium carbonate with outer layer of calcium phosphate

INDICATIONS

StaGraft DBM products are to be used for filling bony voids or gaps in the extremities and pelvis that are not intrinsic to the bony stability of the structure, and as an autograft extender in the spine. StaGraft Plus may also be used as a bone void filler in the spine (posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. StaGraft DBM may also be used for filling craniofacial defects and craniotomies that are no larger than 25cm^2. The amount of StaGraft DBM products to be used should be based on the type of procedure and size of the graft site.

CONTRAINDICATIONS

1. StaGraft DBM products are contraindicated in patients with incomplete skull growth.
2. StaGraft DBM products are contraindicated if active or latent infection is observed in or surrounding the implantation site.

WARNINGS

1. StaGraft DBM products are aseptically processed and remain aseptic during the stated shelf-life in an unopened and undamaged package. The product must be used before the expiration date. StaGraft DBM must not be used under any of the following conditions:
   a. If any of the package or product elements appear to be missing, tampered with or damaged;
   b. If the product label or identifying bar code is severely damaged, illegible, or missing;
   c. If the expiration date shown on the package label has passed.
2. Do not subject StaGraft DBM products or their packaging to disinfection or sterilization procedures. StaGraft DBM is intended for single patient use only. To prevent cross-infection of graft recipients and graft contamination, do not use the contents on multiple patients. Empty or partially used containers should be disposed of in accordance with recognized procedures for discarding medical waste materials.
3. The production of all StaGraft DBM products is performed in environmentally controlled conditions and under rigorous quality controls. The DBM component is processed with 50 units/mL Bacitracin, 500 units/mL Polymyxin B, Isopropyl Alcohol, Hydrochloric Acid, Sodium Phosphate Buffer, Hydrogen Peroxide and Allowash® solution, and may contain traces of these processing agents.
4. StaGraft DBM products must be appropriately placed and/or fixed according to the clinical requirements for the specific procedure to avoid potentially adverse effects.
5. Closed suction or drainage is recommended to prevent wound fluid accumulation when using StaGraft DBM products.
6. StaGraft DBM products may extrude into facial soft tissues and the effect of extrusion in cranial applications, due to lack of soft tissue, has not been investigated.
7. Use of StaGraft DBM may result in loss of contour.
8. The use of StaGraft DBM in a closed cavity may result in possible pressurization of the cavity which could produce fat embolization or embolization of device into the blood stream.
9. When used to fill craniofacial defects with minimal tissue coverage, care should be taken to avoid overfilling the defect site with StaGraft. Excessive pressure or tension on the overlying tissue by an overfilled defect could cause the wound to re-open. In addition, the use of StaGraft should be limited to craniofacial defects 25 cm² and smaller which are characterized by pronounced bony margins that can effectively contain the product at the site.
10. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.
11. Read the instructions prior to use.

PRECAUTIONS

1. Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing have been used in the qualification of all tissue donors. Despite the extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of infectious diseases through the use of this tissue graft is still possible. Infection at the graft site may also occur. Any adverse outcomes potentially attributable to StaGraft DBM products must be reported promptly to Biomet Trauma.
2. Product is for single use only. Re-use may result in product contamination, patient infection, and/or failure of the device to perform as intended.

OSTEOINDUCTIVE POTENTIAL

1. Each lot of DBM incorporated into StaGraft DBM is assayed for its osteoinductive potential. The assay measures the alkaline phosphatase production of a myoblast cell line (C2C12) in the presence of human DBM compared to positive and negative controls (osteoinductive index). Results of the assay have been correlated with results from implantation of DBM into athymic rat muscle, which demonstrated a correlation coefficient of 0.88 ($p<0.0005$) and accurately predicted the *in vivo* osteoinductivity in 20 donor lots.[1]
   [1]Han B, Tang B, and Nimni M. Quantitative and Sensitive in vitro Assay for Osteoinductive Activity of Demineralized Bone Matrix. J Ortho Res, 2003, 21:648-54.
2. The combination of DBM, the carrier and, in some formulations, ceramic granules has not been evaluated for osteoinductivity; therefore it is unknown to what extent the formulation components may alter the osteoinductive character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via the *in-vitro* "C2C12" bioassay will correlate with human clinical performance of StaGraft DBM products.

Storage

StaGraft DBM products should be stored in a clean, dry place at ambient temperature. Keep out of direct sunlight and do not freeze. It is the responsibility of the tissue dispensing service and user facility/clinician to maintain any tissue in appropriate conditions prior to use.

PRODUCTION

Tissue Processing Procedures:

StaGraft DBM products are produced by a validated proprietary production process. Tissue processing is completed in a facility accredited by the American Association of Tissue Banks (AATB). The lipid carrier and ceramic granules have been irradiated with a Cobalt 60 source.

Summary of Donor Records:
The completed donor chart for the enclosed tissue (including but not limited to, serology results, recovery culture results, medical and social history evaluation and hemodilution calculation that was conducted by or contract tested by and for the tissue provider) has been approved for transplantation by the tissue provider's Medical Director.

Donor Screening and Testing:
1. Prior to donation, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues. The tissue provider's policies and procedures for donor screening, serologic and microbiologic testing meet current standards established by the AATB. Contraindications for tissue donation include, but are not limited to, the following: presence of infectious disease, malignant disease, neurological degenerative diseases, disease of unknown etiology, and exposure to toxic substances. The donor's medical/social history was also screened for HIV high risk factors in accordance with current United States Public Health Services Recommendations for the Prevention of HIV Transmission through Tissue and Organ Donation.
2. Testing of donor blood and tissue samples began at the site of recovery and continued throughout processing. Donor blood samples taken at the time of recovery were tested and found negative (acceptable) for the following:
    a. Hepatitis B surface antigen (HBsAg)
    b. Hepatitis B core antibody (anti-HBc)
    c. Hepatitis C antibody (anti-HCV)
    d. Human immunodeficiency virus Type 1 and Type 2 antibodies (anti-HIV-1 and anti-HIV-2)
    e. Human T-lymphotropic virus Type 1 and Type 2 antibodies (anti-HTLV-1 and anti-HTLV-2)
    f. Syphilis (RPR or FTA)
    g. Nucleic Acid Testing (NAT) for HIV-1
    h. NAT for HCV
3. The individual tissues collected at recovery were subject to microbiological testing and determined to be free of specific aerobic/ anaerobic microorganisms and fungal contaminants whose presence would preclude the tissue from transplantation.
4. The above tests were performed by laboratories certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA).

INSTRUCTIONS FOR USE
StaGraft DBM products have been processed aseptically and are ready to use. The StaGraft DBM products are provided in sterile syringes or vials. The product is then packaged in two sterile peel pouches. The outer peel pouch can be used to aseptically transfer the sealed inner pouch to the sterile field. Follow these instructions:
1. Peel open outer pouch using proper sterile technique.
2. Pass inner pouch into sterile field.
3. Peel open inner pouch and remove product.
4. Remove cap.
5. Express from syringe or remove from vial.

StaGraft DBM products require no reconstitution prior to use. They do not require rehydration or any special preparation. Do not subject StaGraft DBM products or their packaging to additional disinfection or sterilization procedures. StaGraft DBM is intended for single patient use only. To prevent cross-infection of graft recipients and graft contamination, do not use the contents on multiple patients. Empty or partially used containers should be disposed of in accordance with recognized procedures for discarding medical waste materials.

Patient Records
The clinic or hospital is responsible for maintaining recipient records for the purpose of tracing allograft tissue post-implantation. Ensure that the following information is recorded in the patient's medical record and the hospital implant records (1-3 are required and 4-10 are suggested):
1. Description of Tissue
2. Donor Identification Number
3. Product Code
4. Expiration Date
5. Quantity Implanted
6. Antibiotics Used
7. Description of Procedure
8. Date and Time of Procedure
9. Surgeon Name
10. Any Other Pertinent Information

As a convenience, a Graft Tracing Record has been included to be completed at the time of the surgical procedure. A completed original is to be retained in the patient record and the copy sent back to Biomet Interpore Cross, as indicated on the enclosed Graft Tracing Record. If the entire tissue product was discarded, return the Graft Tracing Record and explain the reason for discard.
Once completed, return the bottom copy of the form using the self-mailer (or fax) to Biomet Interpore Cross for our permanent records. File the top copy in the patient chart.

STERILITY
Do not sterilize.

Caution: Federal law (USA) restricts this device to sale, distribution, or use by or on the order of a licensed physician.
Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., 56 East Bell Drive, P.O. Box 587, Warsaw, Indiana 46581-0587 USA, Fax: 574-372-3968.

SYMBOL LEGEND


Manufacturer


Date of Manufacture


Do Not Reuse


Caution, Consult accompanying Documents

STERILE EO — Sterilized using Ethylene Oxide

STERILE R — Sterilized using Irradiation

STERILE — Sterile

STERILE A — Sterilized using Aseptic Processing Techniques

STERILE — Sterilized using Steam or Dry Heat


Use By


WEEE Device

REF — Catalogue Number

LOT — Batch Code

Rx Only — CAUTION: Federal (USA) restricts this device to sale by or on the order of a licensed physician.

Flammable

EC REP — Authorized Representative in the European Community