XTANT MEDICAL

OsteoMax DBM Putty – Product Instructions & Information Guide

Contents: Donated Human Tissue. In accordance with FDA Article 21 CFR Part 1271, this package contains donated human cells, tissues, and cellular and tissue-based products (HCT/Ps).

Donor Screening & Testing: The enclosed human tissue allograft was processed, packaged, and labeled by Surgenex. All tissue was recovered, processed, stored and distributed for use in accordance with the Standards of the American Association of Tissue Banks (AATB), FDA requirements for Human Cellular and Tissue Based Products (HCT/Ps 21 CFR Part 1271), and applicable State regulations. Surgenex has determined the Donor to be eligible, based on the results of screening and testing. The Donor has been tested using FDA licensed, approved, or cleared donor screening test kits and was found negative or non-reactive for:

- Human Immunodeficiency Virus Types 1 and 2 Antibody (anti-HIV-1/anti-HIV-2)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody - Total (anti-HBc)
- Hepatitis C Virus Antibody (anti-HCV)
- Human Immunodeficiency Virus 1, Hepatitis B Virus and Hepatitis C Virus Nucleic Acid Test(s) (HIV 1/HBV NAT/HCV NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay

Additional tests, including but not limited to HTLV I/II, CMV or West Nile Virus, may have been performed and were found to be acceptable for transplantation. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing in accordance with the 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).

Product Details: The enclosed product is a 100% human demineralized bone graft, which is used as a filler for voids or gaps in the bone that are not intrinsic to the stability of the bony structure. It should be gently packed into osseus defects which may be surgically created or resulting from traumatic injury to the bone. The graft provides a filler that resorbs and is replaced by the growth of new bone during the healing process. These allografts can be used in a number of orthopedic, spine, general and reconstructive surgical applications. This allograft is intended to be used on a single patient, on a single occasion, only.

Surgenex and its affiliates furnish this allograft product without any expressed or implied warranties. All statements or descriptions are informational only and are not to be implied as a warranty of the allograft product. Surgenex and its affiliates make no guarantee regarding the biological characteristics of this product. The end-user shall be held responsible for determining the appropriate application and usage of this product.

Federal law limits this HCT/P to be used by, or on the order of, a licensed healthcare professional. Any violations shall be subject to Federal law.

This HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent. Human Tissue for transplant shall not be offered, distributed or dispensed for veterinary use.

This product is provided sterile. This product has been terminally sterilized via Gamma irradiation to achieve a Sterility Assurance Level (SAL) of 10^{-6}. DO NOT STERILIZE OR RE-STERILIZE THIS PRODUCT BY ANY MEANS. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide, or other chemical sterilant may render the allograft unfit for use.

It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain this tissue allograft in its original packaging, in appropriate storage conditions prior to further distribution or transplant. This allograft may be stored at temperatures between 15-30°C (59-86°F), until the expiration date indicated on the product label. THIS PRODUCT MUST NOT BE FROZEN.

Contraindications: The enclosed allograft should not be used on (1) areas with active or latent infection and/or (2) a patient with a disorder that would create an unacceptable risk to their health while using this product.

Caution should be taken when administering this product to immunocompromised individuals, such as patients suffering from HIV or other highly immunocompromised conditions. This allograft has not been tested in combination with other products.

Precautions: Although Surgenex, LLC has taken great measures to ensure the safety of these allograft products, application and use of any allograft tissue may potentially have negative outcomes. However, this risk is greatly reduced by using processing treatments shown to reduce risk as well as strict donor screening criteria, laboratory testing and terminal irradiation of the final allograft product.

This allograft was processed using some or all the following agents to clean and disinfect the allografts: povidone iodine, physiological buffers, alcohols and saline solutions. Traces of these reagents may remain on the tissue allografts.

Healthcare professionals should discuss possible complications with the recipient prior to product use. General risks and complications arising from application of allografts may include but are not limited to infection, bleeding, swelling, redness, and potential injury to nerves and other soft tissue.

Current technologies cannot preclude the transmission of certain diseases known or unknown. Therefore, Surgenex, LLC can make no claims concerning the biological properties and safety of allograft tissue.

Precautions (continued): Adverse outcomes may occur with allograft use, including but not limited to: 1) transmission of communicable diseases; 2) transmission of infectious disease agents; and 3) immune rejection of, and/or allergic reaction to the HCT/P.

Any adverse outcomes potentially attributable to the HCT/P must be reported promptly to Xtant at +1(888) 886-9354 or email cs@xtantmedical.com

Preparation and Use: Before use, examine the allograft packaging. If any of the following conditions are observed, do not use the allograft product and notify Surgenex, LLC immediately:

- Any of the package elements appear to be missing, tampered with or damaged.
- The product label or identifying bar code is severely damaged, illegible or missing.
- The expiration date shown on the package label has passed.

Open the cardboard shelf box and remove the enclosed pouch. The inner pouch, containing the syringe, and the inside of the outer pouch are sterile. The outside of the outer pouch is not sterile. Use standard aseptic/sterile technique to open the pouches. Once the outermost Tyvek seal has been compromised, the tissue must be either transplanted, if appropriate, or otherwise discarded.

Using sterile technique, peel open the outer Tyvek pouch, at the chevron seal and transfer the inner foil pouch into the sterile field. Next, peel open the foil pouch and remove the syringe. Once the seal on the foil pouch has been breached, the product should be used within an hour of opening. Remove cap from end of syringe. The graft can either be applied directly to the surgical site from the syringe or, can be extruded from the syringe to be placed manually in and around the surgical site. Keep syringe caps on syringe when not using product to prevent product from drying out. Discard any unused product as required.

HCT/P Tracking: FDA 21 CFR 1271.290, Regulation of Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps) requires that documentation regarding tissue disposition enabling tracking from donor to the consignee and/or final disposition be maintained.

Joint Commission standard QC.55.310.7 requires that the organization that receives tissue provides a system that fully complies with the completion of tracking tissue usage via Tissue Tracking/Transplant Record (TTR) or provides a web-based program for traceability of the allograft used.

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide the information pertaining to the traceability of the allograft used. Complete the enclosed Transplant Utilization Record in detail and return as indicated.

If the graft is not used for any reason after opening, complete the enclosed Transplant Utilization Record in detail, noting the method of disposal, and return as indicated. Copies of this information should be retained by the transplant facility.

Returns: If for any reason tissue must be returned, a return authorization is required from Xtant Medical prior to shipping. Please contact Customer Care at +1(888)886-9354, or email cs@xtantmedical.com to facilitate the safe and proper return of tissue.

Allograft(s) must be packaged and returned securely in a box with the RMA # noted on your preferred carrier's shipment label. You can mail or ship the package by any common carrier; however, we recommend that a tracking number and insurance for the original value be secured and retained.

Xtant will not be held liable for packages that were lost or damaged while in transit to us. Allograft(s) must be shipped to Xtant within 24 hours of RMA # being issued.

Xtant reserves the right to refuse to issue credit if the conditions of the above criteria have not been met; or deems the tissue unacceptable for return.

Processing and Donor Eligibility Determination Conducted By:

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