XTANT MEDICAL

## OSTEOMAX DBM PUTTY PACKAGE INSERT AND TISSUE TRACKING INFORMATION

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

This human tissue allograft was processed and packaged 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), the FDA requirements for Human Cellular and Tissue Based Products, and applicable State regulations. Surgenex® has determined the Donor to be eligible, based on the results of screening and testing. Screening includes a review of medical and social history, available hospital records, infectious disease testing, autopsy reports (if performed), and physical examination of the Donor, at the time of recovery. 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, if performed, 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).

## STORAGE

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant. This allograft tissue may be stored at ambient temperature until the expiration date, indicated on the product label. DO NOT FREEZE.

## THIS ALLOGRAFT IS SUPPLIED STERILE

This tissue allograft has been sterilized, via Gamma irradiation, to a SAL of $10^{-6}$ (Sterility Assurance Level). This allograft must not be sterilized or re-sterilized by your facility.

## WARNINGS AND PRECAUTIONS

- This allograft is intended for use in one patient, on a single occasion only.
- This tissue is intended solely for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.
- Allografts are processed using some or all of the following agents: povidone iodine, physiological buffers, alcohols and saline solutions. Traces of these reagents may remain on the tissue allografts.

Although this tissue has been tested and screened for relevant communicable diseases and disease agents, and processed under aseptic conditions, application and use of any allograft tissue may potentially have negative outcomes. Occurrence of complications at the affected site may transpire post-treatment, without early warning signs. These include, but are 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 Medical.

## WARNINGS AND PRECAUTIONS (continued)

Caution should be taken when administering this product to immunocompromised individuals, such as patients suffering from HIV or other highly immunocompromised conditions. Although Xtant Medical has taken great measures to ensure the safety of our allograft products, current technologies cannot preclude the transmission of certain diseases known or unknown. Therefore, Xtant Medical can make no claims concerning the biological properties and safety of allograft tissue.

Xtant Medical 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. Xtant Medical 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.

## TISSUE PREPARATION

**BEFORE USE – Examine Allograft Packaging – Do Not Use This Allograft If:**

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

If any of the above conditions exist or are suspected, this allograft must **NOT** be used.

- Remove putty dispensing syringe from sterile pouch
- Remove cap from dispensing syringe and dispense as needed
- Use product within 30 minutes of opening the syringe
- Discard any unused product as required

## TISSUE TRACKING

This graft is packaged in sterile, single-patient-use containers and the Unique Graft Serial Number, expiration date, product code, size, and additional information are listed on the package label.

The Hospital must maintain records so that possible infections or other adverse reactions associated with this graft can be linked back to the original source. It is the responsibility of the user surgeon to complete recipient records for the purpose of tracking tissue post-transplant. 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.

**DISTRIBUTED BY:**

XTANT MEDICAL
664 CRUISER LANE
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WWW.XTANTMEDICAL.COM

**DONOR ELIGIBILITY DETERMINATION AND PROCESSED BY:**

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