OssiGraft Prime™

Viable Bone Matrix

FEDERAL LAW (USA) RESTRICTS THIS ALLOGRAFT FOR USE BY A LICENSED PHYSICIAN ONLY.

DESCRIPTION

OssiGraft Prime™ is a cryopreserved viable bone matrix allograft. OssiGraft Prime™ is a Human Cells, Tissues, and Cellular and Tissue-based Product (HCT/P) as defined by the U.S. Food and Drug Administration in 21 CFR 1271.3(d). OssiGraft Prime™ meets the criteria set out in 21 CFR 1271.10 for regulation solely under section 361 of the Public Health Service Act. OssiGraft Prime™ is sourced from donated human tissue from the generous gift of an individual or his/her family. OssiGraft Prime™ is processed aseptically and treated with a cryoprotective solution containing 10% Dimethyl Sulfoxide (DMSO) and 2 mg/mL antifreeze glycoprotein in pre-sterilized inner and outer pouches. OssiGraft Prime™ is packaged by volume and verified by mass.

Graft Sizes	
OssiGraft Prime™ Item Number	Size
OSSM-009-025	2.5 cc
OSSM-009-050	5 cc
OSSM-009-100	10 cc
OSSM-009-150	15 cc

INDICATIONS FOR USE

OssiGraft Prime™ is intended for the repair or reconstruction of musculoskeletal defects.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Use in any patient who has a known or suspected allergy to DMSO or any of the antibiotics, antimycotics, and/or reagents listed under the Warnings and Precautions section of this document.
- Use in immune compromised patients.
- Stand-alone use in load-bearing applications.
- Patients with active infections.

WARNINGS AND PRECAUTIONS

- Ossium Health employs stringent guidelines regarding donor tissue, processing treatment, and laboratory testing to reduce the risk of infectious agent transmission. As with any donor tissue, the potential for transmission of infectious agents exists.
- Use on a single occasion for a single patient only.
- During processing, tissue is exposed to solutions that may contain hydrogen peroxide, sodium hypochlorite, and isopropyl alcohol. In addition, OssiGraft Prime™ is treated with dimethyl sulfoxide (DMSO10%) and antifreeze glycoprotein (2 mg/mL), which are decanted prior to cryopreservation. Trace amounts of these solutions may remain.
- Do not use past expiration date or if package or label integrity has been compromised or damaged.
- **OssiGraft Prime™ is not terminally sterilized. Do not sterilize.**
- Do not use if tissue has not been stored according to the recommended storage requirements.
- Do not refreeze after thawing.

STORAGE REQUIREMENTS

After removal from the shipper, OssiGraft Prime™ must be stored immediately in its original packaging at -60°C or colder until ready for use or date of expiration, whichever occurs first. Do not store in the liquid phase of Liquid Nitrogen (LN2). OssiGraft Prime™ may incur temperature excursions above -60°C up to 5 minutes due to cycling or opening of freezer doors. It is the responsibility of the end user to document and maintain storage at these conditions.

POTENTIAL ADVERSE EVENTS

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions.
Potential adverse events or outcomes include, but are not limited to: disease transmission, infection, allograft tissue rejection, allergic reaction to residual reagents, re-operation, and/or death.

Promptly report any adverse event(s) or outcome(s) potentially attributable to OssiGraft Prime™ (see Complaints and Returns section).

QUALITY CONTROL TESTING

Quality Control testing is performed on each lot of OssiGraft Prime™. The following Quality Control criteria were met for this lot of OssiGraft Prime™.

Required Quality Control Testing	
Test	Acceptance Criteria
USP <71> Sterility	No Growth

DONOR SCREENING AND TESTING

All donors have been screened and tissues recovered, processed, stored, tested, and distributed in accordance with current FDA regulations as promulgated in 21 CFR 1271.
This allograft was deemed eligible for implantation by Ossium Health's physician medical director following donor eligibility evaluation of the following: infectious disease test results, current donor medical history, behavioral risk assessment interview, physical assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or coroner reports (if performed).
All donors are tested for relevant infectious diseases. Testing for relevant infectious diseases is performed by laboratories that are registered with the U. S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR 493. Test methods that are FDA-licensed, approved, or cleared for donor screening are used as available. See the full summary of infectious disease testing performed provided with the product.

TRACEABILITY

The end user is responsible for completing and maintaining records to trace the allograft to the recipient. As a convenience, pre-printed labels are included with each allograft to record the allograft tissue identification information in the patient's medical record. In addition, an Allograft Usage Report is included with the allograft. The end user must complete the report, affix a pre-printed label to the report, return a copy of the report to Ossium Health, and maintain the report in the patient's medical record.

COMPLAINTS AND RETURNS

For further information on returns or to report a complaint or adverse event, please contact Ossium Health at (415) 513-5535 or at complaints@ossiumhealth.com and have the identification number available (see label).

WARRANTY STATEMENT

Due to the inherent variability of allograft tissue, biological and biomechanical properties cannot be guaranteed by Ossium Health.

OssiGraft Prime™

Viable Bone Matrix

INSTRUCTIONS FOR USE
IT IS IMPORTANT TO READ AND UNDERSTAND THE FOLLOWING INSTRUCTIONS PRIOR TO CLINICAL USE. IMPROPER PREPARATION TECHNIQUE MAY ADVERSELY AFFECT HANDLING PROPERTIES AND/OR PERFORMANCE.

FROM FREEZER TO OPERATING ROOM

Do not remove OssiGraft Prime™ from the dry ice shipper or freezer until ready to begin thawing. Transport OssiGraft Prime™ to operating room using preferred method that maintains the temperature at -60°C or below without excursions above -60°C for longer than 5 minutes. It is the responsibility of the end-user to maintain an acceptable temperature.

REQUIRED MATERIALS

- 2 sterile basins (1 for thawing, 1 for the implant)
- 2 liters warm (35°C to 39°C) sterile isotonic solution (e.g., saline)
- Thermometer
- Sterile absorbent material (e.g., gauze, lap sponge, etc.)

OPTIONAL MATERIALS

- Sterile scissors
- Sterile forceps

THAWING INSTRUCTIONS

STEP ONE:

Prewarm at least 2 liters of sterile isotonic solution to a starting temperature of 35°C to 39°C. Pour the warm solution into a sterile basin.

NOTE: Starting temperature does not need to be maintained during the thawing process.

STEP TWO:

Non-Sterile Team Member: Remove pouch from cardboard box. Open outer layer of pouch by peeling or cutting with sterile scissors. Aseptically present the inner graft pouch directly to a Sterile Team Member.

STEP THREE:

Sterile Team Member: Completely submerge graft pouch in warm sterile isotonic solution.

STEP FOUR:

Keep the graft pouch submerged until the contents of the pouch are no longer hard or ice cold to the touch (approximately 5 minutes). Remove the graft pouch from the sterile isotonic solution, dry with sterile absorbent material, and place on sterile field away from heat. Do not open pouch until ready to implant.

NOTE: OssiGraft Prime™ must be used within 2 hours from when the pouch was removed from the water bath. Additionally, once the container seal has been compromised, OssiGraft Prime™ must be transplanted, if appropriate, or otherwise discarded.

STEP FIVE:

When ready to implant, open the graft pouch by peeling or cutting with sterile scissors. Dispense bone matrix in a sterile basin with sterile gloves and/or sterile forceps. Mix the bone matrix thoroughly to homogenize before implanting. Any residual liquid can be squeezed out to obtain the desired graft consistency.

Processed and Distributed by:
Ossium Health, Inc.
5742 W 74th Street
Indianapolis, IN 46278