IMPLADENT LTD.
198-45 Foothill Avenue, Holliswood NY 11423
800 526-9343 fax 718 464-9620

RECONSTITUTION ADVISEMENT
IRRADIATED FREEZE-DRIED BONE

Note: Please record Tissue ID Number in the patient's record for future reference

Complete information requested on reverse of this form and fax copy to 718 464-9620

PRODUCT DESCRIPTION

This package contains Human Allograft Material (referred to as "Graft") collected from human cadaveric donors. All tissue processed for Impladent Ltd. is recovered by U.S. tissue banks as well as, a completed donor chart for the enclosed product including but not limited to: serology results, preprocessing culture results, medical and social history evaluation and serodilution calculations that are conducted by or contract tested for the tissue bank. It has been reviewed and approved for transplantation by the tissue bank's Medical Director. Donor screening and testing is performed in accordance with the American Association of Tissue Banks (AATB) standards and U.S. Food and Drug Administration (FDA) regulations. All processing documentation has been reviewed and approved by the tissue bank's Quality Assurance department; each lot of product is manufactured using tissue from a single donor. There is no pooling of donor tissue.

A donor serum sample is tested by a CLIA Certified Lab using FDA licensed screening tests and found to be negative or non-reactive for antibodies to human immunodeficiency virus type 1 and type 2 (anti-HIV 1 and anti-HIV 2), hepatitis B surface antigen (HbsAg), hepatitis B core antibody (HbcAb), antibodies to the hepatitis C virus (anti-HCV), and the human T-lymphotrophic virus type I antibody (anti-HTLV I). The serum tests negative for syphilis using a FDA licensed confirmatory test. The donor also tests negative for HIV using Polymerase Chain Reaction (PCR) technology or an FDA-licensed NAT test.

CONTRAINDICATIONS

- Severe vascular or neurological disease.
- Uncontrolled diabetes.
- Severe degenerative bone disease.
- Pregnancy.
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol.
- Hypercalcemia.
- Renal impairment.
- Patients with a history of or active Pott's disease.
- Active or latent infection in or about the surgical site.
- The Graft should NOT be used if the expiration date has been surpassed, the container in which the product is stored has been damaged, the container is not labeled, or if the product has not been stored at the recommended temperature. No other absolute contraindications are known to exist. However, a small amount of hydrogen peroxide, alcohol, betadine, ascorbic acid, and HCl may be present and caution should be exercised if the patient is allergic or sensitive to these agents.

ADVERSE EFFECTS

Possible adverse effects include but are not limited to:

- Wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery.
- Fracture or extrusion of the product with or without generation of particulate debris.
- Deformity of the bone at the site.
- Incomplete or lack of osseous growth into bone void, as is possible with any bone graft substitute.

In the event of a severe adverse reaction to the product, a second surgery may be required to remove any remaining product.

WARNINGS AND PRECAUTIONS

- The Graft remains sterile and non-endotoxic as long as the package is not opened and/or damaged. The Graft must be used before the expiration date.
- Appropriate placement and fixation are critical factors in the avoidance of adverse effects on the Grafts service life.
- Discard all damaged or mishandled Grafts or if possible contamination of the Graft has occurred.
- Return all packages with flaws in the sterile barrier to Impladent Ltd.
- **Do not re-sterilize,** unused Graft should be properly discarded.
- Single patient use only.
- As with any surgical procedure, the possibility of infection exists.
- Although tissue has been terminally sterilized, and all possible precautions have been taken, in rare incidences allograft tissue may transmit infectious agents.
- Adverse reactions should be immediately reported to Impladent LTD at Toll Free **(800)-526-9343.**

STORAGE AND SHELF LIFE

Tissue may be stored at room temperature (approximately 68ºF to 77ºF) up to five (5) years from the date of sterilized. See expiration date on product label.

INSTRUCTION FOR USE

1. Peel off plastic and metal cap from bottle and wipe rubber stopper with alcohol or betadine. Using a syringe, inject sufficient saline or air to release vacuum. If vacuum is present, plunger will be drawn down. Do not use if vacuum is not present. Wipe off rubber stopper with alcohol or betadine. Remove rubber stopper with the aid of sterile forceps.
2. If desired, culture each graft individually prior to touching or removing graft from vial.
3. Place graft in sterile basin and cover with normal saline. Addition of antibiotics of choice is optional. IMPORTANT: CRUSHED BONE (cancellous, corticocancellous, bone powder) SHOULD BE RECONSTITUTED FOR 30-45 MINUTES.
4. Reconstitution solution may be cultured prior to implantation of graft if desired.

WARNING:
DO NOT USE IF THERE IS EVIDENCE OF DEFECTS IN PACKAGE
GRAFT MAY NOT BE STERILIZED OR RESTERILIZED
SINGLE USE ONLY

Impladent Ltd.
198-45 Foothill Avenue, Holliswood NY 11423-1611
1-800-526-9343 FAX 1-718-464-9620

ALLOGRAFT TISSUE UTILIZATION RECORD
PATIENT USAGE FEEDBACK REQUEST

Tissue ID Number:_____ Expiration:_____
Micron Size:_____ Vial Size: _____ cc

IRRADIATED FREEZE-DRIED BONE POWDER

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REFER TO RECONSTITUTION DETAILS ON REVERSE OF THIS FORM
THIS GRAFT MAY NOT BE RESTERILIZED.

This tissue is intended for use by qualified health care specialists such a physicians, dentists, or podiatrists, and is intended for single recipient on a single occasion application only.

Patient Last Name:_____ First:_____ MI:___

Date of Birth:_____ Sex:_____ Patient ID:_____

Hospital _____
Patient ID _____
Surgeon Name _____
Surgery Date _____
Type of Surgery _____

Data provided by:_____ Date:_____

Comments:_____
_____
_____

It is the responsibility of the clinician to complete the information requested herein and to fax a copy of same to Impladent Ltd. at 1-718-464-9620