DIRECTIONS FOR USE

XEMPLIFI™

DBM Gel and Putty

For Single Patient Use on a Single Occasion Only

The Inner Package and its Contents are Sterile

This allograft product is derived from voluntarily donated human tissues.

INDICATIONS FOR USE
XEMPLIFI™ is indicated for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. XEMPLIFI™ is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender (extremities, spine and pelvis) and as a bone void filler of the extremities and pelvis. These defects may be surgically created or from the result of traumatic injury to the bone.

DESCRIPTION
XEMPLIFI™ DBM Gel and Putty are human tissue that has been demineralized, mixed with poloxamer reverse phase medium and formulated into a gel or putty-like form. As a biological material, some variations in the product should be expected, such as in appearance and in handling. XEMPLIFI™ is provided in a sterile, single patient use package.

Donor Eligibility: Donor eligibility (screening and testing) is performed in accordance with AATB Standards and FDA regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor eligibility has been determined by an AlloSource® Medical Director.

Serological testing: Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493. The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. The records of this testing are maintained at AlloSource at the address listed at the bottom of this document. The following required testing was performed and found to be negative or non-reactive:

- Antibody to Human Immunodeficiency Virus 1& 2 (HIV 1 & 2)
- Human Immunodeficiency Virus Type 1 (HIV NAT)
- Antibody to Hepatitis C (HCV)
- Hepatitis C Virus (HCV NAT)
- Hepatitis B Core IgG/IgM Antibody (HBcAb)
- Hepatitis B Surface Antigen (HBsAg)
- Rapid Plasma Reagin or Serologic Test for Syphilis (RPR or STS)

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II) may have been performed at the time of donor screening and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed will be provided upon request.

INSTRUCTIONS FOR USE
These instructions are intended as guidelines for the use of XEMPLIFI™ as a part of established surgical techniques. They are not intended to replace or change standard procedures for treatment of bone defects involving bone grafting and internal fixation. Procedures involving bone grafting can experience highly variable results. Factors to be considered in selecting the bone grafting material and the surgical technique to be utilized are as follows:

- Age of the patient
- Quality of the patient's bone
- Location of the defect
- Anticipated loading conditions
- Proximity of the graft to a suitable blood supply
- Ability to achieve direct apposition of the graft to viable host bone
- Presence/addition of autogenous bone or bone marrow at the graft site
- Elimination of gaps in the graft site
- Ability to suitably stabilize the graft site
- Complete coverage of the graft material to prevent migration

For best results, extreme care should be exercised to assure the correct graft material is selected for the intended application.

TO OPEN PUTTY:
1. Peel open outer package.
2. Using aseptic technique, transfer contents to a sterile field.
3. Peel open inner package and remove spatula and vial.
4. Twist off vial lid and remove putty using small spatula or other hand instrument.
5. Discard any unused portion.

TO OPEN GEL:
1. Peel open outer package.
2. Using aseptic technique, transfer contents to a sterile field.
3. Peel open inner package and remove syringe.
4. Remove protective cap from syringe tip.
5. Apply pressure to the plunger to extrude gel.
6. Discard any unused portion.

PREOPERTIVE PREPARATION
Aseptic technique must be maintained to minimize the risk of postoperative complications. The amount needed is based on the type of procedure and size of the defect being treated. When XEMPLIFI™ is being mixed with autograft, a ratio of 1:1 should be used. XEMPLIFI™ does not require rehydration prior to use.

Radiographic evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of XEMPLIFI™ and fixation devices.

Surgical Procedure Notes: XEMPLIFI™ does not possess sufficient mechanical strength to support the reduction of a graft site prior to tissue in-growth. Therefore, anatomical reduction and rigid fixation, on all planes, should be obtained independent of XEMPLIFI™.

For best results, XEMPLIFI™ must fill the defect and contact as much viable bone as possible. Do not overfill the defect site.

XEMPLIFI™ must not be used to repair bone defects where complete soft tissue coverage cannot be achieved.

POSTOPERATIVE CARE
Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices. The patient should be cautioned against early weight bearing and premature ambulation which could lead to loosening and/or failure of the fixators or loss of reduction. The length of time a defect should remain in a reduced state of loading is determined by the complexity of the defect site and the overall physical condition of the patient. Hardware should not be removed until the defect is healed.

CONTRAINDICATIONS
XEMPLIFI™ is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:

- 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 around the surgical site

Polymyxin Sulfate B and Bacitracin are used in processing XEMPLIFI™ DBM Gel and Putty and trace amounts may remain. Since it is impossible to quantify the levels at which any individual may have an allergic response, this product is contraindicated in patients with known sensitivity.

WARNINGS AND PRECAUTIONS
XEMPLIFI™ is sterile during the stated shelf life in an unopened and undamaged package. The product must be used prior to the expiration date.

Do not use if the packaging has been damaged and/or the product has been contaminated. In the event of contamination, discard the product. Damaged packaging should be returned to Globus Medical, Inc.

XEMPLIFI™ does not require rehydration prior to use.

Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects. Do not over-fill the defect site. As with all biological products, the tissue in XEMPLIFI™ has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissue selection and laboratory tests. To date, there have been no reports of experimental or clinical viral seroconversion using demineralized bone powder.

As with any surgical procedure, the possibility of infection exists.

Although the production is designed to eliminate antigenic properties of the product, the possibility of such a reaction is present.

Adverse outcomes potentially attributable to the product must be reported promptly to Globus Medical, Inc. If any dissatisfaction with the product performance or packaging occurs, notify Globus Medical, Inc. immediately and promptly return product and/or packaging.

OSTEOINDUCTIVE POTENTIAL
XEMPLIFI™ DBM Gel and Putty have been shown to have osteoinductive potential in the athymic rat model. Every lot of XEMPLIFI™ DBM Gel and Putty is tested via an *in vivo* assay to ensure the osteoinductive potential of the final product. It is unknown how the osteoinductive potential, measured in the athymic rat, will correlate with clinical performance in human subjects.

STERILIZATION
XEMPLIFI™ has been sterilized by electron beam irradiation. The inner package and its contents are sterile. The package should be inspected prior to use to ensure the sterility barrier has not been compromised. This product is for single use only and should not be re-sterilized. The product must not be used beyond the stated expiration date.

DO NOT RE-STERILIZE

STORAGE
Do not refrigerate or freeze. Do not expose to extreme heat. Store at room temperature (15°C to 30°C) in a clean, dry place. It is the responsibility of the tissue dispensing service and user (facility/clinician) to maintain the product under appropriate conditions prior to use.

RECORD KEEPING
The clinician or hospital is responsible for maintaining recipient records for the purpose of tracing tissue post-implantation. A *Transplantation Record & Feedback Form* and preprinted peel-off labels are included with each package of tissue. Record the patient name or ID number, the transplantation facility name and address, the allograft tissue identification information (using the peel-off stickers) and comments regarding the use of the tissue on the *Transplantation Record & Feedback Form*. Return the completed form to Globus Medical, Inc. and retain a copy in the patient medical record. If the tissue has been discarded, please return the *Transplantation Record & Feedback Form* to Globus Medical, Inc. with the graft identification information and reason for discard.

CAUTION: Federal (U.S.) Law restricts the use of this device to sale by or on the order of a physician.

Symbol	Meaning
REF	Catalogue Number
LOT	Batch Code
STERILE R	Sterilized by Irradiation
	Caution, consult accompanying documents
	Do not re-use
	Temperature Limitation
	Use By Date

CONTACT INFORMATION

Please contact Globus Medical, Inc. at 1.866.GLOBUS-1 (1-866-456-2871) to promptly report any unanticipated or adverse events, or should you require further information.

Distributed by:

GLOBUS MEDICAL

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