maxxeus™ by CTS

DBM Putty

Tissue Insert & Usage Form

www.maxxeus.com/ifu

QC-605-F-23 V6.0

Symbol Glossary

Consult Instructions For Use	Do Not Reuse
Use By Date	SN Serial Number
Manufacturer	Do Not Use If Package Is Damaged
LOT Batch Code	STERILE R Sterilized Using Irradiation
REF Catalogue Number	MR Magnetic Resonance Safe
Do Not Resterilize	Rx Only Prescription Use Only

All symbols may not appear in labeling

Description

Donated Human Tissue. Tissue recovery was performed using aseptic techniques. Once processed, the tissue is sterilized by gamma irradiation. The implant is composed of 100% human bone tissue and does not contain any additive or extrinsic carrier. The bone is demineralized using a simple process that has been validated to perform viral inactivation. The DBM putty is composed of demineralized cortical bone. This DBM product provides a variety of handling characteristics that can be chosen to fit the application. The procedures executed to manufacture this graft including recovery, donor screening, testing, processing, packaging, labeling, storage, and distribution were performed in compliance with all applicable local, state, and federal regulations, including the U.S. Food and Drug Administration (FDA) regulations published at 21 CFR Part 1271, and the American Association of Tissue Banks Standards for Tissue Banking.

SCREENING AND TESTING

The Donor has been determined to be eligible by a Community Tissue Services Medical Director at 349 S. Main St., Dayton, OH 45402 based on the results of screening and testing. Screening includes a review of medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical exam. Donors are tested and found negative (acceptable) for anti-HIV 1/2, HBsAg, anti-HBc, anti-HCV, HIV NAT, HBV NAT, HCV NAT and syphilis. FDA licensed test kits are used when available. Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. 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, or that has met equivalent requirements as determined by the Centers of Medicare and Medicaid Services (CMS).

Intended Use

The graft is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. It should be gently packed into bony voids or gaps of the skeletal system. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The graft provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process. It can be mixed with autogenous bone marrow prior to use at the physician's discretion.

Contraindications

Do not use the graft in the presence of any contraindication. The graft is contraindicated where the graft is intended as structural support in the skeletal system. Other conditions representing relative contraindication include:

- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- pregnancy
- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors
- severely impaired renal function

Warnings

The graft is sterilized by gamma irradiation. Content of package is STERILE unless opened or damaged. Once the user breaks the container seal, the tissue graft must be transplanted or discarded. Contact distributor and manufacturer and do not use if packaging is damaged. Read expiration date before use. Do not use if expiration date has been exceeded. It is recommended to use the graft within one hour of opening the package. Intended for use in one patient, on a single occasion only. The tissue may not be sterilized or re-sterilized as any attempt may cause a loss of functionality or contaminate the graft. While every effort has been made to ensure the quality of this allograft, Community Tissue Services and Berkeley Advanced Biomaterials makes no claims concerning its biological or biomechanical properties. As with any allograft, despite strict screening/testing procedures, this allograft has the potential to transmit infectious agents to the recipient. This allograft may contain trace amounts of processing/cleaning agents such as iodine, ethanol, glycerol, or hydrogen peroxide. This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.

Precautions

The graft is not intended for load-bearing uses. It is important to ensure that the area where the graft has been implanted be properly secured mechanically with rigid fixations to strengthen the surroundings. Attempts should not be made to modify the size of the graft or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The effect of the graft on patients with the following conditions is unknown:

- documented renal disease
- pregnancy and nursing
- long-term infection
- metabolic bone disease
- radiation bone therapy
- cardiovascular disease precluding elective surgery

The implant must be secured to prevent potential migration or embolization of the graft into the blood stream. The implant should only be used in surgical procedures where bone grafts are adequately contained. The implant may extrude into soft tissues (e.g. facial applications or iliac crest backfill) and cause inflammation. Do not overfill the site.

Adverse Reactions

A graft may not elicit proper response from the recipient (e.g. fusion/union with adjacent tissue). It is possible for a host site to become infected. The graft may also lead to a deformity of the bone at the site. The graft may cause an inflammatory response. While efforts are made to ensure the safety of the tissue, current technologies may not preclude the transmission of disease, including hepatits and HIV. Adverse outcomes potentially attributable to this tissue must be reported promptly to Community Tissue Services.

Tissue Preparation

1. Inspect for package integrity and expiration date prior to opening.
2. Peel outer package down and aseptically deliver inner package to the sterile field or sterile team member.
3. Remove tissue from inner package and remove cap at the end of the syringe to dispense the graft.
4. Follow accepted procedures for grafting with fixation.

If the material is not positioned satisfactorily, remove the implant and start over with a new dose of the graft.

Insert continued on reverse side below Allograft Tissue Usage form.

maxxeus™ by CTS

Allograft Tissue Usage Form

FDA Regulations and Joint Commission Standards require tissue usage systems in all facilities using allograft tissue for transplantation. In order to comply with these requirements, please complete this form.

How to return this form:	
Email	tissueusage@communitytissue.org
Fax	937-222-2538
Mail	Community Tissue Services Attn: Tissue Usage 2900 College Dr. Kettering, OH 45420

Patient ID or Date of Birth: _____

Date of Surgery: _____

Surgical Procedure: _____

Completed By: _____ Date: _____

Comments: _____

One patient, one procedure per usage form. Place peel-off label for up to 3 allografts or write tissue ID# in the spaces provided.

Community Tissue Services does not consider the information requested on this form to be protected health information (PHI), as defined under the HIPAA regulations. Information considered to be PHI by the originator should not be released to Community Tissue Services.

Allograft Tissue ID#	Allograft Tissue ID#	Allograft Tissue ID#
_____	_____	_____
Place Peel-Off Label Here	Place Peel-Off Label Here	Place Peel-Off Label Here

Tissue Insert Continued

Storage Conditions

Optimal Storage Conditions: 15-30°C (59-86°F) in a secure and dry environment. DO NOT FREEZE. DO NOT EXPOSE TO EXCESSIVE HEAT. Store below 50 °C(122°F). 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.

Shelf Life and Disposal

The expiration date is printed on the label. DO NOT USE AFTER THE EXPIRATION DATE. Packaging materials are recyclable. The graft is supplied sterile. Residual materials may be discarded with other medical waste.

Tissue Usage

Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Complete the Allograft Usage Form on the back of this form and return to Community Tissue Services. Federal Regulations (21 CFR 1271.290(b)) and Joint Commission Standards (TS.03.02.01, EP 7) require proper tracking of this tissue. It is the responsibility of the end-user to provide this information, which enables Community Tissue Services to maintain records for the purpose of tracing the tissue post-transplant.

Other Information

MAXXEUS is a registered trademark of Community Tissue Services. The DBM Putty is manufactured by Berkeley Advanced Biomaterials, Berkeley, CA (USA).

Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of the graft, and for the choice of post-operative follow-up procedures rests entirely with the physician. In case of complaint or for further information on the product and its uses, please contact Community Tissue Services.

Released and Distributed By:
COMMUNITY TISSUE SERVICES
Center for Tissue, Innovation and Research
Manufacturing and Distribution Center
2900 College Dr.
Kettering, OH 45420
800-684-7783
Fax 937-461-4237