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Allograft Particulates

Tissue Insert & Usage Form

www.maxxeus.com/ifu

QC-605-F-29 V7.0

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 grafts are recovered from deceased human donors. All tissue is recovered, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB). Tissue is manufactured in a clean room environment, following rigorous quality assurance standards. Tissue labeled as STERILE R has been sterilized to an SAL of 10-6 (Sterility Assurance Level.) Tissue labeled as STERILE R or irradiated has been Gamma (Cobalt 60) terminally sterilized. Tissue labeled as Allowash® has been processed using Allowash®, a patented bone and soft tissue cleaning technology under license from LifeNet Health.[1] 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

TESTINGThe 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 has been performed by a laboratory registered with the 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 for Medicare and Medicaid Services (CMS).

Storage

Freeze-dried tissue must be stored at ambient temperature or colder. 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.

Tissue Preparation

1. Inspect for package integrity and expiration date prior to opening.
2. Tissue in Vacuum Sealed Jar: Peel off metal cap and wipe rubber stopper with alcohol or betadine. Using a syringe, inject sufficient saline or air to release vacuum. Remove rubber stopperwith aid of sterile forceps. Place tissue in sterile basin and cover with saline or isotonic solution of choice.
3. Tissue in Dappen Dish: Peel outer package down and aseptically deliver inner package to the sterile field or sterile team member. Remove container from inner package. Secure the container in the upright position and ensure that the bone particulate is settled in the base of the container. Unscrew the lid and place the lid in the upright position on the sterile field. Cover with saline or isotonic solution of choice in the container.
4. Antibiotics of choice may be added.
5. IMPORTANT! Grafts should be rehydrated or at least 5 minutes. Final determination of allograft reconstitution should be made by the physician prior to use.
6. Tissue should be used as soon as possible after reconstitution. If tissue is to be stored for longer than 2 hours after reconstitution, it should be refrigerated at 1 to 10°C in an aseptic container for no longer than 24 hours.

Warnings and Precautions

- Intended for use in one patient, on a single occasion only.
- Do not use if package integrity has been compromised. Once the user breaks the container seal, the tissue grafts must be transplanted or discarded.
- Tissue may not be sterilized or re-sterilized.
- This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.
- Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- Adverse outcomes potentially attributable to this tissue must be reported promptly to Community Tissue Services.
- Tissue has been processed with Bacitracin and/or Polymyxin B and traces may remain. Demineralized tissue has also been processed with HCl, alcohol, sodium phosphate (monobasic and dibasic) and traces may remain.

Tissue Tracking

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.

Community Tissue Services is accredited by the American Association of Tissue Banks. Community Tissue Services – Center for Tissue, Innovation and Research is ISO 13485 certified. Health Canada Registration: 100076.

Community Tissue Services makes no claims concerning the biological or biomechanical properties of the provided tissue. Community Tissue Services disclaims all liability and responsibility for any misuse of tissue provided for clinical application.

Please contact Community Tissue Services at 800-684-7783 should you require further information.

Processed, 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

[1] Allowash® is a registered trademark of LifeNet Health. Products and processes may be covered by one or more of the following U.S. patents: 6,024,735, 5,977,032, 5,977,034, 5,820,581, 5,797,871, and 5,556,379. Community Tissue Services licenses the Allowash® Service from LifeNet Health, Virginia Beach, VA.

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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:
- ☐ (71) Immediate Implant Placement
- ☐ (70) Ridge Augmentation
- ☐ (72) Periodontal Graft
- ☐ (73) Socket Preservation
- ☐ (58) Sinus Augmentation
- ☐ (42) Other 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.

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

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.