

**Allograft  
PARTICULATES****Tissue Insert  
and Usage Form**

| SYMBOL GLOSSARY  |                              |
|------------------|------------------------------|
|                  | Do not reuse                 |
|                  | Do not resterilize           |
| <b>STERILE R</b> | Sterilized using irradiation |
|                  | Consult instructions for use |

Processed By:  
Community Tissue Services  
2900 College Drive  
Kettering, Ohio 45420  
(800) 684-7783  
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QC-605-F-29 V6.0

**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). 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. U.S. Food and Drug Administration (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).

Tissue labeled as **STERILE R** has been sterilized to an SAL of 10<sup>-6</sup> (Sterility Assurance Level.) Tissue labeled as **STERILE R** or irradiated has been Gamma Irradiated with Cobalt 60. 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 labeled as Allowash® has been processed using Allowash®, a patented bone and soft tissue cleaning technology under license from LifeNet Health.<sup>1</sup>

**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.

**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 and that recipient records must be maintained for the purpose of tracing tissue post-transplantation.

**TISSUE USAGE**

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.

**TISSUE PREPARATION**

1. Inspect for package integrity and expiration date prior to opening.
2. Peel off metal cap 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.** Remove rubber stopper with aid of sterile forceps.
3. Remove tissue from vial and place in sterile basin and cover with normal saline or isotonic solution of choice. Antibiotics of choice may be added.
4. **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.

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.

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

<sup>1</sup> 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



### Allograft Tissue Insert and 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<br>Attn: Tissue Usage<br>2900 College Dr.<br>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#      |
| _____                     |
| Place Peel-Off Label Here |

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

|                           |
|---------------------------|
| Allograft Tissue ID#      |
| _____                     |
| 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.