

ALLOGRAFT PACKAGE INSERT

DONATED HUMAN TISSUE

THIS ALLOGRAFT IS SUPPLIED STERILE

This human tissue allograft is processed and supplied by CellRight Technologies. All tissue was retrieved, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB), FDA requirements for Human Cellular and Tissue Based Products (HCT/PS 21 CFR Part 1271), and applicable State regulations. The Donor has been determined to be eligible based on the results of screening and testing. Screening includes a review of medical and social history, available hospital records, infectious disease screening, autopsy report (if performed), and physical exam. The Donor has been tested and was found negative or non-reactive for:

- Human Immunodeficiency Virus Types 1 and 2 Antibody (anti-HIV-1/anti-HIV-2)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody - Total (anti-HBc)
- Hepatitis C Virus Antibody (anti-HCV)
- Human Immunodeficiency Virus 1, Hepatitis C Virus, Hepatitis B Virus Nucleic Acid Test (HIV 1/HCV/HBV NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- *West Nile Virus Nucleic Acid Test (WNV NAT)

*Birth Tissue Only

Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. U.S. Food and Drug Administration (FDA) licensed, approved, or cleared donor screening test kits are used when available. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing 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). A list of additional communicable disease test(s) performed will be provided upon request.

CellRight Technologies Medical Director has determined this donor tissue to be suitable for transplantation. The testing and medical release records are maintained by CellRight Technologies. The names and addresses of the testing laboratories, the interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are kept on file at CellRight Technologies and are available upon request.

Tissue has been sterilized, using Cobalt 60, to a SAL of 10^{-6} (Sterility Assurance Level). Allografts are processed using some or all of the following agents: physiological buffers, acids, alcohols, surfactants, hydrogen peroxide, Gentamicin Sulfate, Vancomycin HCl, Amphotericin B, Polymyxin B, and/or Ciprofloxacin and traces may remain.

Tissues may be supplied freeze dried, air dried, hydrated, or frozen. CellRight provides storage requirements in the package insert and on the final label that accompanies each graft. Additionally, osseous grafts may undergo demineralization. Grafts that have been demineralized will have a residual calcium level $\leq 8\%$. When applicable, a description of how the tissue is supplied (Freeze Dried, Air Dried, or Frozen; Demineralized or Mineralized) is contained in the upper right hand corner of the final label included with the graft.

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 seal on the inner-most pouch, the tissue grafts must be transplanted or discarded.
- Tissue may not be sterilized or re-sterilized by your facility.

- This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrist.
- Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- 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.

STORAGE

HYDRATED DBM- Maintain tissue at room temperature (15°C - 30°C).

FREEZE-DRIED/AIR DRIED TISSUE - Maintain tissue at ambient temperature.

FROZEN TISSUE – Maintain tissue at -40°C or colder. Short term storage of up to 6 months is acceptable if tissue is maintained at -20°C to -39°C.

TISSUE PREPARATION

BEFORE USE – Examine Allograft Packaging – Do Not Use This Allograft If:

1. Any of the package elements appear to be missing, tampered with or damaged.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed
4. Frozen allograft has not been stored according to storage temperature requirements or the allograft has been prematurely thawed.

If any of the above conditions exist or are suspected, this allograft should NOT be used.

PREPARATION OF HYDRATED DEMINERALIZED BONE MATRIX (DBM) AND FREEZE DRIED INDUCTIVE CARRIER MATRIX (ICM) FOR USE:

1. PRODUCT TYPE
 - a. Hydrated DBM is Ready to use – does not require thawing or rehydration.
 - b. Freeze Dried ICM – Requires hydration prior to use. A label located on the container of product indicates the amount of solution to add.
2. Opening Peel Packages: peel outer package down and aseptically deliver inner peel pouch to the sterile field or sterile team member.
3. The product is contained inside the inner pouch in a jar, syringe, or other storage container.
4. Remove container of product from the Inner peel pouch.
 - a. Jar – Unscrew the top. (Freeze Dried ICM - add solution and mix) Remove the product from the jar. Mold into desired shape and press into defect.
 - b. Syringe – Remove protective cap from syringe tip or remove the syringe end cap completely. Apply pressure to the plunger to extrude the DBM. Mold into desired shape and press into defect.
5. Irrigation resistant once molded and pressed into the defect.
6. For best results. The DBM must fill the defect and contact as much viable bone as possible.

PREPARATION OF FREEZE-DRIED / AIR-DRIED ALLOGRAFT TISSUE FOR USE

1. Opening Peel Packages: peel outer package down and aseptically deliver inner peel pouch to the sterile field or sterile team member.
2. Remove tissue from Inner peel pouch.
3. Tissue may be maintained within the inner pouch in a jar, syringe, or other storage container.
 - a. Jar – Unscrew the top. Rehydrate tissue in jar or transfer tissue to a basin for rehydration.
 - b. Syringe – Rehydrate tissue in syringe or transfer to a basin for rehydration.
4. Rehydrate the tissue, when applicable.
 - a. Final determination of allograft reconstitution should be made by the physician prior to use. Rehydrate using a sterile isotonic solution or solution of physicians' choice.
 - b. Recommendation - Non-weight bearing osseous grafts and soft tissue should be reconstituted for a minimum of 30 minutes.
 - c. Recommendation - Weight bearing grafts should be reconstituted approximately 1 hour.
 - d. Recommendation – Grafts that are to be manipulated by drilling or cutting or require force to insert may require a longer period of reconstitution prior to manipulation to reduce the chance of fracturing.
 - e. Recommendation – Amniotic Membrane may be applied dry or hydrated.
5. 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°C to 10°C in an aseptic container for no longer than 6 hours.
6. IMPORTANT! Peel away and remove all internal packaging materials, if present, from the graft (i.e. gauze or mesh) prior to implantation.

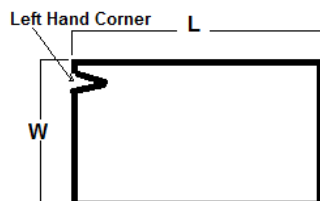
PREPARATION OF FROZEN ALLOGRAFT TISSUE FOR USE

1. Opening Peel Packages: peel outer package down and aseptically deliver inner peel pouch to the sterile field or sterile team member.
2. Remove tissue from Inner peel pouch.
3. Remove tissue from inner package and place in sterile basin and cover with normal saline or isotonic solution of choice. Antibiotics of choice may be added.
4. Tissue should remain in solution until thawed. Tissue thawing temperature should not exceed ambient or room temperature. DO NOT MICROWAVE.
5. Tissue should be used as soon as possible after thawing. If tissue is to be stored for longer than 2 hours after thawing, it should be refrigerated at 1°C to 10°C in an aseptic container for no longer than 6 hours.
6. Do not refreeze product if thawed.
7. IMPORTANT! Peel away and remove all internal packaging materials, if present, from the graft (i.e. gauze or mesh) prior to implantation.

FROZEN DERMIS ORIENTATION

Frozen Dermis has two distinct sides, the side that would have been oriented nearest the basement membrane of the epithelium, referred to in this document as the "Basement Membrane" side and the side oriented toward the donor's adipose, referred to as the "Dermal" side.

To determine the orientation of Frozen Dermis, position the graft so the indication notch is in the upper left-hand side of the tissue, facing left. This will assure that the basement membrane side is facing up.



Every effort is made to ensure all hair has been effectively removed from the allograft. If any hair is present, remove them before implantation. If they cannot be easily removed, please contact CellRight Technologies.

RETURNS

With prior approval, unused, unopened tissue may be returned to CellRight provided CellRight personnel have authorized the return and issued a return authorization number. The responsible individual at your facility must obtain a Tissue Return Authorization Form from CellRight Technologies, complete the required information and provide a signature declaring the unopened tissue has been continuously stored according to instructions and that proper transportation has been utilized to ensure tissue integrity during the return. This form must be completed for credit to be issued.

Contact Customer Service at CellRight Technologies by email or phone.
Email: CustomerCare@CellRightTechnologies.com
Phone: 1-210-659-9353

ADVERSE OUTCOMES

Adverse outcomes potentially attributable to this tissue must be reported promptly to CellRight Technologies.

TISSUE TRACKING

Complete the enclosed Allograft Tracking Form and mail to CellRight Technologies. US 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 CellRight Technologies to maintain records for the purpose of tracing the tissue post-transplant.

Processed and Distributed By:



**1808 Universal City Blvd
Universal City, TX 78148
210-659-9353
Fax: 210-659-9556**

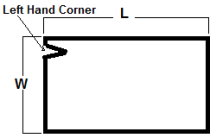
www.CellRightTechnologies.com

CellRight Technologies holds:
AATB Accreditation No. 00212
US FDA Registration No. 3009234552
Canadian Registration No. 100228
California Tissue Bank ID No. CNC80949
Florida License No. 212
Maryland Tissue Bank No. TB1898
New York State Tissue Bank ID No. CPI73TP141TS145

DOCUMENT APPROVALS

	Signature	Date
Author/Revised By:		
<input checked="" type="checkbox"/> NA Department Head:	NA	NA
<input checked="" type="checkbox"/> NA Medical Director:	NA	NA
V.P. Operations:		
CEO:		
Quality:		

REVISION HISTORY

REV #	CCN	DESCRIPTION AND JUSTIFICATION
A	NA	ORIGINAL
B	CCN14-0006	<p>Add Form # and Rev to front, top, left hand corner of form for easy identification. Add info for DBM Putty and combine frozen dermis addendum with form.</p> <p>STORAGE <u>DEMINERALIZED BONE MATRIX (DBM) GRAFTS - Maintain tissue at room temperature (15°C - 30°C).</u></p> <p>PREPARATION OF DBM FOR USE <u>1. Ready to use – DBM is provided as a paste, putty, gel or crunch product that is ready for implantation. It does not require thawing or rehydration.</u> <u>2. Opening Peel Packages: peel outer package down and aseptically deliver inner peel pouch to the sterile field or sterile team member.</u> <u>3. DBM is contained inside the inner pouch in a jar, syringe, or other storage container.</u> <u>4. Remove container of DBM from the Inner peel pouch.</u> <u>a. Jar – Unscrew the top. Remove DBM from the jar. Mold into desired shape and press into defect.</u> <u>b. Syringe – Remove protective cap from syringe tip or remove the syringe end cap completely, Apply pressure to the plunger to extrude the DBM. Mold into desired shape and press into defect.</u> <u>5. Irrigation resistant once molded and pressed into the defect.</u> <u>6. For best results. The DBM must fill the defect and contact as much viable bone as possible.</u></p> <p>PREPARATION OF FREEZE-DRIED or DEHYDRATED ALLOGRAFT TISSUE FOR USE 3. Tissue may be maintained within the inner pouch in a jar, syringe, or other storage device <u>container</u>. 4. Rehydrate the tissue, <u>when applicable</u>.</p> <p>FROZEN DERMIS ORIENTATION <u>Frozen Dermis has two distinct sides, the side that would have been oriented nearest the basement membrane of the epithelium, referred to in this document as the “Basement Membrane” side and the side oriented toward the donor’s adipose, referred to as the “Dermal” side. To determine the orientation of Frozen Dermis, position the graft so the indication notch is in the upper left-hand side of the tissue, facing left. This will assure that the basement membrane side is facing up.</u></p>  <p><u>CellRight Technologies holds:</u> <u>AATB Accreditation No. 00212 ; US FDA Registration No. 3009234552 ; Canadian registration No. 100228 ; California Tissue Bank ID No. CNC80949 ; Florida License No. 212 ; Maryland Tissue Bank No. TB1898 ; New York State Tissue Bank ID No. CP173TP141TS145</u></p>

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<p>C</p>	<p>CCN16-0030</p>	<p>The Donor has been determined to be <u>eligible/suitable</u> based on the results of screening and testing. Human Immunodeficiency Virus 1, and Hepatitis C Virus, <u>Hepatitis B Virus</u> Nucleic Acid Test (HIV 1/HCV/<u>HBV</u> NAT) • Syphilis Rapid Plasma Reagin or Treponemal Specific Assay Additional tests, including but not limited to HTLV I/II <u>and HBV Nucleic Acid Testing</u>, may have been performed and were found to be acceptable for transplantation. <u>Tissues may be supplied freeze dried, hydrated, or frozen. CellRight provides storage requirements in the package insert and on the final label that accompanies each graft. Additionally, osseous grafts may undergo demineralization. Grafts that have been demineralized will have a residual calcium level ≤8%. When applicable, a description of how the tissue is supplied (Freeze Dried or Frozen; Demineralized or Mineralized) is contained in the upper right hand corner of the final label included with the graft.</u> STORAGE FREEZE-DRIED or DEHYDRATED TISSUE - Maintain tissue at <u>ambient temperature</u> room temperature (15°C – 30°C) . DEMINERALIZED BONE MATRIX (DBM) GRAFTS <u>HYDRATED DBM</u>- Maintain tissue at room temperature (15°C - 30°C). (DBM) AND FREEZE DRIED INDUCTIVE CARRIER MATRIX (ICM) FOR USE: 1. <u>PRODUCT TYPE a. Hydrated DBM is</u> Ready to use – DBM is provided as a paste, putty, gel or crunch product that is ready for implantation. It does not require thawing or rehydration. b. <u>Freeze Dried ICM – Requires hydration prior to use. A label located on the container of product indicates the amount of solution to add.</u> 3. <u>DBM</u> <u>The product</u> is contained inside the inner pouch in a jar, syringe, or other storage container. 4. Remove container of <u>DBM product</u> from the Inner peel pouch. a. Jar – Unscrew the top. (<u>Freeze Dried ICM - add solution and mix</u>) Remove <u>DBM the product</u> from the jar. Mold into desired shape and press into defect. PREPARATION OF FREEZE-DRIED or DEHYDRATED</p> <table border="1" data-bbox="349 724 1526 940"> <thead> <tr> <th>Tissue Type</th> <th>Supplied</th> </tr> </thead> <tbody> <tr> <td>CG</td> <td>Freeze Dried, Mineralized</td> </tr> <tr> <td>FRZ ST and FRZ Derm</td> <td>Frozen</td> </tr> <tr> <td>FD Derm</td> <td>Freeze Dried</td> </tr> <tr> <td>DCM</td> <td>Freeze Dried, Demineralized</td> </tr> <tr> <td>DBMW</td> <td>Hydrated DBM, Demineralized</td> </tr> <tr> <td>DBMWP</td> <td>Hydrated DBM, Demineralized/Mineralized</td> </tr> <tr> <td>DBMD</td> <td>Freeze Dried ICM, Demineralized</td> </tr> </tbody> </table> <p>JUSTIFICATION: Revisions made in response to AATB 14th Edition of the standards that become effective 01/01/2017. HBV NAT added as a required test – FDA Requirement for HCT/Ps.</p>	Tissue Type	Supplied	CG	Freeze Dried, Mineralized	FRZ ST and FRZ Derm	Frozen	FD Derm	Freeze Dried	DCM	Freeze Dried, Demineralized	DBMW	Hydrated DBM, Demineralized	DBMWP	Hydrated DBM, Demineralized/Mineralized	DBMD	Freeze Dried ICM, Demineralized
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DBMD	Freeze Dried ICM, Demineralized																	
<p></p>	<p>03/13/17</p>	<p>Minor Change – Change Suitable back to eligible on page 1. RMS 03/13/17 / JH 03/13/17</p>																
<p>D</p>	<p>CCN17-0015</p>	<p>Updated Logo <u>*West Nile Virus Nucleic Acid Test (WNV NAT) *Birth Tissue Only</u> Tissues may be supplied freeze dried, <u>air dried</u>, hydrated, or frozen. When applicable, a description of how the tissue is supplied (Freeze Dried, <u>Air Dried</u>, or Frozen; Demineralized or Mineralized) STORAGE FREEZE-DRIED/<u>AIR DRIED</u> TISSUE - Maintain tissue at ambient temperature. PREPARATION OF FREEZE-DRIED / <u>AIR-DRIED</u> ALLOGRAFT TISSUE FOR USE <u>4.e. Recommendation – Amniotic Membrane may be applied dry or hydrated.</u> JUSTIFICATION: Amniotic Membrane requirements added. Version D will be used for amniotic membrane only until the current supply of version C is exhausted.</p>																



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DEPARTMENTS

M&S – Marketing and Sales. P&MM – Purchasing and Materials Management, PRO– Processing Technicians/Circulators, DT – Decontamination Technicians, FO – Facilities Operations, R&S – Receiving and Shipment, R&D – Research and Development, QC – Quality Control, DS – Donor Services, LAB – Laboratory

<input checked="" type="checkbox"/> M&S	<input type="checkbox"/> P&MM	<input type="checkbox"/> PRO	<input type="checkbox"/> DT	<input type="checkbox"/> FO	<input type="checkbox"/> R&S	<input type="checkbox"/> R&D	<input checked="" type="checkbox"/> QC	<input type="checkbox"/> DS	<input type="checkbox"/> LAB
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EMPLOYEE REVIEW

NAME (print)	Department/Title	Signature	Date
Patricia Cappelli	QC		
Samuel Kelley	PRO		
David Mares	QC		
Elaine Mendoza	DS		
Douglas Nelson	FC		
Gianna Rodriguez	QC		
Shane Sallee	M&S		
Vince Trevino	QC		