VNEW® Precut Shaped Decellularized Dermal Allograft Instructions For Use

ARMSV-7506 Rev. A

DESCRIPTION

VNEW® Precut Shaped Decellularized Dermal Allografts are produced from donated human tissue intended for transplant. All tissue is recovered, processed, stored, and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB) and U.S Federal Regulations CFR 21 part 1270 and 1271.

VNEW® Precut Shaped Decellularized Dermal Allografts are intended to be used to provide reinforcement, repair, or replacement of damaged or inadequate or inadequate integumental tissue or for other homologous uses of human integument.

DONOR SCREENING / TESTING

Donors have been determined to be eligible for donation by CellRight Technologies at 1808 University City Blvd., Universal City, TX 78148. A Medical Director (licensed physician) evaluates donors for eligibility. Donor eligibility is 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.

Infectious disease testing is performed by a laboratory registered with the U.S. Food and Drug Administration (FDA) and certified under CLIA standards or equivalent requirements. Test kits are FDA licensed or approved for donor testing. The following test criteria were met for this allograft:

Required Infectious Disease Tests and Acceptable Result	
Blood Test	Acceptable Result
HIV I/II Antibody: Human Immunodeficiency Virus Type I/II	Negative/ Non-reactive
HBsAG: Hepatitis B Surface Antigen	Negative/ Non-reactive
HBcAB: Hepatitis B Total Core Antibody	Negative/ Non-reactive
HBV NAT: Hepatitis B Virus Nucleic Acid Test	Negative/ Non-reactive
HCV NAT: Hepatitis C Virus Nucleic Acid Test	Negative/ Non-reactive
HIV NAT: Human Immunodeficiency Virus Nucleic Acid Test	Negative/ Non-reactive
HCVAb: Hepatitis C Virus Antibody	Negative/ Non-reactive
RPR/STS for Syphilis	Negative/ Non-reactive

*Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation.

PROCESSING / STERILIZATION

Tissue is processed aseptically in a clean-room environment using a validated method to remove the epidermis, cells, and cell remnants. Preparation exposes the skin to antibiotics (Gentamicin, Nystatin, Vancomycin, Polymixin B, Imipenem) and processing reagents including sodium dodecyl sulphate, DNase, RNase, and glycerol. Tissue is treated to reduce residual content of reagents, however traces may remain.

NOTE: Follow instructions for allograft preparation prior to application.

Tissue labeled as STERILE R has been sterilized using gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6}.

STORAGE

Storage Method	Special Instructions
Ambient	Do not freeze
	Protect from excessive heat
	Must use once opened

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.

VNEW® ALLOGRAFT PREPARATION

1) Inspect for package integrity and expiration date prior to opening.
2) Peel outer package open and aseptically deliver inner package to the sterile field or sterile team member.
3) Partially fill a sterile basin with normal saline or isotonic solution of choice. For product sizes ≥ 12 cm^2, use a minimum of 400 mL, for product sizes <12 cm^2, utilize a minimum of 100 mL. It is recommended that the temperature of the solution be not greater than 98.6°F or 37°C.
4) Remove the allograft from inner package and discard packaging mesh. **IMPORTANT:** DO NOT implant packaging mesh.
5) Immerse the allograft in the sterile basin for 10 minutes, providing periodic gentle agitation.
6) VNEW® should be used as soon as possible after opening. If the allograft is to be stored for longer than 2 hours after opening, it should be refrigerated at 34°F to 50°F (1°C to 10°C) while immersed in normal saline or isotonic solution in an aseptic container. An opened allograft should be stored for no longer than 24 hours.

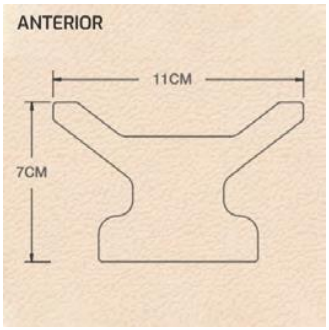

Fig 1.0: VNEW® Anterior

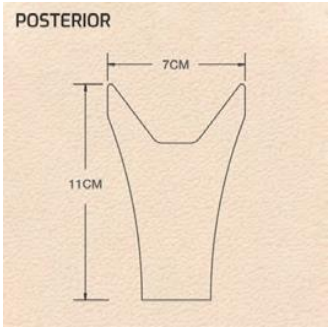

Fig 2.0: VNEW® Posterior

VNEW® ALLOGRAFT APPLICATION

This section provides instructions for VNEW® Non-Oriented anterior and posterior application.

IMPLANTED APPLICATION

1) **VNEW®**: Place the allograft into the area needing integumental tissue. Utilizing sterile scissors or scalpel, remove excess VNEW®.
2) Secure the allograft with sutures if needed.

WARNINGS/ 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 package seal, the allograft must be transplanted or discarded within 24 hours.
  - Do not use past expiration date listed on the product label.
- Do not sterilize or re-sterilize the allograft.
- This allograft is intended for use by qualified healthcare specialists.
- Although this allograft has been tested and screened for human pathogens and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- Adverse events potentially attributable to this allograft must be reported promptly to CellRight Technologies at (210) 659-9353 or by email to customercare@cellrighttechnologies.com.

ADVERSE EFFECTS

As with any allograft tissue, some risk of disease transmission exists. Adverse effects may include but are not limited to infection, allergic reaction to residual processing reagents, immune response to allograft tissue, or loss of integrity/functionality of tissue. Caution should be used if the patient has a known sensitivity to any of the reagents/antibiotics listed in this insert.

TISSUE TRACKING

Complete the enclosed Allograft Tracking Form and return to ARMS Medical. 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 ARMS Medical to maintain records for tracing the tissue post-transplant.

Tissue tracking forms may be returned to ARMS Medical via mail to the address below, email to implant@armsmedical.com, or fax to (781) 839-9802.

Document Control
10581 Marin Ranches Dr.
Cooper City, FL 33328

CUSTOMER SERVICE

Please contact TRX BioSurgery at (855) 452-0133 should you require additional information.

CellRight Technologies makes no claims concerning the biological or biomechanical properties of the provided tissue. CellRight Technologies disclaims all liability and responsibility for any misuse of tissue provided for clinical application. CellRight Technologies is accredited by the American Association of Tissue Banks.

DEFINITION OF SYMBOLS

	Read Instructions for Use
	Single Patient Use Only
	Store at Ambient Temperature
Rx only	For use by licensed professional only
STERILE R	Gamma irradiated for sterility
	Manufacturer
	Do Not re-sterilize

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CellRight Technologies
1808 University City Blvd
Universal City, TX 78148
1-210- 659-9353

TRX BioSurgery
1808 University City Blvd
Universal City, TX 78148
1-855-452-0133
www.tissueregenixus.com

CellRight Technologies holds:
AATB Accreditation No. 00212
US FDA Registration No. 3009234552
Canadian Registration No. 100228

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ARMS Inc. is doing business as ARMS Medical.