ari®

Acellular Allograft Amniotic Membrane

ari® is a room temperature stable allograft derived from human placental tissue collected from consenting donors. Prior to being packaged in a double pouch packaging system and terminally sterilized using low dose gamma irradiation, ari® is processed, stabilized, and configured using proprietary technologies.

Preparation and quality assurance methodologies applicable to this ari® allograft product were employed at an FDA registered tissue establishment accredited by the American Association of Tissue Banks (AATB) and comply with federal requirements for Human Cellular and Tissue Based Products (HCT/P) found in 21 CFR 21 Part 1270 and 1271, all applicable state requirements, and AATB Standards.

Donated Human Tissue

INSTRUCTIONS FOR USE

PROCESSED BY:

Seed Biotech, Inc.
3116 Commerce Street
Suite A
Dallas, TX 75226
www.seedbiotech.com

Customer Service
1.214.741.6314
FEI: 3000779542

ALLOGRAFT PROCESSING

Technical Quality Assurance standards are rigorously maintained by Seed Biotech, Inc. This allograft was processed, stabilized, configured and packaged using aseptic techniques in ultra-clean controlled micro-environments after which it is was terminally sterilized via a ISO11137 validated low dose gamma irradiation method (17.5-21kGy). Supplemental lot-to-lot validated sterility testing is performed to achieve maximum confidence.

Seed Biotech, Inc. allografts are prepared using proprietary processing and stabilization technologies designed to remove unwanted material, such as cells, intracellular genetic material, and antigens, while preserving the native extracellular matrix (ECM) and non-cellular constituents of the tissue material, such as the basement membrane, fibrous proteins, non-fibrous proteins, glycosaminoglycans and proteoglycans. Clinically relevant analyses of native and processed material from single donor tissue material lots were performed as a part of the verification and validation activities conducted for the allografts provided by and processes used by Seed Biotech, Inc. DNA % reduction, residual DNA quantification, immunohistochemical detection of critical basement membrane and ECM constituents & histological assessment of tissue material organization and microarchitecture were some of the evaluations conducted to assess licensed proprietary process technologies prior to Seed Biotech, Inc. implementation and use for preparation of offered allografts. In addition to initial studies conducted, Seed Biotech, Inc. employs lot to lot bioanalytical testing methodologies to offer industry innovative quality assurance of every processed tissue material lot which requires satisfaction of end process acceptance criteria and material specifications of clinical relevance. End process criteria is used as a final determination and verification that the process activities conducted for any and all donated tissue material lots resulted in sufficient reduction/removal of unwanted constituents. In addition to characterization and testing related to ensuring decellurization process, performance of GLP biocompatibility and toxicity preclinical testing according to ISO10993 including pyrogenicity, cytotoxicity, genotoxicity, sensitivity, irritation, systemic toxicity, endotoxicity, and hemolysis testing; performance of shelf life and distribution packaging validations and conduct in vivo performance evaluations demonstrated all products safety and suitability for clinical use.

ALLOGRAFT GENERAL USE

This allograft is intended for homologous use and can be used in a variety of ophthalmic, orthopedic, surgical, spinal, and wound covering applications. Aseptic technique should be used to open outer pouch and pass sterile inner pouch to sterile field. Sterile technique should be used to open sterile inner pouch and remove allograft.

DONOR CONSENT, RECOVERY & SCREENING

Seed Biotech, Inc. uses select FDA registered tissue recovery partners for collection of donor tissue intended for transplantation. Subsequent to the conduct of a comprehensive review of the donor of this allograft's informed consent, medical history, risk assessment interview, physical examination, available medical records, collection & transport records, collection microbiology culture results, and infectious disease test results the medical director of Seed Biotech Inc., a licensed physician, determined that the donor of this allograft tissue satisfies the medical eligibility requirements identified in Seed Biotech, Inc.'s Donor Acceptance Criteria Policy which exceeds requirements established by the Federal Drug Administration and specified in the AATB standards.

Prior to processing, blood specimens collected at the time of tissue recovery from the donor of this allograft tissue were tested for the relevant communicable disease agents found in Table 1 and non-reactive or negative test results were obtained. All serological and microbiological testing was conducted using FDA approved tests. Communicable disease testing was performed by a CLIA certified laboratory registered with the FDA to perform donor testing.

INFECTIOUS DISEASE TESTING	
BLOOD TEST	**ACCEPTABLE RESULT**
HIV-1 / HIV-2 Antibody	Negative / Non-Reactive
Hepatitis C Virus Antibody	Negative / Non-Reactive
Hepatitis B Surface Antigen	Negative / Non-Reactive
Hepatitis B Core Antibody (Total)	Negative / Non-Reactive
Syphilis Rapid Plasma Reagin or Treponemal Specific Assay	Negative / Non-Reactive
Human T-Cell Lymphotropic Virus I	Negative / Non-Reactive
Human T-Cell Lymphotropic Virus II	Negative / Non-Reactive
Hepatitis B NAT	Negative / Non-Reactive
Hepatitis C NAT	Negative / Non-Reactive
HIV NAT	Negative / Non-Reactive
West Nile Virus NAT	Negative / Non-Reactive

Table 1

In addition to the preclinicinal safety testing, lot to lot bioanalytical testing, donor screeening and testing, and process validation, comprehensive, a Quality Assurance review of processing & packaging records, finished tissue microbiology cultures, and the labeling & gamma irradiation records associated with the donor of this allograft was performed prior to this allograft being released for distribution. The names and addresses of Seed Biotech, Inc.'s tissue recovery partners and clinical testing service providers, the testing and interpretation of all donor screening and infectious disease test results, the list of the documents reviewed as part of this donor's relevant medical records, and the name of the person determining the suitability of this donated human tissue are on file at Seed Biotech, Inc. and are available upon request.

ALLOGRAFT STORAGE

Maintain this allograft in a clean, dry environment at room temperature.
No refrigeration is necessary. Do not freeze.

See package label for expiration date. It is the responsibility of the tissue dispensing service and/or the end user to maintain this allograft in the appropriate storage conditions prior to transplant.

ALLOGRAFT PACKAGING, LABELING & SHIPPING

This allograft tissue is identified by its own unique serial ID and was packaged in a sterile, single-patient-use inner pouch which was placed in a secondary peel pouch and labeled with the expiration date, serial ID, and allograft tissue size and description.

ALLOGRAFT USE RECOMMENDATIONS

SUBCUTANEOUS IMPLANTATION:

a. Select the proper allograft size according to the defect or exposed area of abutting structure. The size selected should permit the edges of the allograft to extend beyond the perimeter of the defect on all sides and/or cover the entire exposed area of the abutting structures. Allograft selection should be prior to placement. If necessary, however, the dry allograft can easily be trimmed prior to placement and multiple pieces of the allograft may be placed or sutured together and used to cover exposed structures or defects in the event a single allograft large enough to cover defect or structure is not available.

b. Absorbable or non-absorbable suture material may be used to prevent displacement and/or to secure the allograft. Select the appropriate needle and suture size for the surgical procedure. Place the stitches at least 3-5mm from the edge of the allograft to achieve a resultant minor to moderate tension.

c. After placement, the allograft should be rehydrated using sterile saline.

WOUND COVERING:

a. Select the proper allograft size according to the tissue defect or exposed area. The size selected should permit the edges of the allograft to abut the edges of the defect or extend beyond the edges of the defect covering the defect completely. Allograft size selection should be done so as to minimize the extent of trimming and manipulation required prior to placement. If necessary, however, the dry implant can easily be trimmed prior to placement and multiple pieces of implant may be placed or sutured together and used to cover defects in the event a single piece of tissue is not large enough for adequate coverage.

b. After placement, the allograft should be rehydrated using sterile saline.

c. Use additional dressings as needed for optimal healing environment.

WARNINGS/CAUTIONS

Careful donor screening, testing, and processing is performed as a part of the qualification of all tissue donors and preparation of all allografts provided by Seed Biotech, Inc. As with any allograft there are limits of the screening, testing, and processing methods that can be employed, and allograft tissue provided by Seed Biotech, Inc. cannot be guaranteed to be free of all pathogens or unwanted constituents, nor can the risk for disease transmission be eliminated.

Residual germicide is performed on a lot to lot basis however trace amounts of ethanol and/or chlorhexidine gluconate may be present in this product.

This allograft must be stored properly until its time of use. Do not use this allograft if it or its packaging appears to be missing, tampered with, or damaged, and notify Seed Biotech, Inc. Customer Services & Support immediately.

This allograft is intended to be single use on a single patient in a single clinical event. This allograft tissue should be used or discarded promptly after the inner sterile pouch it is provided in has been opened.

Do not subject this allograft to additional sterilization procedures.

This allograft should be used with caution where an active infection is present. If the surgeon determines that the clinical circumstances require use in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken.

WARRANTY STATEMENT

This allograft is unique and does not constitute a product under liability laws. No implied warranties of merchantability or fitness for a particular purpose are applicable. No implied warranties exist as to defects in biologics which cannot be detected, removed, or prevented by reasonable use of available scientific procedures or techniques. Furthermore, ALL WARRANTIES ARE DISCLAIMED, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ADVERSE EVENTS

Please immediately report all adverse events to Seed Biotech, Inc.

Seed Biotech Customer Service
P: 1.214.741.6314
E: customerservice@seedbiotech.com

RETURNS

If for any reason the allograft tissue must be returned, a return authorization is required from Seed Biotech, Inc. prior to shipping. Reimbursement, replacement, or financial credit will be given at the sole discretion of Seed Biotech, Inc. It is the responsibility of the health care institution returning the allograft to adequately prepare and identify the tissue for return shipment.

TRACKING & TISSUE UTILIZATION RECORD

Recipient records must be maintained for the purpose of tracking this allograft. Serialized allograft description labels have been provided with this allograft tissue for the use of completing patient's medical records.

A Tissue Utilization Record (TUR) labeled specifically to this allograft has been provided. Please complete in full and return the record to Seed Biotech, Inc. The TUR card should be submitted even if the allograft was discarded.

SYMBOL KEY

	Consult Instructions for use
EXP or 	Expiration date
	Do not re-sterilize
 38°C (100°F)	Storage temperature limits
	Single use only. Do not reuse.
$\mathrm{Rx}_{\mathrm{only}}$	Caution: Federal (USA) law restricts the use of this allograft to sale by or on the order of a licensed physician, dentist, and podiatrist.
REF	Catalog number
LOT	Lot number (Donor ID)
SN	Serial number (Tissue ID)
	Do not use if inner package is damaged.
STERILE R	Sterile by irradiation.
	Manufacturer

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