ATTENTION OPERATING SURGEON - READ BEFORE USING

DermaSpan™ ACD

Human Acellular Dermis Allograft Tissue

DermaSpan™ ACD is provided to Biomet® by Tissue Banks International (TBI). See contact information below.

Allografts are provided from DONATED HUMAN TISSUE

CAUTION: ALLOGRAFT IS FOR SINGLE USE ONLY

THIS TISSUE WAS RECOVERED FROM A SINGLE HUMAN DONOR WITH DOCUMENTED PERMISSION FOR DONATION AND RECOVERY. THE TISSUE IS SUPPLIED FROM U.S. TISSUE BANKS ONLY. THE RECOVERY, PROCESSING, AND PACKAGING WAS PERFORMED USING ASEPTIC TECHNIQUES. THE ALLOGRAFT IS TERMINALLY STERILIZED IN ITS FINAL PACKAGING.

DESCRIPTION

DermaSpan™ ACD is human allograft skin minimally processed to remove epidermal and dermal cells. The process utilized preserves the remaining bioactive components and extracellular matrix of the dermis. The resulting acellular matrix is freeze-dried (lyophilized) without damage to the matrix components and is designed to be rehydrated quickly with sterile isotonic solution such as normal saline or lactated Ringer's. The resulting allograft functions as a framework to support cellular repopulation and vascularization at the surgical site.

INDICATIONS FOR USE

DermaSpan™ ACD is processed to remove cells while maintaining the integrity of the matrix with the intent to address the issues of the specific and nonspecific inflammatory responses. It is to be used for the repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument. DermaSpan™ Meshed ACD is to be used as a covering for skin wounds (burns, ulcers), and should not be used in any application where the allograft is to bear load. The standard allograft (non-meshed) may also be used for supplemental support, protection, reinforcement or covering of tendon. Each package of DermaSpan™ ACD is intended for use in one patient, on a single occasion by a licensed physician, surgeon, dentist or podiatrist.

CONTRAINDICATIONS

Use of DermaSpan™ ACD in patients exhibiting autoimmune connective tissue disease is not recommended. When applied properly DermaSpan™ ACD has been shown to support the migration of host cells from wound margins and surrounding tissue. Conditions that could inhibit migration of host cells include, but are not limited to the following:

- Fever
- Uncontrolled diabetes
- Pregnancy
- Low vascularity of the surrounding tissue
- Local or Systemic Infection
- Mechanical Trauma
- Poor nutrition or general medical condition
- Dehiscence and/or necrosis due to poor revascularization
- Specific or nonspecific immune response to some component of the allograft
- Inability to cooperate with and/or comprehend post-operative instructions
- Infected or nonvascular surgical sites

DermaSpan™ ACD may contain trace amounts of processing agents listed in the WARNINGS section of the insert. DermaSpan™ ACD should not be used in patients sensitive or allergic to these specific agents.

WARNINGS

Potential adverse effects that may result from placement of DermaSpan™ ACD include, but are not limited to the following: wound or systemic infection; seroma; dehiscence; hypersensitive; allergic or other immune response; sloughing or failure of the allograft; and disease transmission.

- Avoid usage of DermaSpan™ ACD in patients who are allergic to or have exhibited sensitivity to Gentamycin.
- Trace amounts of processing agents include, but are not limited to, Triton X-100.
- DermaSpan™ ACD is for single patient use only. Unused DermaSpan™ ACD, whole or partial may not be repackaged.
- Do not sterilize.
- Biomet® and TBI make no claims regarding the biologic or biomechanical properties.
- Do not use meshed allograft in load bearing applications.

Extensive medical screening procedures have been used in the selection of all tissue donors for TBI (please see Donor Selection, Screening and Testing). Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material may transmit infectious agents or diseases.

Donor Selection, Screening and Testing (Summary of Records)

TBI's commitment to tissue safety begins with donor selection and screening. Potential donors are screened for high risk behavior and contraindications to transplant through medical/social history interview, review of medical records, assessment of the donor's body, and review of post mortem-examination results (when applicable).

Individuals with risk factors for, conditions indicating, clinical evidence of, and/or physical evidence of infectious diseases, or communicable disease agents or diseases at the time of death are ineligible for donation. Examples include, but not limited to the following:

- HIV/AIDS, including risk factors such as injectable drugs for non-medical use, or high risk behavior
- Viral hepatitis
- Sepsis/systemic infection
- West Nile Virus
- Human transmissible spongiform encephalopathy (TSE), including Creutzfeldt - Jakob disease (CJD)
- Dementia, or any degenerative or demyelinating disease of the central nervous system or other neurological disease of unknown etiology
- Epstein Barr Virus
- Malaria
- Malignancy
- Autoimmune, connective tissue, and collagen diseases
- Communicable disease risks associated with xenotransplantation
- Other infectious diseases or disease of unknown etiology

Donors are also excluded for conditions or behaviors that significantly affect tissue quality.

All donors are subjected to communicable disease marker testing by a laboratory registered with 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), on a hemodilutionally qualified blood sample and found to be negative or non-reactive for a minimum of:

- HIV type 1 and 2 antibody (HIV-1 & 2 Ab)
- HIV type 1 nucleic acid test using PCR and/or TMA format (HIV-1 NAT)
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core antibody total (HBcAb)
- Hepatitis C virus (HCV Ab and HCV NAT)
- Syphilis by rapid plasma reagin (RPR) or other serological tests

Additional tests, including Human T-lymphotrophic virus I/II, may have been performed at the time of screening, and results were found acceptable for transplantation. A list of additional test(s), if performed can be provided upon request.

Tissue from this donor has passed bacteriological testing by a CLIA Certified Laboratory.

Donor eligibility determination made by TBI/Tissue Banks International staff in compliance with U.S. Food and Drug Administration (FDA) regulations (21 CFR 1270 and 1271) and American Association of Tissue Banks (AATB) Standards. TBI/Tissue Banks International's Medical Director further determines final eligibility and acceptability for transplantation after review of donor screening and testing records.

Based on the results of screening and testing this donor has been determined to be eligible for transplant.

Transportation, Storage and Handling

DermaSpan™ ACD must be stored and handled as follows:

- The freeze-dried allograft(s) are shipped at ambient temperature and can be stored between 1°C and 36°C (33.8°F and 96.8°F) until prepared for use.
- DermaSpan™ ACD must not be frozen.
- It is the responsibility of the transplant facility or clinician to maintain the allograft intended for transplantation in the appropriate recommended storage conditions prior to transplant.

How Supplied

DermaSpan™ ACD is supplied freeze-dried and terminally sterilized with N-Terface® membrane backing applied to the basement layer side. The allograft is then enclosed inside a sterile Tyvek inner pouch. The allograft and inner pouch are then enclosed in a secondary outer Poly-Foil pouch. The outer Poly-Foil pouch is labeled and then placed inside a labeled box.

Approximate dimensions and thicknesses are indicated on the labels as well as the expiration date.

Sterility Control

DermaSpan™ ACD is provided sterile following an internationally recognized validation method and monitoring process, in combination with a proprietary irradiation system using gamma radiation from cobalt-60 source material, to a target dose of 17 – 23 kGy.

Precautions

DermaSpan™ ACD should not be used under any of the following circumstances:

- If the expiration date shown on the labeling has passed.
- If the package integrity is damaged or compromised.
- If the labels or identifying barcodes are severely damaged, not legible or missing.
- Recommended storage conditions have not been maintained.

Instructions for Use

Minimum Equipment Required

- Two sterile basins large enough to accommodate the DermaSpan™ ACD without bending.
- Sterile isotonic solution volumetrically sufficient to completely submerge the allograft(s).
- Sterile forceps or similar instrument.

Rehydration Procedure

1. Peel open the outer pouch and introduce the sterile inner Tyvek pouch containing the allograft onto the sterile field.
2. Peel open the inner pouch and place the DermaSpan™ ACD into the sterile basin. Do not attempt to peel off the N-Terface backing from the allograft at this time.
3. Cover the allograft with sufficient volume of room temperature sterile isotonic solution to completely submerge the allograft. A surgical instrument can be placed on top of the allograft to aid in submerging. If desired, antibiotics may be added to the preparation basin.
4. The N-Terface backing will begin separating from the basement layer side of the allograft approximately 5-10 minutes after submersion and should be gently removed from the allograft.
5. When rehydrating multiple pieces, ensure that the pieces are not overlapping or clumping together as this will slow rehydration. If necessary, utilize multiple basins.
6. After 30 minutes, if the allograft is not rehydrated, transfer the allograft to a second basin with fresh, room-temperature sterile isotonic solution. Again ensure the allograft is completely submerged.
7. For 0.5 – 1.5 mm thick ACD, hydration typically takes 15 to 30 minutes. For 2.0 – 3.5 mm thick ACD, an additional 15 to 30 minutes may be required. Depending on the individual donor properties, hydration of some ACD pieces may take longer than others.
8. When DermaSpan™ ACD is fully rehydrated, it is soft and pliable throughout. At this stage, the ACD may be aseptically trimmed to desired dimensions and transferred to the surgical site.

NOTE: Once the inner Tyvek pouch containing DermaSpan™ ACD has been opened, the allograft must be transplanted during that surgical procedure, otherwise the allograft must be discarded if not used.

NOTE: If aseptic technique was suspect of being compromised during opening or rehydration processes, obtain a swab culture of the allograft and submit to your clinical laboratory for aerobic and anaerobic testing.

Orientation

DermaSpan™ ACD has distinct basement membrane and dermal sides. The basement membrane side has a distinctive dull appearance and repels blood. The dermal side has a distinctive shiny appearance and absorbs blood. The basement membrane can be distinguished as the side with the N-Terface membrane backing. Additionally, the standard allograft (non-meshed) contains a 2-3 mm orientation guide slit. When the allograft is orientated with the vertical slit in the upper right hand corner this indicates the basement membrane side is facing upward.

Optimal results are obtained when grafting by placing the dermal side of the allograft against the wound bed (basement membrane up). When utilized as an implant the dermal side should be orientated towards the most vascularized tissue.

If utilized to cover wounds with exposed internal organs, it is recommended that the basement membrane side be orientated toward the organs to decrease the likelihood of adhesion formation from the organ(s) to the allograft.

Tissue Tracing

The physician is responsible for completing the recipient records for the purpose of tracing tissue post transplant. As a convenience, an Allograft Tracking Form has been included to be completed at the time of the surgical procedure. A completed original is to be retained in the patient record and the copy sent back to Biomet Interpore Cross as indicated on the enclosed Allograft Tracking Form. If the entire tissue product was discarded, return the Allograft Tracking Form and explain the reason for discard.

Adverse Reactions

The physician is responsible for promptly reporting any adverse reaction that may be potentially attributable to the DermaSpan™ ACD allograft. Comments regarding this tissue can be directed to: Attn Regulatory Department Biomet Biologics 56 E. Bell Drive Warsaw IN 46581 (800) 348-9500.

Provided By

DermaSpan™ ACD is provided by Biomet® and prepared by TBI/Tissue Banks International, a non-profit, non-governmental network of eye and tissue banks.

TBI San Francisco is accredited by the American Association of Tissue Banks (AATB).

TBI/TISSUE BANKS INTERNATIONAL
Innovative Allografts. Maximum Safety.

Prepared By:

TBI San Francisco
880 Harbour Way South
Richmond CA 94804
Voice: 800-922-3100
Fax: 510-307-9896

BIOMET BIOLOGICS

Distributed By:

Biomet Biologics
56 E. Bell Drive
Warsaw IN 46581
Phone: 800-348-9500