

# DermaSpan™ ACD

**DONATED HUMAN TISSUE FROM U.S. TISSUE BANKS.  
THE RECOVERY AND PROCESSING WAS PERFORMED USING  
ASEPTIC TECHNIQUES. THE ALLOGRAFT IS TERMINALLY  
STERILIZED IN ITS FINAL PACKAGING.**

## DESCRIPTION

DermaSpan™ Acellular Dermal Matrix (ACD) is human allograft skin minimally processed to remove epidermal and dermal cells while preserving the remaining bioactive components and extracellular matrix of the dermis. The resulting ACD is freeze-dried (lyophilized) without damage to the matrix components and is designed to be rehydrated quickly with sterile isotonic solution or other physiologic fluid of the physician's choice. The resulting allograft functions as a framework to support cellular repopulation and vascularization.

## INDICATIONS FOR USE

DermaSpan™ ACD 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 (e.g. burns, ulcers) and should not be used in load-bearing applications. The standard allograft (non-meshed) may also be used for supplemental support, protection, reinforcement or covering of tendon or ligament, but is not intended to bear the load. Each package of DermaSpan™ ACD is intended for use in one patient on a single occasion by a licensed physician, surgeon, dentist or podiatrist.

## DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

DermaSpan™ ACD was prepared from a single donor with documented permission for donation and recovery, determined to be suitable based on the results of screening and testing. Donors are screened for high risk behavior and contraindications to transplant through medical/social history interview, review of medical records, physical assessment, and review of post mortem-examination results (when applicable). Tissue from this donor has passed bacteriological testing by a CLIA Certified Laboratory. Communicable disease testing was performed 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) 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 virus (HBV NAT and 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-lymphotropic virus I/II, may have been performed at the time of screening, and results were found acceptable for transplantation. A list of any additional test(s) performed can be provided upon request. Donor eligibility determination was made by Aziyo Biologics in compliance with U.S. FDA regulations (21 CFR 1270 and 1271) and American Association of Tissue Banks® (AATB®) Standards. The Medical Director determined final eligibility and acceptability for transplantation after review of donor screening and testing records.

## CONTRAINDICATIONS

Use of DermaSpan™ ACD in patients exhibiting autoimmune connective tissue disease is not recommended. DermaSpan™ should not be used in patients with sensitivities to processing agents (see WARNINGS).

## WARNINGS

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

- Trace amounts of processing agents include, but are not limited to gentamicin.
- Do not re-sterilize or reuse once opened.

Extensive medical screening procedures have been used in the selection of all tissue donors (see Donor 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.

## TRANSPORTATION, STORAGE AND HANDLING

The transplant facility or clinician must maintain the graft in the appropriate recommended storage conditions prior to transplant.

- DermaSpan™ ACD is shipped at ambient temperature and should be stored between 1°C and 36°C (33.8°F and 96.8°F).
- Do not freeze.

## HOW SUPPLIED

DermaSpan™ ACD is supplied freeze-dried and terminally sterilized with backing applied to the basement layer side. The graft is enclosed inside a sterile inner pouch, which is then enclosed in a secondary outer pouch. The outer pouch is contained inside a labeled box.

## STERILITY

DermaSpan™ ACD is sterilized to a Sterility Assurance Level of 10<sup>-6</sup> using an internationally recognized validation method and a proprietary irradiation system using gamma radiation from cobalt-60 source material.

## INSTRUCTIONS FOR USE

DermaSpan™ ACD should not be used if:

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

### Minimum Equipment Required

- Two sterile basins large enough to accommodate the DermaSpan™ ACD without bending.
- Sufficient sterile isotonic solution to completely submerge the graft.
- Sterile forceps or similar instrument.

### Rehydration Procedure

- Peel open the outer pouch and introduce the sterile inner pouch containing the graft onto the sterile field.
- Peel open the inner pouch and place the DermaSpan™ ACD into the sterile basin. Do not attempt yet to peel off the backing from the graft.
- Cover the graft with sufficient volume of room temperature sterile isotonic solution to completely submerge the graft. A sterile surgical instrument can be placed on the graft to aid in submersion.
- The backing will begin separating from the basement layer side of the graft approximately 5-10 minutes after submersion and then should be gently removed from the graft.
- After 30 minutes, if the graft is not rehydrated, transfer the graft to a second basin with fresh, room temperature sterile isotonic solution, ensuring the graft is completely submerged.
- For ACD grafts 0.5-2.0mm thick, hydration typically takes 15 to 40 minutes. For grafts greater than 2.0mm thick, an additional 15 to 30 minutes may be required.
- Once DermaSpan™ ACD is fully rehydrated, it is soft and pliable throughout and may be aseptically trimmed to desired dimensions.

**NOTE:** Once the inner pouch containing DermaSpan™ ACD has been opened, the graft must be transplanted during that surgical procedure. If the graft is not to be used within approximately two hours, maintain sterility and store at 2°C to 8°C. Use within 24 hours or discard.

**Orientation:** DermaSpan™ ACD has two distinct sides: a basement membrane and a dermal side. The basement membrane appears dull and repels blood. The dermal side appears shiny and absorbs blood. The non-meshed graft has a 2-3 mm slit that when oriented vertically in the upper right corner, the basement membrane is facing upward. The dermal side should be oriented against the wound bed or towards the most vascularized tissue. If covering wounds with exposed internal organs, the basement membrane should be orientated toward the organs to prevent adhesions from forming between the organ and allograft.

## ADVERSE REACTIONS

The end user clinician must promptly report any adverse reaction potentially attributable to DermaSpan™ ACD to: Attn. Regulatory Department Biomet Biologics (800) 348-9500.

## TRACEABILITY

The physician is responsible for updating the recipient records to ensure traceability to the donor. As a convenience, an Allograft Tracking Form is provided to be completed at the time of use. A completed original is to be retained in the patient record and the copy sent back to Biomet Interpore Cross. If the entire graft was discarded, return the Allograft Tracking Form with the reason for discard.

### Processed By:

**AZIYO**  
BIOLOGICS

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FDA Registration No. 1000100754  
CTO Registration Certificate No. 100242  
Accredited by the AATB®

### Distributed By:

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