HealthTech Wound Care, Inc.
1891 W 2100 S
Salt Lake City, UT 84119

DermaBind FM™ Instructions for Use

DermaBind FM™

Advanced placental wound covering
DermaBind FM™ is a dehydrated intact placental membrane allograft intended for use as a covering.

PRODUCT CODE
DFM2, DFM3, DFM4, DFM7

HOW SUPPLIED
This package contains a human cell and tissue allograft product (HCT/P) that is regulated by the Food and Drug Administration (FDA) under 21 CFR Part 1271 and Section 361 of the Public Health Service Act. In addition to this product insert, the following items should be included in the product package:

- Placental membrane covering
- Packing List
- Product Label(s)
- Instructions for use

STORAGE AND HANDLING
DermaBind FM™ is supplied/shipped dry until the package is opened. DermaBind FM™ should be stored at room temperature in dry conditions until the used or expiration date is reached. DermaBind FM™ may be stored up to the expiration date if the package has not been breached, and the temperature of the product does not fall below 4°C or above 30°C. If you find the package has been breached in any way or that the temperature has not been maintained, dispose of it appropriately. DO NOT USE.

The tissue product is for a single patient, one-time use only. Once opened, the tissue must be used immediately or disposed of appropriately. Please refer to the product ID label for expiration information. Proper storage is the responsibility of the end user.

GUIDANCE
This human cell and tissue product is not recommended for people who have a known sensitivity to DermaBind FM™. This product is intended for external wounds only.

PRECAUTIONS
Do not use the if the package seal is broken. Discard material if mishandling has caused possible damage or contamination.

Do not re-sterilize.

Shed the outer pouch before placing it onto the sterile field. Only the interior pouch is sterile.

DermaBind FM™ must be used before the expiration date on the product label.

PROCESSING
DermaBind FM™ is processed in a controlled, aseptic environment using methods designed to prevent contamination of the tissues. Final products are sized and packaged according to approved specifications and procedures.

RECOMMENDED INSTRUCTIONS FOR USE
These recommendations are designed to serve only as general guidelines. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

DermaBind FM™ is packaged in a double peel-pouch packaging configuration. The outer pouch is not sterile. The inner pouch that contains the DermaBind FM™ graft is sterile (unless the pouches are damaged or compromised).

PREPERATION
1. Open the outer pouch using the chevron opening and present the inner pouch into the sterile field, taking care to avoid contamination of the sterile field with the non-sterile surfaces of the outer package.

2. Peel open the inner pouch using the chevron opening and aseptically remove the graft with non-toothed, sterile forceps from the pouch before use. Please take great care when removing the graft from the internal pouch. The allograft is thin and extremely lightweight.

3. To shape the patch, sterile scissors should be used to cut the allograft as desired. Please note, DermaBind FM™ may change very slightly in size and shape upon hydration.

Application of DermaBind FM™

1. Ensure the wound and/or skin are clean and free of infection. If applicable, debride the wound surface before the application of the allograft.
2. DermaBind FM™ may be secured to the wound before or after hydration. The allograft is to be rehydrated in one of three ways.
    a. Use sterile water if hydrated before securing to the wound. Fully hydrated membranes may curl and stick. Take care when transferring from the dish to the patient.
    b. The allograft can be hydrated passively by wound exudate if applied before hydration to a lightly exuding wound.
    c. Hydrate with sterile water after securing the wound.
3. To apply DermaBind FM™, place the allograft onto the wound surface with the amnion (epithelial) side facing the wound. Smooth the allograft with non-toothed forceps. The grafts are packaged amnion (epithelial) side facing down. The pouch label will identify “amnion side down”, meaning the amnion will face the opaque layer of packaging. DermaBind FM™ will lightly adhere to the wound surface following hydration.
4. To aid in this identification, a small incision is placed on the patch so that when the incision is observed on the

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upper right side of the patch, the amniotic (epithelial) side will be down, as shown below.

5. To discourage allograft displacement following transplantation, DermaBind FM™ may be affixed to the site using an aseptic technique with a variety of wound closure mechanisms, including absorbable sutures, non-absorbable sutures, non-adhesive wrapping, adhesive wrapping, and/or tissue adhesive appropriate for the procedure type. Note that the allograft will be easier to suture before hydration.

RECIPIENT TRACKING

The FDA requires a system of record keeping that enables the tracking of human tissue-based products from donor to consignee and vice versa. It is the responsibility of the practitioner to maintain sufficient records to permit prompt identification of the recipient to ensure product-to-patient traceability.

WARNINGS

Adverse reactions or outcomes that potentially involve the use of this product must be reported immediately to HealthTech Wound Care. If a disease transmission complication from DermaBind FM™ use is confirmed to be fatal, report immediately to the state health department and HealthTech Wound Care. If a user has an adverse reaction related to the use of DermaBind FM™, discontinue its use and immediately contact HealthTech Wound Care.

QUALITY ASSURANCE

DermaBind FM™ is manufactured under cGMP, cGTP, and ISO 13485 requirements. DermaBind FM™ is processed from the placental membranes collected from donors with normal, full-term pregnancies. Each donor is carefully screened. Comprehensive medical and social histories of donors are obtained, and tissues are procured, processed, and tested according to FDA requirements for Relevant Communicable Disease Agents or Diseases (RCDAD) to minimize potential risks of disease transmission to recipients.

Infectious disease testing is performed at a certified laboratory by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493. Current testing cannot provide absolute assurance that the tissue will not transmit an infectious disease to the recipient. Each allograft is held to the following standards.

DermaBind FM™ QUALITY TESTING

Test	Specification
HIV-1/HIV-2 - Antibody	Negative
HIV-1/HIV-2 – NAT	Non-Reactive
HIV-1 p24 Antigen	Negative
Hepatitis B - Surface Antigen	Negative
Hepatitis B - Core Antibody	Negative
Hepatitis B – NAT	Non-Reactive
Hepatitis C – Antibody	Negative
Hepatitis C – NAT	Non-Reactive
T-lymphotropic virus (HFMV)-1/2 - Antibody	Negative
Syphilis (*T.pallidum*)	Non-Reactive
West Nile Virus	Non-Reactive

The Health Care Practitioner receiving this human cell and tissue product shall have sole discretion and responsibility to determine by applicable law and professional standards if the product is usable and suitable for any uses to which the Health Care Practitioner shall apply the product, and upon delivery of the human tissue by HealthTech Wound Care to the Health Care Practitioner and thereafter the Health Care Practitioner accepts and shall have full responsibility and liability concerning such product.

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