DermaBind CH™ Instructions for Use

DermaBind CH™

Advanced placental-derived wound covering

DermaBind CH™ is a dehydrated intact chorionic membrane covering that preserves the structural integrity of the tissue for use as a wound covering or barrier to the external environment.

Product Code

DCH10, DCH20, DCH30

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:

- Chorionic membrane covering
- Packing List
- Product Label(s)
- Instruction for use

STORAGE AND HANDLING

DermaBind CH™ is supplied/shipped dry until the package is opened. DermaBind CH™ should be stored at room temperature in dry conditions until used or until the expiration date is reached. DermaBind CH™ 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 disposed of 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 CH™. This product is intended for external wounds only.

PRECAUTIONS

Do not use it 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 CH™ must be used prior to the expiration date on the product label.

PROCESSING

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

Preparation

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 prior to 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 that DermaBind CH may change very slightly in size and shape upon hydration.

Application of DermaBind CH™

1. Ensure the wound and/or skin is totally clean and free of infection. If applicable, debride the wound surface before the application of the allograft.
2. DermaBind CH™ may be secured to the wound before or after hydration. Allograft is to be rehydrated in one of three ways.
    a. Use sterile water if hydrated before securing to the wound.
    b. Fully hydrated membranes may curl and stick. Take care when transferring from the dish to the patient.
    c. Allograft can be hydrated passively by wound exudate if applied before hydration to a lightly exuding wound.
    d. Hydrate with sterile water after securing the wound.

3. To apply DermaBind CH™, place the allograft onto the wound surface with the amnion side facing the wound. Smooth the allograft with non-toothed forceps. The grafts are packaged amnion side facing down. The pouch label will identify "amnion side down", meaning the amnion will face the opaque layer of packaging.

4. To discourage allograft displacement following transplantation, DermaBind CH™ 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 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 CH™ 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 CH™, discontinue its use and immediately contact HealthTech Wound Care.

QUALITY ASSURANCE

DermaBind CH™ is manufactured under cGMP, cGTP, and ISO 13485 requirements. DermaBind CH™ is processed from the chorionic membrane 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 in accordance with FDA requirements to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a certified laboratory in accordance with 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 CH™ 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
Syphilis (*T.pallidum*)	Non-Reactive
West Nile Virus	Non-Reactive
Zika Virus	Donor Screened

The Health Care Practitioner receiving this human cell and tissue product shall have sole discretion and responsibility to determine in accordance with applicable law and professional standards if the product is usable and suitable for any and all 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 with respect to such product.

ALL HUMAN TISSUE FURNISHED BY HealthTech Wound Care, INC. TO THE HEALTH CARE PRACTITIONER IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT OF THIRD-PARTY PROPRIETARY RIGHTS UNLESS DISCLAIMING SUCH WARRANTIES IS PROHIBITED BY LAW.

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