

Plurivest[®] and Dermavest[®]

Human Placental Connective Tissue Matrix

Description

Plurivest and Dermavest Human Placental Tissue Matrix (HPTM) is comprised of donated human placental tissue (placenta disc, amnion/chorion and umbilical cord) that has been particularized, processed to remove cells, cellular material and contamination, freeze-dried to remove moisture, pressed into a sheet then E-beam irradiated at a minimum 17.5 kGy with a validated sterilization process. Plurivest and Dermavest are processed and distributed by Aedicell, Inc 100 Latona Road Building 318 Door A Rochester NY, 14652. (www.Aedicell.com).

Indications for use

Plurivest and Dermavest provide a scaffold to replace damaged or inadequate integumental tissue. Each individual Plurivest and Dermavest unit is intended for one person, on a single occasion.

Regulatory status

Plurivest and Dermavest are regulated by the FDA as a human tissue based product under section 361 of the Public Health Service Act. This product is distributed only to licensed healthcare professionals. Plurivest and Dermavest are processed and marketed in accordance with the FDA's requirements for banked human tissue (21 CFR, Part 1270 and Part 1271) as well as the state guidelines of California, New York, Maryland and Illinois. These products are only distributed to licensed healthcare professionals.

Donor Screening and Testing

Donated human tissue manufactured by Aedicell is acquired and determined eligible by Birth Tissue Recovery, 3051 Twenwest Drive Winston-Salem, NC 27103. Donor eligibility is based on the review of comprehensive medical and social histories as well as testing records according to the standards established by FDA requirements to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a FDA (42 CFR part 493) registered and CLIA-certified laboratory. The following tests are performed on the donor's maternal blood samples: HBsAg; HCV Ab; HIV-1/O/2 Ab; HTLV-I/II Ab; HBc Total; RPR; and, HIV/HCV/HBV NAT; WNV NAT.

Sterilization

Plurivest and Dermavest undergo a validated E-beam irradiation process. Plurivest and Dermavest are tested post sterilization for endotoxin (USP <85>), with an acceptance criteria below 20 EU/Sheet and is tested to "pass" for cytotoxicity according to USP <87>.

Warnings

Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material will transmit disease. No long-term studies have been conducted to evaluate the carcinogenic potential or mutagenic potential or reproductive impact of the clinical application of Plurivest and/or Dermavest. Plurivest and Dermavest must not be placed in contact with any chemicals or substances other than those listed in the Instructions for Use below. If a patient has an immunologic reaction, use of Plurivest and Dermavest should be immediately discontinued.

Contraindications

Plurivest and Dermavest are contraindicated in patients with a known hypersensitivity to Plurivest and/or Dermavest. Adverse outcomes attributed to Plurivest and Dermavest must be reported promptly to Aedicell, Inc. Adverse events must be reported by calling (866) 603-2869.

Precautions

- Plurivest and Dermavest are supplied in a foil peel pouch. The pouch contents are sterile if the pouch is unopened and undamaged. Do not use if the package seal is broken. Do not re-sterilize.
- Discard material if mishandling has caused possible damage.
- Discard all open and unused portions of Plurivest and Dermavest. Do not reuse.
- Plurivest and Dermavest must be used prior to the expiration date.
- Plurivest and Dermavest should not be applied until excessive exudate or bleeding, acute swelling, and infection are controlled.

Storage

It is the responsibility of the end-user clinician to store the product in a clean, dry environment at controlled room temperature (15° to 30°C). Provided the mean kinetic temperature does not exceed 25°, transient spikes up to 40° are permitted as long as they do not exceed 24 h. The packaging system for Dermavest and Plurivest have been validated according to ISO 11607 for a four (4) year shelf life under these conditions.

How Supplied

Plurivest and Dermavest are supplied as a single dehydrated, sterile sheet in a single-use, single-patient peel pouch. Pouches containing single sheets are packaged in sealed cardboard envelopes and supplied as a single unit. Plurivest is supplied as a 1x1.5 cm sheet and Dermavest is supplied as either a 1x1.5cm sheet, a 2x3 cm sheet, or a 3x4 cm sheet. More than 1 sheet of Dermavest or Plurivest may be applied to provide the desired coverage. For instance:

- To obtain the equivalent of a **3.0 cm²** Dermavest sheet apply a quantity of 2, 1x1.5 cm Dermavest.
- To obtain the equivalent of a **7.5 cm²** Dermavest sheet apply a quantity of 1, 1x1.5 cm Dermavest and a quantity of 1, 2x3 cm Dermavest.

- To obtain the equivalent of a **9.0 cm²** Dermavest sheet apply a quantity of 2, 1x1.5 cm Dermavest and a quantity of 1, 2x3 cm Dermavest.
- To obtain the equivalent of a **12.0 cm²** Dermavest sheet apply a quantity of 1, 3x4 cm Dermavest.
- To obtain the equivalent of a **15.0 cm²** Dermavest sheet apply a quantity of 1, 3x4 cm Dermavest and a quantity of 2, 1x1.5 cm Dermavest.
- To obtain the equivalent of a **18.0 cm²** Dermavest sheet apply a quantity of 1, 3x4 cm Dermavest and a quantity of 1, 2x3cm Dermavest.
- To obtain the equivalent of a **21.0 cm²** Dermavest sheet apply a quantity of 1, 3x4 cm Dermavest, a quantity of 2, 2x3 cm Dermavest, and a quantity of 2, 1x1.5 cm Dermavest.
- To obtain the equivalent of a **24.0 cm²** Dermavest sheet apply a quantity of 2, 3x4 cm Dermavest.
- To obtain the equivalent of a **30.0 cm²** Dermavest sheet apply a quantity of 2, 3x4 cm Dermavest and a quantity of 1, 2x3 cm Dermavest.
- To obtain the equivalent of a **36.0 cm²** Dermavest sheet apply a quantity of 3, 3x4 cm Dermavest.
- To obtain the equivalent of a **42.0 cm²** Dermavest sheet apply a quantity of 3, 3x4 cm Dermavest and a quantity of 1, 2x3 cm Dermavest.
- To obtain the equivalent of a **48.0 cm²** Dermavest sheet apply a quantity of 4, 3x4 cm Dermavest.
- To obtain the equivalent of a **54.0 cm²** Dermavest sheet apply a quantity of 4, 2x3 cm Dermavest and a quantity of 1, 2x3 cm Dermavest.
- To obtain the equivalent of a **60.0 cm²** Dermavest sheet apply a quantity of 5, 3x4 cm Dermavest.
- To obtain the equivalent of a **120.0 cm²** Dermavest sheet apply a quantity of 10, 3x4 cm Dermavest.

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 end-user clinician to maintain sufficient records to permit prompt identification of the recipient using Plurivest and Dermavest products. Tracking bar code labels are enclosed in the Plurivest and Dermavest packaging to facilitate this process and should be affixed to the patient's medical records. Additionally, Aedicell utilizes a postcard for the consignee to complete. Postage is prepaid and must be returned to Aedicell at earliest convenience.

Instructions for Use

1. Always handle Plurivest and Dermavest using aseptic techniques.
2. The surface of the pouch is NOT considered sterile and should not be placed in a sterile field.
3. Prepare the area for which Plurivest and/or Dermavest is going to be applied using standard methods.
4. Plurivest and Dermavest are pressed particulate sheets and great care should be taken when peeling pouch open to remove the product and placing on the patient.
5. Carefully place Plurivest and/or Dermavest onto the area of application. Tear pieces as needed to fit the site of application. Place enough Plurivest and/or Dermavest to cover the area of application.
6. When possible, use wound exudate to wet Plurivest and Dermavest to allow for coverage and full contact with the site of application. If necessary and as needed, wet the Plurivest and Dermavest with drops of sterile saline.
7. Following reconstitution, it is recommended to use Plurivest and Dermavest product within two hours.
8. After application of Plurivest and Dermavest, use an appropriate, non-adherent, secondary dressing to maintain a moist wound environment.

IMPORTANT

Wound location, size, depth, amount of exudate and user preference determines the optimal secondary dressing. Change the secondary dressing as needed to maintain a moist, clean wound area. Frequency of secondary dressing change will be dependent upon volume of exudate produced and type of dressing used. On inspection, if Plurivest and/or Dermavest is no longer covering the area of application, place an additional piece(s) of Plurivest and/or Dermavest into the site of application. Discontinue placement of Plurivest and/or Dermavest upon complete healing of the area of application. 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.