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 manufactured by Lifeforce BioCeuticals, 270 Northlake Blvd STE 1012, Altamonte Springs, FL 32701 and marketed by Aedicell, Inc. (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, Florida, New York, Maryland and Illinois. These products are only distributed to licensed healthcare professionals.

Donor Screening and Testing
Lifeforce BioCeuticals has determined the donor of the tissue used to manufacture Plurivest and Dermavest to be an eligible donor 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 CLIA-certified laboratory. The following tests are performed on the donors maternal blood samples: Syphilis Screening Assay, Hepatitis B Surface Antigen, HIV 1/2 plus O Antibodies, HIV NAT, HTLV I/II Antibodies, Hepatitis C Antibody, Hepatitis C NAT, Hepatitis B Core Antibody, Hepatitis B NAT, West Nile Virus NAT, Chagas, and CMV.

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.

Contradictions
Plurivest and Dermavest are contradicted 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. and/or the Quality Management Unit at Lifeforce BioCeuticals. Adverse events can 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
Store 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.

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 or a 2x3 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 2, 2x3 cm Dermavest.
- To obtain the equivalent of a **15.0 cm²** Dermavest sheet apply a quantity of 2, 1x1.5 cm Dermavest and a quantity of 2, 2x3 cm Dermavest.
- To obtain the equivalent of a **18.0 cm²** Dermavest sheet apply a quantity of 3, 2x3 cm Dermavest.
- To obtain the equivalent of a **21.0 cm²** Dermavest sheet apply a quantity of 2, 1x1.5 cm Dermavest and a quantity of 3, 2x3 cm Dermavest.
- To obtain the equivalent of a **24.0 cm²** Dermavest sheet apply a quantity of 4, 2x3 cm Dermavest.
- To obtain the equivalent of a **30.0 cm²** Dermavest sheet apply a quantity of 5, 2x3 cm Dermavest.
- To obtain the equivalent of a **36.0 cm²** Dermavest sheet apply a quantity of 6, 2x3 cm Dermavest.
- To obtain the equivalent of a **42.0 cm²** Dermavest sheet apply a quantity of 7, 2x3 cm Dermavest.
- To obtain the equivalent of a **48.0 cm²** Dermavest sheet apply a quantity of 8, 2x3 cm Dermavest.
- To obtain the equivalent of a **54.0 cm²** Dermavest sheet apply a quantity of 9, 2x3 cm Dermavest.
- To obtain the equivalent of a **60.0 cm²** Dermavest sheet apply a quantity of 10, 2x3 cm Dermavest.
- To obtain the equivalent of a **120.0 cm²** Dermavest sheet apply a quantity of 20, 2x3 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 practitioner to maintain sufficient records to permit prompt identification of the recipient. 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.

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 removing it from the pouch 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. 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.