

Human Tissue

Single-Use

No Reuse

This Product is produced from donated human tissue and should be used only once per patient

**Synopsis** It is a biomaterial used for replacement, repair, and reconstruction of human skin tissue.

**Specification** Refer to the label description.

**Storage condition S Derm FD (Freeze dried Acellular Dermal Matrix) :** Store at room temperature(1~30°C) and Frozen storage is prohibited. If freeze-dried products are stored at room temperature (1~30°C), they can be stored for up to 5 years.

**S Derm CP (Cryopreserved Acellular Dermal Matrix) :** This product must be frozen (below -40°C), and refrigeration or room temperature storage is prohibited. If frozen products are stored in a freezer (below -40°C), they can be stored for up to 5 years.

**S Derm HD (Hydrated Acellular Dermal Matrix) :** Store at room temperature(1~30°C) and Frozen storage is prohibited. If hydrated products are stored at room temperature (1~30°C), they can be stored for up to 2 years.

**How to use S Derm FD (Freeze dried Acellular Dermal Matrix) :** This product shall comply with room temperature storage (1~30°C) and be rehydrated individually. ① Open the outer package (box packaging).

② Open the PA-Pouch package and take out the Tyvek. ③ Check if the Tyvek is damaged and open it. ④ Rehydrate the tissue in a container containing a sterilizing solution stored at room temperature according to the following applications.applications. ④ - 1) 0.1mm~less than 1mm: At least 10 minutes ④ - 2) 1mm- less than 3mm: At least 20 minutes ④ - 3) 3mm or more: At least 30 minutes

⑤ Reagents and antibiotics used during treatment may remain in this product, and the rehydration solution is exchanged at least three times for 10 minutes per time to remove the residual reagent.

**S Derm CP (Cryopreserved Acellular Dermal Matrix) : Refrigeration storage (below -40°C) shall be observed and thawed individually.**

① Check if the outer packaging material is damaged and open.  
② Take out the internal packaging material and open it.  
③ Remove the last internal packaging material containing the product and defrost it in a sterilized solution until the product is completely dissolved

④ Open the last internal packaging material, remove the product, and clean it in a sterile solution to remove reagents and antibiotics that may remain. Wash for 5 minutes at least 3 times.

**S Derm HD (Hydrated Acellular Dermal Matrix) : This product must be kept at room temperature (1~30°C).** ① Check if the outer packaging material is damaged and open.

② Take out the internal packaging material and open it.  
③ Clean it in a sterile solution to remove reagents and antibiotics that may remain. Wash for 5 minutes at least 3 times.

**Distribution and return S Derm FD (Freeze dried Acellular Dermal Matrix) :** Tissue banks and use agencies are responsible for storing, distributing, and returning freeze dried acellular dermis in an appropriate storage environment prior to transplantation. Store at room temperature (1~30°C) until immediately before transplantation, and return it at room temperature (1~30°C).

**S Derm CP (Cryopreserved Acellular Dermal Matrix) :** Tissue banks and use agencies are responsible for storing, distributing, and returning cryopreserved acellular dermis in an appropriate storage environment prior to transplantation. Refrigerate (below -40°C) until immediately before transplantation, and return the refrigerant (dry ice) in a container that remains below -40°C.

**S Derm HD (Hydrated Acellular Dermal Matrix) :** Tissue banks and use agencies are responsible for storing, distributing, and returning hydrated acellular dermis in an

appropriate storage environment prior to transplantation. Store at room temperature (1~30°C) until immediately before transplantation, and return it at room temperature (1~30°C).

**Notices** ① Check the expiration date and packing condition before using. ② Be careful not to contaminate the product, and if a contaminated product is found or returned. ③ Only doctors and dentists should be used, and use other than for purposes of use is prohibited. ④ Do not transplant where the site to be transplanted has been infected or is undergoing infection. ⑤ Use the tissue within 4 hours after rehydration. ⑥ Cryopreserved acellular dermis can be broken, so do not throw it.

**Eligibility Determination for donors** The eligibility determination is conducted by the tissue-collecting tissue bank and MedPark confirms the results. This screening is conducted in accordance with the regulations of the American Association of Tissue Banks (AATB) and the Ministry of Food and Drug Safety (MFDS)

**Serum test** The following tests are conducted through a Clinical Laboratory Improvement Measures (CLIA) accreditation laboratory or a country accredited institution, and HTLV&II may be additionally inspected.

· Anti-HIV-1 and anti-HIV-2, HIV-1 NAT  
· HBs Ag, HBe Ab, HBV NAT, HCV ab, HCV NAT, Syphilis

**Microbial test** The following tests are carried out during the tissue collection and processing stages.

· Aerobic bacterium · Anaerobic bacterium · Fungus

**Origin of tissue recovery/Tissue bank** Refer to the label description

**Reagents** NaCl (Sodium Chloride), Antibiotics (Amikacin, Amoxicillin, Vancomycin, Amphotericin B), Sterile Distilled Water, Hydrogen Peroxide, SDS (Sodium Dodecyl Sulfate), Sucrose, Glycerol.

**Action in the event of side effects** ① If the doctor in charge of transplantation finds any serious side effects, he/she shall immediately report them to MedPark. ② The doctor in charge of the transplant takes necessary medical measures and consults with the MedPark distributed to take necessary additional measures.

**Warning** Processing of the tissue, laboratory testing, and careful donor screening minimize the risks of the donor tissue transmitting disease to the recipient patient but due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material will transmit disease.

**Manufacturer** **MedPark**

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