

Human Tissue Single use Do not reuse Do not resterilize

This product is produced with human tissue donated from a donor and is a human tissue transplant material processed by MedPark's specialized technology in a safe manner based on the "Human Tissue Safety and Management Act".

**Tissue Name and Detailed Name** Skin / Freeze-dried skin powder

**Specification of Tissue** Description - see container or packaging

**Storage Method** Store at room temperature (1-30C)

#### How to use

- 1) Check the product's appearance and packaging for any abnormalities.
- 2) Open the outer packaging (box) and retrieve the inner packaging (blister).
- 3) Inspect the inner packaging (blister) for any abnormalities.
- 4) Open the Tyvek sheet of the inner package and remove the sterile syringe and connector, ensuring no contamination.
- 5) Tap the powdered product in the syringe to loosen it.
- 6) Remove the syringe cap, connect the connector, and attach the syringe to sterile physiological saline on the other side of the connector.
- 7) Push the pushrod of the sterile saline syringe fully into the product syringe.
- 8) Holding the syringe on both sides, rehydrate by alternately pushing the stem of each syringe until fully rehydrated.
- 9) After rehydration, the product should be implanted by the transplant surgeon.

#### Precautions

- 1) This product can only be implanted in one patient with a single manufacturing number. In addition, any part of the tissue remaining after transplantation should not be stored and reused, but should be used for single use only.
- 2) This product should be implanted by a qualified physician or dentist in a legitimate medical institution.
- 3) The transplanting physician shall return or self-dispose of any tissue unsuitable for transplantation, unused tissue after opening, broken and opened tissue, or expired tissue after notifying the distributing tissue bank.
- 4) If the opened product is contaminated or suspected of being contaminated before being transplanted into a patient, it should not be used for transplantation and should be returned or self-disposed of by contacting MedPark.
- 5) This product is a sterile product and should not be re-sterilized.
- 6) If the transplant site is infected, it should not be transplanted.
- 7) This product should be used individually and should be used immediately after opening.

#### Donor Suitability Assessment

Donor evaluation is performed by the tissue bank from which the tissue was collected and the results are confirmed by MedPark. This test is conducted in accordance with the regulations of the American Association of Tissue Banks (AATB) and the Korean Ministry of Food and Drug Safety (MFDS).

#### Serologic Tests

The following tests are performed by the Korean Society of Diagnostic Laboratories, Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories, or organizations certified by each country, and HTLV I&II may be tested in addition to these tests.

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

#### Microbiology Tests (bacterial cultures)

The following tests are performed at a later stage after tissue collection and final sterilization.

- Aerobic · Anaerobic · Fungus

#### What to do if side effects occur

- 1) The transplant surgeon shall immediately report any serious adverse events (infectious diseases, malignant tumor metastasis, infections) to MedPark.
- 2) Identify any serious adverse events and notify the head of the Department of Food and Drug Safety within 7 days of the occurrence of adverse events.
- 3) MedPark shall report any adverse events to our medical manager and analyze the cause and take measures for any adverse events that occur.
- 4) The hospital that performed the transplantation and the transplantation doctor shall take necessary medical measures for the patient and take measures in consultation with MedPark.

#### Warning

Despite MedPark's processing, donor screening and evaluation, the risk of transmission of infectious factors cannot be completely excluded due to the limitations of the test technology.

#### Country of Tissue Collection

South Korea, USA (see labeling)

#### Source

MedPark Tissue Bank  
Ace Hi-Tech City 2nd , 1005, 1008, 1009, 1010,  
25 Seonyu-v ro 13-gil, Yeongdeungpo-gu, Seoul, Korea