

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 take out the inner packaging (blister).
- 3) Check the inner packaging (blister) for any abnormalities.
- 4) Open the Tyvek sheet of the inner package and remove the sterile syringe, taking care not to contaminate it.
- 5) Prepare the product in the syringe by shaking it thoroughly before use.
- 6) Check that the product is white or yellow in color and opaque and inject it by the transplant surgeon. However, if an air layer is found in the syringe before implantation, open the cap to release the air before implantation.

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 implantation should not be stored and reused, and 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 that is unsuitable for transplantation, unused after opening, broken and opened, or expired after notifying the tissue bank that distributed it.
- 4) If the opened product is contaminated or suspected of being contaminated before being transplanted into the patient, it should not be used for transplantation and should be returned or discarded 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.
- 8) S Gen Inject may contain air bubbles in the syringe prior to implantation, but this is not a problem for implantation and should be removed by opening the cap.
- 9) If phase separation is found before use, shake the S Gen Inject thoroughly up and down to mix before use.

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 and Laboratory Medicine, Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories, or organizations certified by each country, and may include HTLV 1&2 in addition to these tests.

- Anti-HIV-1 and anti-HIV-2, HIV-1 NAT
- HBs Ag, HBe 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 physician shall immediately report any serious adverse events (infectious disease, malignant tumor metastasis, infection) to MedPark.
- 2) Identify any serious adverse events and notify the Director 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 transplant and the transplant surgeon 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.

Tissue Collection Countries

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