INSTRUCTION FOR USE OSS

A1 NEW BONE NEW LIFE

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

Human Tissue | **Single Use** | **Sterilization** | **No Reuse**

Synopsis It is a biomaterial used for replacement, restoration, and reconstruction when bone is lost due to trauma or osteoporosis.

Storage condition This product can be stored for up to 5 years in an unopened package at a dry room temp(1~30°C, 34~86°F) avoiding direct sunlight.

Standard "Note - refer to container or packaging"

How to use This product must be stored at room temperature (1~30°C, 34~86°F) and individually hydrated.

Vial Type ① Open the outer packaging (Box packaging) ② Remove the Tyvek packaging attached to the blister and take out the vial ③ Check if the vial is damaged and remove the double cap ④ Rehydrate the tissue in a container with a sterile solution stored at room temperature ⑤ The tissue should be used as soon as possible after hydration. **Syringe Type** ① Open the outer packaging (box packaging) and take out the blister. ② Remove the Tyvek pouch (secondary packaging) attached to the blister and take out the inner blister. ③ Remove the Tyvek pouch (primary packaging) attached to the blister and take out the syringe. ④ Pull back on the plunger to create a space and gently tap the syringe to loosen the powder. (Precaution) If directly used, clustered powder may cause unsmooth injection of product. ⑤ Remove the outer protective cap (rubber cap) so that the inner stopper (mesh cap) inside the syringe is not removed. ⑥ Discard the used syringe together with the contents.

Sterilization This product has been sterilized with gamma rays after manufacturing process and packaging, and It has been validated for sterilization against bacteria and fungi.

Notices 1.Do not transplant at the site where is infected or an infection is in progress. 2. According to the Human Tissue Act, the tissue transplant result record must be delivered within one month after tissue transplantation. 3. The tissue should be used immediately after rehydration if possible. 4.Disposable, do not reuse. 5.Check the sterilized packaging before use. 6.Do not use a product that expiration date has passed. 7.If contaminated products are found, discard or return them. 8. It should be used bedoctors and dermatologists, and use other than the intended use is prohibited.

Donor Eligibility Donor Eligibility (screening and testing) is performed in accordance with Ministry of Food and Drug Safety (MFDS) regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor eligibility is determined by Medical Director of MedPark.

Serological Test The following inspections are carried out by Clinical Laboratory Improvement Amedments(CLIA) certified laboratories or institutions accredited in each country, and HTLV I&II can be additionally inspected in addition to these inspection items.

· Anti-HIV-1 and anti-HIV-2, HIV-1 NAT

· HBs Ag, HBc Ab, HBV NAT · HCV ab, HCV NAT · Syphilis

Microbial test The following inspections are performed during tissue collection and processing.

· Aerobic · Anaerobic · Fungus

Tissue Tracking Authorities require that allograft tissue be traceable from the donor to the recipient. It is the responsibility of final distribution tissue bank to complete and maintain the recipient records(tissue bank record forms) for the purpose of tracking.

Origin of Tissue Recovery/Tissue Bank All human tissue product :US, Republic of Korea, Bulgaria

Warning Despite Medpark's processing, donor selection and evaluation, the risk of transmission of infectious agents cannot be completely excluded due to limitations in testing technology. Reagents or solutions (alcohol, hydrogen peroxide) used in tissue processing must be checked for allergy to the transplanted patient.

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MedPark

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