Manual

Alyoss Plus

Cortical and Cancellous Bone Graft Blend

Donated Human Tissue
Only for One patient
Sterile Product
No Reuse

General Information

The enclosed human tissue allograft is a tissue donated from a donor for the purpose of transplantation that has gone through screening, recovery, processing, storage and distribution in a legal and safe manner based on the “Safety, Management, Etc. of Human Tissue Act”.

ORIGIN of TISSUE RECOVERY/ TISSUE BANKS

Republic of Korea, United States, Bulgaria and Czech.

Tissue Processing Method

Processing and sterilization – The manufacturer process tissues with a mixed reagent that may have traceable amount of antibiotics (Bacitracin, Polymyxin B sulfate), alcohol, peroxide and surfactants followed by terminal sterilization using Gamma ray as indicated on the label.

Testing Items and Method

Comprehensive serologic testing is performed on each donor. In addition, numerous microbiological cultures are performed and evaluated by a recovery tissue bank. The test results of serum and fungal culture have been checked by recovery tissue bank and the manufacturer. All the tests have been conducted by certified institution of The Korean Society for Laboratory Medicine or Clinical Laboratory Improvement Amendments (CLIA) of individual country.

Serum Test	Test of Fungal Culture
HBsAg, HBcAb (or HBV HCV Ab, HCV , HIV 1/2 Ab, HIV NAT STS (Serological Test for Syphilis)	Aerobic Culture Anaerobic Culture Fungus Culture

This tissue has been determined to be suitable for transplantation by the manufacturer’s Medical and QA Director after reviewing infectious disease tests, medical and social history questionnaire, physical assessment, medical records, autopsy report (if one was performed), and donor suitability information. Transmission of virus is possible irrespective of thoruough selection of donors and screening examinations.

Recommended Procedure for Storage

The distributor and the medical practitioner should allow and has responsibility of providing adequate environment for storage. Freeze-dried products should be sealed and can be stored under room temperature (1-30° C, 34-86° F) up to 5 years.

Recommended procedure for handling

The freeze-dried product should be kept within the set temperature for storing prior to use and each product should be rehydrated individually.
① Remove double- or triple-wrapping (including outer packaging) and using aseptic technique to remove inner packaging to the practitioner with sterile surgical attire to avoid contamination.
② Check for any damages on the inner packaging.
③ Microbiological culture testing is recommended before the allograft tissue is soaked using saline solution.
④ Rehydrate the allograft at basin containing sterilized solution (physiological saline solution, lactic acid, Ringer’s solution) or other appropriate antibiotic solution of doctor’s preference. The rehydrated allograft should be refrigerated between 1 to 8° C (33.8 to 46.4° F) prior to transplantation.
⑤ Rehydration of the allograft for more than 30 minutes is recommended (Stir the solution using long sterilized rod for 15 seconds).
⑥ The product should be cleansed for about 3 times by changing the solution to remove any remaining reagents.
⑦ All preparations should be carried out before transplanting the allograft.

Notices

① The enclosed human tissue allograft should only be used on one patient.
② The use with non-medical purpose is prohibited and should only be used by health professionals.
③ If the packaging is found defected or destroyed on its receipt, the allograft should be directly returned to the distributing tissue bank without transplantation.
④ If the product is not rehydrated sufficiently, it could be biomechanically weakened.
⑤ Practitioner should return the allograft that is unsuitable for transplantation, unused allograft after opening the package or damaged tissue to the distributing tissue bank or dispose in accordance with the regulations.
⑥ The reagent and solution should be tested for allergic reaction prior to use on the patient.
⑦ If the recipient’s site is infected, then the transplantation should not proceed.
⑧ The allograft should not be re-sterilized.
⑨ The enclosed human tissue allograft is processed and sterilized with each aseptic technology and Gamma radiation in accordance with the “Safety, Management, Etc. of Human Tissue Act”. However, the Practitioner performing the transplant should be aware of the spread of infectious disease.
⑩ Tissue should be used as soon as possible after reconstitution. If the allograft is not to be used within about 2 hours after reconstitution, It should be assure continued sterility and kept at 1 to 8°C for no longer than 24 hours or discard.

Report and countermeasure of side effects

① If the practitioner responsible for transplantation comes across any serious adverse effect, the case should be reported to Dental Solutions Israel Ltd.
② Any reported adverse effects will be examined by the medical director of Dental Solutions Israel and a cross-analysis should be carried out to prevent the spread of the side effect.
③ The practitioner should comply with the medical procedures and talk with the distributor for further step.
④ The tissue bank should report to the Government agency within 7 days of any known or reported serious side effects.

TISSUE TRANSPLANT TRACK RECORD

The Tissue Transplant Return Track (TTTR) should be filled out by the medical practitioner within one month after transplantation according to the regulations and submitted to the distributor.
It is the responsibility of the end-user to provide this information. The tissw bank should maintain records for tracking transplantation.

Contact

Please feel free to contact Dental Solutions Israel Ltd if you should have any questions regarding process, storage, transportation and transplantation.

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