DO BONE™

Cancellous & Cortical Bone

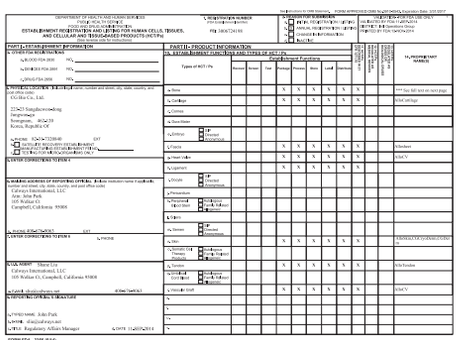
Characteristics

> High quality Dental Allograft Bone Substitute
> Easy handling with syringe container
> Secure absolute stability with thorough donor supervision
> State-of-the-art processing facilities
> Cortical Powder 7: cancellous powder 3

Thorough donor supervision

Article	FDA	KFDA	KATB	AATB	KHTB
HIV 1/2	O	O	O	O	O
HCV Ab	O	O	O	O	O
HBsAg	O	O	O	O	O
STS(RPR)	O	O	O	O	O
HTLV-1/2	X	X	O	O	O
HIV NAT	X	X	X	O	O
HCV NAT	X	X	X	O	O
HBcAb	X	X	X	O	O
HBSAb	X	X	X	X	O

■ DO BONE™ FDA Certificate

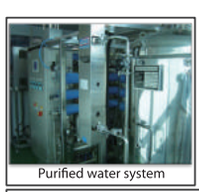


State-of-the-art Processing Facilities

: For processing high-quality and distributing stabilized bone substitute, 'DO BONE' is produced in 'CLASS 100' of Clean-Air facility In with advanced and specialized technique by CTBS (Certified Tissue Bank Specialist qualified by AATB).

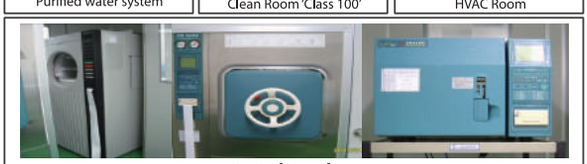
Class 100,000

Class 100


Purified water system


Clean Room 'Class 100'


HVAC Room

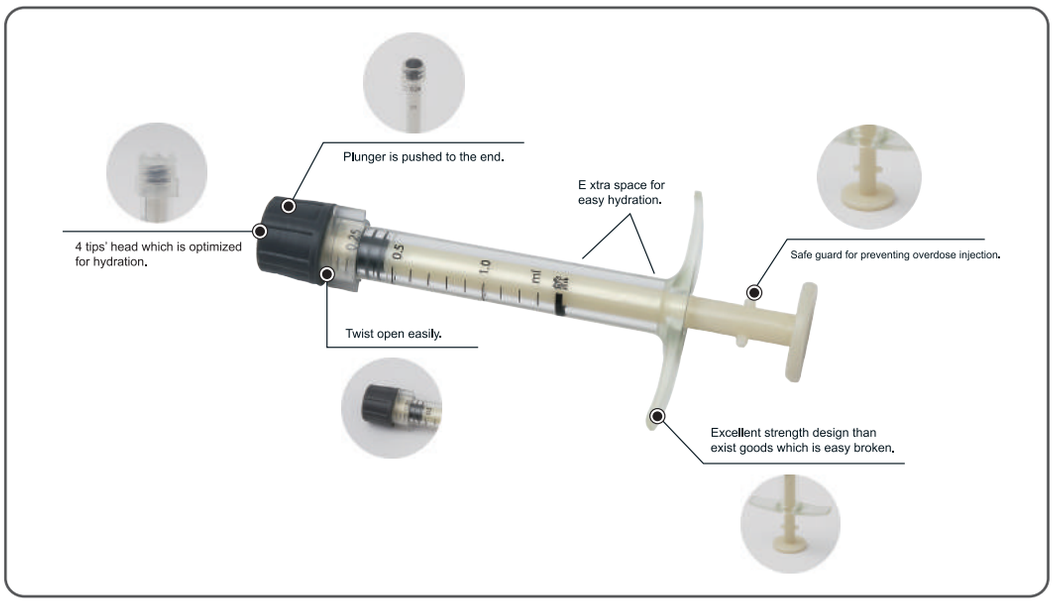

Central Supply

■ What is 'Class 100'?'

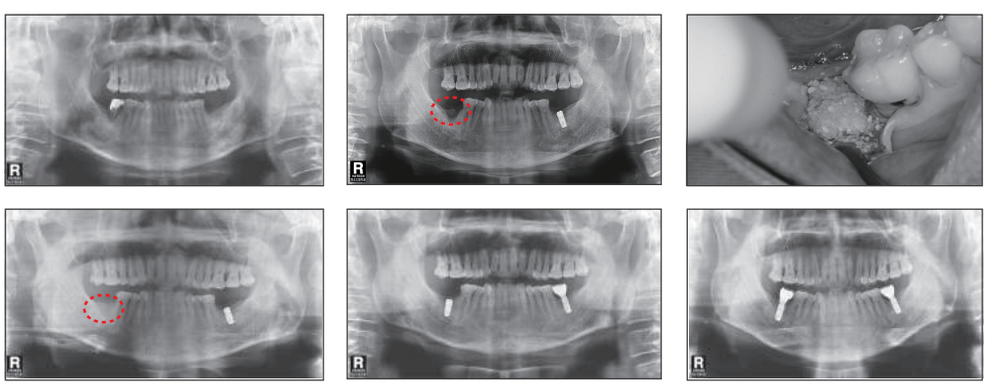
: The space has extremely cleanliness.
It allows less than 100 particles which is smaller than 0.5㎛ per feet.

* The cleanliness of brain surgery room : Class 10,000

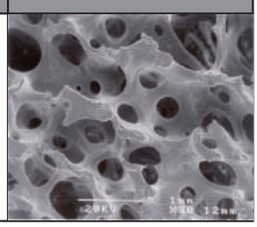
Specially Customized Syringe for User Convenience.



DO BONE™ Case Studies



Product Description

Classification	Product	Categorization	Volume	Particle	SEM
Allograft	DO Bone	7:3	0.25cc	M: 0.4~0.71mm L : 0.71~1.6mm	
			0.5cc		
			1.0cc		

Allo-Bone

FDBA (Freeze Dried Bone Allograft)

Allo-Bone and Allo-Bone Plus, are the allograft options from Daewoong. By utilizing the 100% cortical bone and 100% cancellous bone powder, patients bone void area can be reinforced with allograft. The powder comes in different volumes so that it can be mixed with synthetic grafts as well.

Composition

- 100% Cortical bone

Physical Form

- Powder

Specification

Ingredient	Volume	Granule Size
100% Bone Powder	0.25cc / 0.50cc / 1.00cc	M size : 0.40-0.71mm
		L size : 0.71-1.60mm

Indications

- Endodontic Cyst
- Horizontal ridge augmentation
- Sinus Lift

Allo-Bone PLUS

FDBA (Freeze Dried Bone Allograft)

Allo-Bone and Allo-Bone Plus, are the allograft options from Daewoong. By utilizing the 100% cortical bone and 100% cancellous bone powder, patients bone void area can be reinforced with allograft. The powder comes in different volumes so that it can be mixed with synthetic grafts as well.

Composition

- 100% Cancellous bone

Physical Form

- Powder

Specification

Ingredient	Volume	Granule Size
100% Bone Powder	0.25cc / 0.50cc / 1.00cc	M size : 0.40-0.71mm
		L size : 0.71-1.60mm

Indications

- Endodontic Cyst
- Horizontal ridge augmentation
- Sinus Lift

Manual

Allo-Bone®

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

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 CGBio.
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 CGBio 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.

Tissue Processing Method

Processing and sterilization – CGBio 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.

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 CGBio immediately.
② Any reported adverse effects will be examined by the medical director of CGBio 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. CG Bio should maintain records for tracking transplantation.

Contact

Please feel free to contact CGBio if you should have any questions regarding process, storage, transportation and transplantation.

Manufactured by
CGBio CELL & GENE BIOTECHNOLOGY
Main Office/R&D Center(Production and R&D)
244 Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

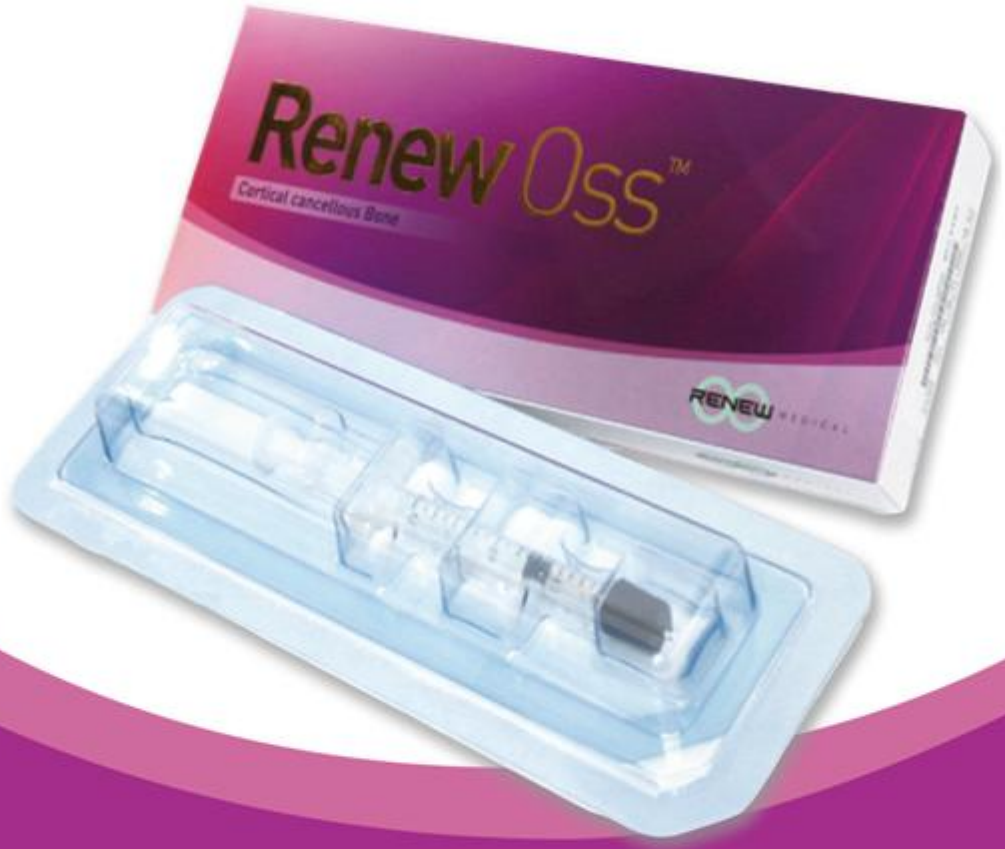
Rev.no.: CG-AB-I-02

Revised on Jan. 2014

RENEW MEDICAL

Renew Oss (English Version)

Cortical Cancellous Bone



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TEL +82-32-326-1055 / FAX +82-32-326-1044
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www.renewmedical.net

Renew Oss™ _Renew Medical Co., Ltd.

Renew Oss™ is the allograft bone grafting substitute produced by Renew Medical Co., Ltd. Renew Medical Co., Ltd. has established tissue bank and hit the road the business to be a new market leader of dental bone grafting substitutes.

To explain firstly about allograft bone, the raw material of allograft bone grafting substitute is not from a patient's own bone but from the donated cadaver at a medical facility. It is collected safely and processed disinfected and sterilized.

Allograft bone grafting substitute has a very good effect on new bone formation safely. Basically, human bone consists of mineral and organic parts. To gain a grafting substitute from it, organic part is removed completely with physical and chemical method and gamma sterilization to eliminate the factor of immune rejection.

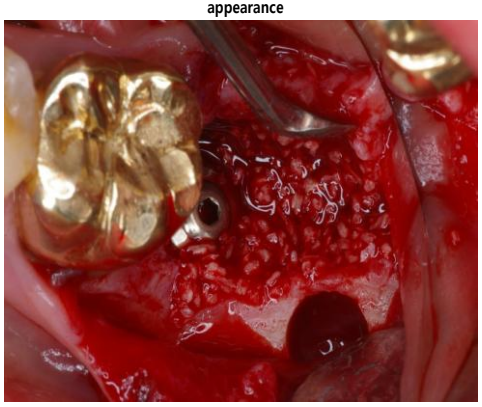
And Allograft bone substitute composed of allograft and carrier component to support and transfer it. The product is the grade 4 of medical equipment. It is produced with the mixing of demineralized bone matrix and viscous gel.

The allograft bone grafting substitute is divided into Cancellous bone and Cortical bone. Cancellous bone is to be the base role to make new bone formation because bone growth is being done in it. And Cortical bone which is stopped growing though is to be the role of filling out tightly and safely in extraction site

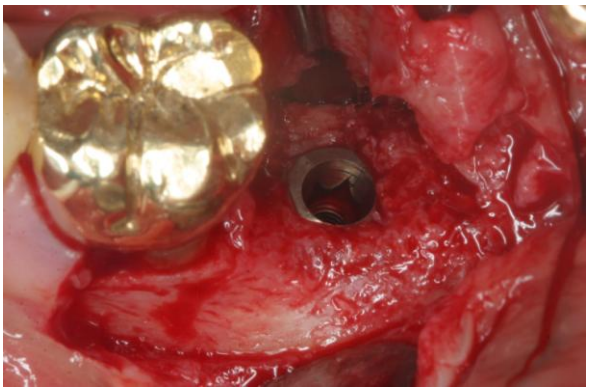
The manufacturer of **Renew Oss™** is the Korea Bone Bank Co., Ltd. which has No. 1 market share in domestic tissue bank market in Korea.
◎By using the sterilization method of high-dose gamma ray (50Kgray) which can eliminate all bacterial on the earth, it make us free from the infiltration concern of pathogens. And this is the only and one product in the country that using the bio clearant technique to get rid of the bacteria without damaging the bone matrix.
◎Mixture ratio is Cortical powder(70%) AND Cancellous powder(30%)

Classification	Product	Size	Remark
allograft	Renew-Oss™	0.3cc	Human bone
		0.5cc	
		1.0cc	

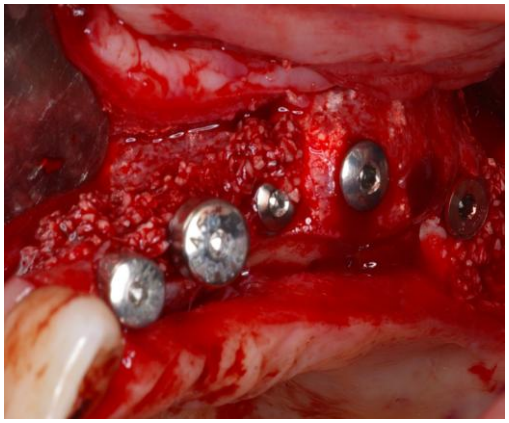
Centrifugal side defect DentGen 37 after placement transplanted appearance



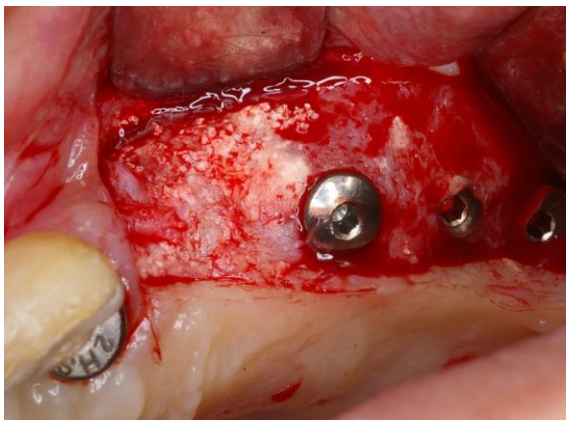
Bone regeneration, well look after 3 months



Implanted on the buccal of # 22,23,24 DentGen appearance



24 4 months after the buccal bone regeneration, well look (# 22,23 - stage procedures.)



Successful Clinical Evidence below photos.