

Bone graft of GENOSS - OSTEON™ Xeno Collagen

A Product description

This product is manufactured by mixing hydroxyapatite derived from bovine bone and Type I Collagen derived from pig tendon. It is used for convenience of use and to assist bone regeneration when transplanting to areas requiring bone regeneration.

B Indication for use

It is used for transplantation in areas where masticatory pressure does not apply to depressed areas caused by destruction or loss of alveolar bone to assist bone regeneration.

C Contraindication

The general contraindications are as follows, but the practitioner judges them according to their respective circumstances.

- 1) Symptoms of allergy to Collagen.
- 2) Endocrine dysfunction (hypothyroidism, hyperthyroidism, parathyroid dysfunction, adrenocortical diseases, etc.)
- 3) Circulatory diseases (angina, myocardial infarction, congestive heart failure, chronic heart valves, hypertension, hypotension, etc.)
- 4) Respiratory diseases (bronchial asthma, etc.)
- 5) Kidney disease, blood.
- 6) Bone diseases (osteoporosis, osteomalacia, Behcet's disease, marble disease, etc)
- 7) Faculty sickness.
- 8) Other pregnant women, nursing mother, menstruation, newborns, drug addiction, alcoholism, Allergic diseases, etc.

D Directions for use

- 1) After opening the affected area, completely remove the inflammatory tissue and residue and allow fresh blood to come out.
- 2) Clean the surgical site to remove saliva and contaminants, and prepare so that OSTEON Xeno Collagen can contact the surrounding bone.
- 3) If necessary, OSTEON Xeno Collagen can be cut to the desired size using sterilized tools in a dry state.
- 4) The height of the bone graft material is transplanted to the surgical site according to the bone level.
- 5) Use sterilized instruments for transplantation, but avoid excessive filling.
- 6) The mucoperiosteal plate must be completely sutured. Surgical dressing is performed over 1 to 2 weeks.

E Preparation before use

- 1) Check the condition of the product's internal packaging. The inner packaging is sealed and sterilized, so it cannot be used if the seal is torn, has impurities, foreign substances, etc., or is opened.
- 2) Check the expiration date of the product.

F Warning

A. Warning













- 1) The surgical technique for implanting this product requires special and complicated procedures. Formal training in product implantation surgery is recommended.
- 2) Before using this product, establish a treatment plan through appropriate radiographic measurements and direct palpation, and establish a treatment plan through visual inspection of the area where the product will be implanted.
- 3) The operator must be familiar with the surgical method, clinical indications, precautions, etc. using the surgical instruments of this product.
- 4) For patients with contraindications, use of the product is restricted at the discretion of the practitioner.

- 5) This product must be implanted in contact with the bone tissue at the defect site.
- 6) For stable bone regeneration, it is recommended to use an absorbable periodontal tissue regeneration inducer that can prevent soft tissue penetration.
- 7) Since this product is a sterilized product, ensure that it remains sterile during the procedure, and do not use products whose expiration date has expired.

B. Side effect

- 1) This product is a product that uses ingredients of animal origin and may cause allergies.
- 2) Complications such as foreign body reactions, inflammation, and swelling may occur after using the product
- 3) Depending on the severity and type of complications, the removal of the product or antibiotic therapy may be required at the discretion of the clinician.
- 4) Bone regeneration may be delayed during transplantation when bone tissue and conjugation are improper or blood is insufficient.

G Symbols

 REF	Catalogue number	 LOT	Batch code
	Do not re-use		Date of manufacture
	Caution		Use by date
	Temperature limit		Manufacturer
	Fragile, handle with care		Sterilized using irradiation
	Do not use if package is damaged and consult instructions for use		Do not re-sterilize

H Storage

Room temperature storage (1 ~ 30°C)

I Expiration data

3 years from the date of manufacture

J Usage count

Disposable sterile medical device, no reuse

K Articles

A. Cylinder

Type name	Diameter(mm)	Height(mm)
XC0310	3	10
XC0320		20
XC0605	6	5
XC0610		10

B. Block

Type name	Length(mm)	Width(mm)	Height(mm)
XC0508	8	8	5
XC0510	10	8	5
XC0808	8	8	8
XC0810	10	8	8
XC1010	10	10	10

Made in Korea

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