Bone graft of GENOSS - OSTEON™ Xeno

A Description

OSTEON Xeno is a bone mineral powder consisting of natural hydroxyapatite (HA) extracted from bovine bones, and when bone defects are formed due to dental disease, it can be transplanted into a space in bone tissue to promote the formation of new bones.

B Intended Use

It is a bone graft material derived from animals (bovine) and is used to repair bone defect.

C Directions for use

A. Vial type

1) This product is used for bone formation when alveolar bone defects occur.
2) The sterile blister/paper packaging is opened, a glass vial container containing bone graft material (granule) is taken out, and the appropriate amount of bone graft material is placed in a sterile/sterile mixed container.
3) Before applying to the affected area, mix the bone graft well with saline solution and the patient's blood.
4) Bone graft material should be sufficiently soaked.
5) If there is too much saline and medicine in the patient's blood, it is better to mix the bone graft material with the appropriate amount of saline and the patient's blood because the bone graft material can flow well.
6) Using a sterile instrument, bone graft material is brought to the surgical site.
7) Using a sterile instrument, bone grafts are later loosely filled into the area where the alveolar bone is defective. At this time, if too much force is applied, the granule form can break down and cause structural damage.
8) Excessive amounts of transplantation at the site of defects and surgical procedures should be avoided.
9) To ensure the formation of new bones, bone grafts should be placed in direct contact with the well Vascularized bone.
10) The mucous periosteum plates at the site of the defect and at the surgical site should be subjected to a perfect primary suture without tension.
11) The mucous periosteum plate is covered and tightly sutured so that the transplant.
12) Since swelling is expected after surgery, double sutures are strongly recommended.
13) Surgical dressing is performed at the site of the defect and at the surgical site for 1–2 weeks.
14) The patient should be advised not to apply pressure such as excessive authoring force to the defect site and the surgical site during the bone healing period.
15) Careful examination and evaluation of allergic reactions due to the implantation of bone grafts should be carried out.
16) The site where the bone graft material is transplanted requires a healing period of at least 6 months.

B. Block type

1) After opening the affected area, the inflamed tissue and residue are completely removed and fresh blood is released.
2) The surgical site is cleaned free of saliva and contaminants, and the OSTEON Xeno Block is prepared for contact with the surrounding bones.
3) If necessary, the OSTEON Xeno Block can be cut from dry to any size using sterile tools.
4) Bone graft material is implanted at the surgical site.
5) Transplant using sterile instruments, but avoid excessive filling.
6) The mucosal periosteum plate should be fully sutured. Surgical dressing is performed over a period of 1–2 weeks.

D Preparation before use

Pre-use product inspection and precaution

1) The mucoperiosteal flap is turned over to expose the bone defect site, and then a curette is used to remove the inflamed tissue above the defect.
2) The surgical site where the bone graft material will be implanted is wased clean using sterile or Saline solution.
3) As long as it is not opened or damaged before use, the inside of the package is sealed and sterile.
4) Check the expiration date before use. Products that have expired should not be used.

E ⚠ Warnings

1) Bone graft material transplantation should not be subjected to excessive compression.
2) Filled particles are good to cover the membrane.
3) If the area of the procedure is large, the membrane should be used compulsory.
4) It should be used in areas with an abundant blood supply and direct contact with the bone.
5) It should be prevented from being exposed to the outside or from flowing saliva into the contamination.
6) Do not reuse.
7) The following patients should limit their use according to the doctor's recommendation:
   ① Metabolic patients (diabetes, hyperepithelial hyperplasia, osteochloride).
   ② Patients on long-term medication of Corticosteroids.
   ③ Patients with osteomyelitis at the surgical site.
   ④ Patients with vascular damage at the implant site.
   ⑤ People with liver disease, kidney disease.

F Side effect

This product is a product that uses ingredients of animal origin and may cause allergies.
Complications such as foreign body reactions, inflammation, and swelling may occur after using the product.
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.
Bone regeneration may be delayed during transplantation when bone tissue and conjugation are improper or blood is insufficient.

G Contraindication

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

1) Symptoms of allergy to bone grafts.
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.).

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7) Faculty sickness.
8) Other pregnant women, nursing mother, menstruation, newborns, drug addiction, alcoholism, Allergic diseases, etc.

H Symbols

REF	Catalogue number	LOT	Batch code
	Do not re-use		Date of manufacture
	Caution		Use by date
1°C 30°C	Temperature limit		Manufacturer
	Fragile, handle with care	STERILE R	Sterilized using irradiation
	Do not use if package is damaged and consult instructions for use		Single sterile barrier system with protective packing outside
MD	Medical Device		Do not resterilize
BIO	Contains biological material of animal origin	UDI	Unique device identifier
	Consult instructions for use		

I Strorage

Store at room temperature (1-30°C)

J Expiration Date

3 years from the date of manufacture

K Usage count

Disposable sterile medical device, no reuse.

L Articles

Type	Type name	Size	Weight (g)
Granule (vial)	GXS015	Small size (0.2-1.0mm)	0.15
	GXS025		0.25
	GXS050		0.5
	GXS100		1.0
	GXS200		2.0
	GXM015	Medium size (0.5-1.0mm)	0.15
	GXM025		0.25
	GXM050		0.5
	GXM100		1.0
	GXM200		2.0
	GXS015	Large size (1.0-2.0mm)	0.15
	GXS025		0.25
	GXS050		0.5
	GXS100		1.0
	GXS200		2.0
Block	GXB050808	5 x 8 x 8 mm	0.12
	GXB050810	5 x 8 x 10 mm	0.15
	GXB050812	5 x 8 x 12 mm	0.17
	GXB080808	8 x 8 x 8 mm	0.13
	GXB080810	8 x 8 x 10 mm	0.22
	GXB080812	8 x 8 x 12 mm	0.45
	GXB081012	8 x 10 x 12 mm	0.51
	GXB051010	5 x 10 x 10 mm	0.16
	GXB051015	5 x 10 x 15 mm	0.21
	GXB101010	10 x 10 x 10 mm	0.39
	GXB101015	10 x 10 x 15 mm	0.75
	GXB151515	15 x 15 x 15 mm	1.50

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