Bone graft of GENOSS - OSTEON™ 3

A Product Description

OSTEON 3 is a synthetic osteoconductive bone graft substitute composed of 60% hydroxyapatite (HA) and 40% beta-Tricalcium phosphate (β-TCP).
OSTEON 3 presents well interconnected porous structure, similar to that of human cancellous bone. It is supplied sterile by gamma irradiation.

B Indication for use

The use of OSTEON 3 may be considered when autogenous bone is not indicated, or insufficient in quantity to fulfill the needs of the proposed surgical procedure. Case selection and use of appropriate surgical procedure are at the discretion of the physician.

C Contraindication

OSTEON 3should not be used in patients with:
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia).
- Chronic high does therapy with corticosteroids.
- Osteomyelitis at the surgical site.
- Vascular impairment at the implant site.
- Severe renal dysfunction, liver disease.

D Directions for use

- After exposure of the bony defect with mucoperiosteal flap, all inflammatory tissue and debris must be carefully removed using curettes.
- The surgical site should be cleaned with sterile water or sterile saline and aspirated to prepare the bone for the placement of OSTEON 3.
- Mix OSTEON 3 with sterile normal saline or with patient's blood in a sterilized dish.
- In order to enhance the formation of new bone, OSTEON 3 should only be placed in direct contact with well vascularized bone. Cortical bone should be mechanically perforated.
- Transfer OSTEON 3 granules to the defect site using a sterile instrument. Fill in the defect site loosely with OSTEON 3 material to avoid crushing the particles and loss of trabecular architecture.
- The mucoperiosteal flaps should be sutured to achieve primary closure. A surgical dressing may be placed over the wound for one to two weeks.

E Precaution

- Effect on pediatric patients is not known.
- Effect on patients with a preexisting disease condition is not known.

F Warning

- Single use only. Do not resterilize or reuse.
- Not intended for immediate load-bearing.
- Do not leave defect open.
- Do not compromise blood supply to the defect area.
- Do not apply excessive force when implanting OSTEON 3 at the surgical site
- Do not use if package is opened or damaged or if expiration date has been exceeded.
- It is recommended to cover the implant site with a membrane when using OSTEON 3.
- Use this product in well vascularized bone.
- Product should be protected from contamination due to touching patient's tongue or saliva.
- Open the cap from the arrow mark. (▽)

G Adverse effect

No adverse reactions have been reported.
- Local complication could appear such as edema, numbness, bleeding after surgery, ulcer of soft tissue, infection etc.

H Symbols

LOT	Batch code		Date of manufacture
	Do not reuse		Use by date
STERILE R	Sterilized using irradiation		Fragile, handle with care
	Caution		Manufacturer
1℃ 30℃	Temperature limit		Do not resterilize
REF	Catalogue number		Keep away from sunlight
EC REP	Authorized representative in the European Union		Single sterile barrier system with protective packaging outside
MD	Medical device		Consult instructions for use
CE 2195	CE Mark	UDI	Unique device identifier
	Do not use if package is damaged and consult instructions for use		

I Strorage

- Store in room temperature away from sunlight(1~30℃)

J Expiration data

- The expiry date is described on the container and packaging.

K Articles

REF	Volume(cc)	Particle size (mm)
3G0205010	0.1	0.2~0.5
3G0205025	0.25	
3G0205050	0.5	
3G0205100	1.0	
3G0205200	2.0	
3G0210010	0.1	0.2~1.0
3G0210025	0.25	
3G0210050	0.5	
3G0210100	1.0	
3G0210200	2.0	
3G0510010	0.1	0.5~1.0
3G0510025	0.25	
3G0510050	0.5	
3G0510100	1.0	
3G0510200	2.0	
3G1020010	0.1	1.0~2.0
3G1020025	0.25	
3G1020050	0.5	
3G1020100	1.0	
3G1020200	2.0	

Made in Korea

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