Osteoconductive Synthetic bone substitute – OSTEON™ II

A Product Description

OSTEON™ II is a synthetic osteoconductive bone graft substitute composed of 30% Hydroxyapatite(HA) and 70% Beta-Tricalcium Phosphate (β-TCP). OSTEON™ II presents an interconnected porosity structure, similar to that of human cancellous bone. OSTEON™ II is available as irregular shaped granules of size 0.2~2.0mm. It is supplied sterile in vials or syringes.

B Indications for use

The use of OSTEON™ II 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 is at the discretion of the physician

C Contraindication

OSTEON™ II should not be used in patients with;
1) Metabolic diseases
(diabetes, hyperparathyroidism, osteomalacia).
2) Injecting corticosteroids for a longtime.
3) Osteomyelitis at the surgical site.
4) Vascular impairment at the implant site.
5) Severe renal dysfunction, liver disease.

D Directions for use

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

E Precaution

1) Effect on pediatric patients in not known.
2) Effect on patients with a preexisting disease condition is not known.

F Warning

1) Single use only. Do not resterilize or reuse.
2) Do not intended for immediate load-bearing.
3) Do not overfill defects.
4) Do not compromise blood supply to the defect area.
5) Do not apply excessive force when implanting OSTEON™ II at the surgical site.
6) Do not use if package is opened or damaged or if expiration date has been exceeded.
7) It is recommended to cover the implant site with a membrane when using OSTEON™ II.
8) Use this product in well vascularized bone.
9) The implantation of titanium fixtures should not take place until about 6months after the use of OSTEON™ II in any implant site.
10) Product should be protected from contamination due to touch ing patient's tongue or flowing in saliva.
11) Use under proper sterile technique.
12) Open product just before operation.
13) Open the cap from the protruded part

G Adverse effect

No adverse effect reactions have been reported.
- Local complication could appear such as edema, numbness, bleeding after surgery, ulcer of soft tissue, infection 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
	Do not resterilize	STERILE R	Sterilized using irradiation
	Do not use if package is damaged and consult instructions for use		Fragile, handle with care

I Storage

Store in a dry place below 30℃ in its original packaging.

J Expiration date

The expiry date is described on the container and packaging.

K Articles

REF	Volume(cc)	Particle size (mm)
DT7G0205025	0.25	0.2 ~ 0.5
DT7G0205050	0.5	
DT7G0205100	1.0	
DT7G0510025	0.25	0.5 ~ 1.0
DT7G0510050	0.5	
DT7G0510100	1.0	
DT7G1020025	0.25	1.0 ~ 2.0
DT7G1020050	0.5	
DT7G1020100	1.0	

Made in Korea

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