Bone Graft Material, Composite - OSTEON™ II Collagen

A Product description

OSTEON™ II Collagen is a bone void filler composed of synthetic bone graft (OSTEON™ II) and bovine Type I collagen. OSTEON™ II Collagen is trimmable and moldable thanks to the collagen coating. The collagen is absorbed slowly over several weeks after helping the initial shaping. OSTEON™ II Collagen is sterilized by gamma-radiation.

B Indication for use

OSTEON™ II Collagen is intended to augment the ingrowth of new hard and soft tissues into bony defects around teeth and on alveolar ridges.
- Ridge augmentation
- Extraction sites (implant preparation / placement)
- Cystic Cavities
- Sinus Lifts
- Periodontal / infrabony / defects

C Contraindication

OSTEON™ II Collagen should not be used in patients with:
- Infected wound
- A known allergy to collagen
- Metabolic diseases(diabetes, hyperparathyroidism, osteomalacia)
- Chronic high dose therapy with corticosteroids
- Osteomyelitis at the surgical site
- Vascular impairment at the implant site
- Severe renal dysfunction, liver disease

D Directions for use

1) After exposure of the bony defect with a mucoperiosteal flap, remove all inframmatory tissue and debris carefully using curettes.
2) Minimize salivary and other contaminations by aspiration to prepare the bone for placement of the OSTEON™ II Collagen.
3) If necessary, the OSTEON™ II Collagen may be cut to the required size with sterile scissors or curettes, in dry condition of after moistening with blood or saline solution.
4) Delivery the OSTEON™ II Collagen to the defect site using a sterile instrument.
5) Fill it in the defect site using a sterile instrument. Overfilling of the defects should be avoided.
6) 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 Precautions

1) OSTEON™ II Collagen should be used with caution for patients with
   - acute or chronic infection
   - prolonged corticosteroid therapy
   - autoimmune disease
   - radiotherapy
   - heavy smoking
2) Side effect on pediatric patients is not known
3) Side effect on pregnant women is not known
4) OSTEON™ II Collagen containing bovine collagen may induce BSE risks

F Warning

1) Single use only. Do not resterilize or reuse
2) Do not intend to use it for load-bearing
3) Do not use patients who have a known allergy to collagen
4) Do not overfill defects.
5) Keep the blood supply smooth into the defect area.
6) Do not apply excessive force when implanting OSTEON™ II Collagen at the surgical site
7) Do not use if package is opened or damaged or if expiration date has been passed.
8) Use this product in well vascularized bone.
9) Product should be protected from contamination due to touching of the patient's tongue or flowing-in saliva.
10) Use under proper sterile environments
11) Open the product just before operation

G Adverse effect

1) OSTEON™ II Collagen contains collagen, and in very rare cases allergic reactions may occur.
2) Possible complications with any periodontal surgery include thermal sensitivity, gingival recession, flap sloughing, resorption or ankylosis of the treated root, some loss of crestal bone height, perforation or abscess formation, pain, swelling, inflammation, infection, gingival irregularities, and complications associated with the use of anesthesia.
3) Depending on the type and severity of the complication, as judged by the clinician, removal of the OSTEON™ II Collagen or antibiotic therapy may be required.

H Symbols

REF	Catalogue number	LOT	Batch code
	Do not re-use		Date of manufacture
	Caution		Use by date
STERILE R	Sterilized using irradiation		Fragile, handle with care
1°C 30°C	Temperature limit		Manufacturer
	Do not resterilize		Do not use if package is damaged and consult instructions for use

I Storage

Store at room temperature

J Expiration date

3 years from the date of manufacture

K Caution

The Clinician must discuss the use of bovine animal tissue related products with patients who may object to their use on religious or ethical grounds, and inform patients of the BSE risk of the device in advance of the procedure.

L Articles

TYPE	REF	Size
Cylinder	OTCC0605M OTCC0610M	Ø6x5mm Ø6x10mm

*Other sizes are available.

MS-P444/IFU-B1006(Rev.14,2610)

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