InterOss® Collagen

Hydroxyapatite + Collagen Composite

DEVICE DESCRIPTION

InterOss® Collagen is a combination of InterOss®, an anorganic hydroxyapatite bone substitute, and collagen fibers for use in periodontal, oral and maxillofacial surgery. This product is a composite of 90% InterOss® (granules of size 0.25 – 1mm) and 10% porcine collagen fibers. InterOss® is a natural bone substitute that provides a mineralized structure similar to human bone and acts as an osteoconductive scaffold for the ingrowth of the adjacent viable bone. The collagen component facilitates the adaptation of InterOss® to the defect site allowing easier handling. The product is non-pyrogenic, single use only, and terminally sterilized via gamma-irradiation.

INDICATIONS FOR USE

InterOss® Collagen is indicated for filling of extraction sockets to enhance preservation of the alveolar ridge. InterOss® Collagen is recommended for:

- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Filling of periodontal defects in extraction sockets in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)

INSTRUCTIONS FOR PREPARATION

InterOss® Collagen should be used by licensed dentists or oral surgeons only. When handling the product, general principles of sterile handling, safety, hygienic clinical practice, and patient medication must be followed.

Opening the Product

- The package should be inspected prior to use to confirm the sterile barrier has not been compromised. Ensure the presence of a red sticker on the package to identify the product is sterile.
- Do not use if the integrity of the package is compromised.
- Do not use if the expiration date has been exceeded.

Site Preparation

- A thorough clinical and radiographic examination of the bone defect site is recommended to determine the amount of InterOss® Collagen required to fill the bone defect.
- Raise the mucoperiosteal flap to expose the bone defect and remove the granulation tissue of the bone defect region using a curette.
- Clean the site using 0.9% saline or distilled water.

Proper placement and containment of device

- InterOss® Collagen may be cut to the desired size using sterile instruments. Trimming may be conducted in dry form or after wetting with patient's blood or sterile 0.9% saline.
- The optimal soaking time for InterOss® Collagen in patient's blood of sterile 0.9% saline is 30 seconds to 60 seconds.
- Ensure that InterOss® Collagen is placed in direct contact with well vascularized, bleeding bone surfaces.
- InterOss® Collagen should be secured to prevent motion and migration, use in areas where the grafts can be adequately contained.
- Fill the bone defect with InterOss® Collagen. Do not overfill the defect; remove any excess residual material. Use of excessive force can lead to loss of interconnected pore structure and should be avoided.

Site Closure

- Cover the mucoperiosteal flap then suture the site firmly so that the implantation site is not exposed. The soft tissue flap should be free of tension and completely cover the implanted InterOss® Collagen.
- It is strongly recommended to cover InterOss® Collagen with a membrane barrier for stabilization and immobility of InterOss® Collagen during the healing period.

Patient Care Following Treatment

- Apply a surgical dressing on the surgical area for 1 to 2 weeks.
- Dentist should instruct patients not to apply pressure to the surgical site during the bone healing process.
- Patients should be advised to avoid physical exercise in the first 72 hours after the procedure.
- Surgical site should be limited to soft brushing for the first 2 weeks.
- A soft diet for one week should be recommended.
- The surgical site must be maintained clean using antiseptic mouthwash 3 times per day for 14 days.

CONTRAINDICATIONS

Conditions representing contraindications include:

- Presence of infected wounds, acute or chronic infection (e.g. osteomyelitis) at the surgical site or surrounding area
- Patients with a known hypersensitivity to porcine collagen

- Patients with liver disease and/or kidney disorders
- Degenerative bone disease (e.g. osteoporosis)
- Metabolic diseases (e.g. diabetes, hyperparathyroidism, osteomalacia) or systemic bone disorders
- Patients with vascular diseases
- Common user of steroids (e.g. high dose therapy with corticosteroids)
- Autoimmune disease
- Prior history of radiotherapy to implant site
- Current or previous use of medication that may affect bone turnover (such as bisphosphonates)
- Heavy smoking

ADVERSE EFFECTS

Possible adverse effects include but not limited to:

- Allergy to bone graft
- Hematoma
- Adverse tissue reaction
- Infection
- Swelling at the surgical site
- Flap sloughing
- Bleeding
- Local inflammation
- Bone loss

PRECAUTIONS

- InterOss® Collagen should only be used by trained dentists or oral surgeons. A local/institutional training programs are strongly recommended. For training, contact your local representative.
- InterOss® Collagen should be implanted in vital bony tissue in direct contact with the host bone.
- InterOss® Collagen is not intended for immediate load-bearing.
- A recommended 6 months healing time should be observed before implant placement.
- Effect on pediatric patients is not known.
- Effect on patients with pre-existing disease conditions (e.g. metabolic bone disorder, cardiovascular disease, autoimmune disease) or prior exposure to radiation therapy is not known.
- Safety and effectiveness in pregnant or breastfeeding women have not been established.

WARNINGS

- Single use only. If the product is used more than once, sterility is not guaranteed and adverse reactions can occur. Discard any unused material. Do not re-sterilize or re-use. Do not use on more than one patient or in more than one surgical procedure.
- Do not compromise blood supply to the defect area.

CAUTION

United States Federal law restricts this device to sale by or on the order of a licensed dentist.

MR (Magnetic Resonance) Statement

InterOss® Collagen has not been evaluated for safety and compatibility in the MR environment. InterOss® Collagen has not been tested for heating or migration in the MR environment.

Rx Only

STORAGE

InterOss® Collagen should be stored in a dry, clean, and well-ventilated place at ambient temperature (15-30°C/59-86°F). Keep the product in aseptic conditions until using the product.

EXPIRATION DATE: 1 year

LABELING SYMBOLS

CAUTION, CONSULT ACCOMPANYING DOCUMENTS	DO NOT RE-USE	LOT BATCH CODE	USE BY
REF CATALOG NUMBER	MANUFACTURER	US DATE OF MANUFACTURE	STERILE R STERILIZED USING IRRADIATION
30°C 15°C TEMPERATURE LIMITATION	Rx Only PRESCRIPTION ONLY	CONSULT INSTRUCTIONS FOR USE	DO NOT RESTERLIZE
DO NOT USE IF PACKAGE IS DAMAGED	KEEP AWAY FROM SUNLIGHT	KEEP DRY	MD MEDICAL DEVICE
TRANSLATED BY: Apex Translations 123 B West Water Street Plymouth, NC 27962, USA	**SYMBOLS**		

Manufactured by

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