SUNSTAR

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GUIDOR® *calc-i-oss*® CRYSTAL+

Alloplastic bone graft granules

Composition

calc-i-oss CRYSTAL+ is composed of biphasic calcium phosphate (60 % hydroxyapatite, 40 % beta-tricalcium phosphate). *calc-i-oss* CRYSTAL+ is derived from fully synthetic raw materials. *calc-i-oss* CRYSTAL+ contains no animal- or human-derived substances.

Description / Properties

calc-i-oss CRYSTAL+ is a sterile granular bone graft substitute that is biocompatible and osteoconductive. In the defect, the granules form a macro-porous structure that provides space for blood uptake and formation of autogenous tissue. The biphasic calcium phosphate granules remain embedded in autogenous tissue for prolonged periods of time in order to preserve the volume.

calc-i-oss CRYSTAL+ is available in the particle size range of 450 – 1000 µm.

Indications

calc-i-oss CRYSTAL+ should be used for the filling of unloaded and preferably multi-walled dental or maxillo-facial bone defects. Indications may include:

- Defects after removal of bone cysts
- Periodontal defects
- Augmentation of alveolar crest, e.g. Guided Bone Regeneration (GBR)
- Defects after root end resection
- Extraction defects
- Defects after surgical removal of retained teeth
- Sinus floor augmentations
- Defects after removal of autologous bone

Instruction for use

Aseptic working methods are essential during application.

calc-i-oss CRYSTAL+ should be mixed with the patient's blood or blood preparations (e.g. platelet-rich plasma), sterile saline or autogenous bone prior to application.

The defect should be cleaned from any granulation tissue. Ensure close contact between *calc-i-oss* CRYSTAL+ particles and viable bone in well-vascularized area. Thorough freshening of the bone surface ensures uptake of blood into the graft material.

Dental membranes may be used in combination with *calc-i-oss* CRYSTAL+ to contain the material in the defect for guided bone regeneration or guided tissue regeneration. Proper stability of the augmented site has to be ensured. Primary closure should be attempted. The soft tissue coverage should be complete and tension-free.

Periodontology

Before filling periodontal defects, a sufficient pre-treatment is necessary. This should include sufficient infection and plaque control as well as a successful local treatment of the periodontal lesion (e.g. root planning, debridement).

Contraindications

calc-i-oss CRYSTAL+ should not be applied in case of the presence of any diseases or therapies which are detrimental to the healing of bone.

calc-i-oss CRYSTAL+ should not be used in infected sites.

Precautions

calc-i-oss CRYSTAL+ should only be used by licensed practitioners properly trained in oral tissue regeneration using bone graft substitutes. Common standards and guidelines apply for the surgical procedure and the course of treatment.

calc-i-oss CRYSTAL+ should be used immediately after opening of the sterile package.

In order to facilitate the formation of new bone to a maximum extent, *calc-i-oss* CRYSTAL+ should only be implanted in close contact to well-vascularized surrounding bony tissue (refreshment of bleeding might be necessary).

The implantation site should be free of soft or granulation tissue.

Care should be taken in treating patients with preexisting conditions and therapies that may affect the success of the surgical procedure or impair the healing of bone defects and injuries.

All bone grafting procedures can experience variable results depending on the graft material and the applied technique. Various factors may influence the outcome and should be considered: location and size of the defect, bone quality and age of the patient, adequate filling of the bone void or gap, intimate contact of viable bone and bone graft substitute, wound closure and stabilization of the graft site to prevent migration of the graft material.

Possible adverse effects

Allergic or inflammatory reactions to the implant material or its decomposition products have not been recorded.

In general, possible adverse reactions are comparable to those encountered in autogenous bone or bone graft substitute grafting procedures. These include, but are not limited to: edema, bleeding after surgery, numbness by injured nerve, infection of the soft tissue and / or bone, soft tissue ulceration, incomplete bone formation, lack of bone formation, fracture or inflammation of the newly formed bone.

Any serious incident that has occurred in relation to *calc-i-oss* CRYSTAL+ should be reported to the manufacturer and the competent authority of the country where the dental professional and/or patient is established.

Interaction with other substances

Not known.

Warnings

calc-i-oss CRYSTAL+ is restricted to dental and maxillo-facial applications and to be sold to, or on the order of a licensed physician or dentist. Do not place *calc-i-oss* CRYSTAL+ in direct contact with nerve tissue.

The implantation site should be free of soft or granulation tissue.

No clinical data are available on the use in children and in pregnant or lactating women.

Do not use if package is opened or damaged, or if the expiration date has been exceeded.

calc-i-oss CRYSTAL+ cannot be re-used or re-sterilized. Discard any unused material. Sterility and function are no longer guaranteed in the event of re-use.

Miscellaneous

calc-i-oss CRYSTAL+ is gamma sterilized and intended for single application.

Unused material can be disposed in the domestic waste.

Storage instructions

calc-i-oss CRYSTAL+ must be stored in its original packaging.

Date of issue

2018-10-23

Manufacturer

Degradable Solutions AG*, Wagistrasse 23, 8952 Schlieren / Zurich, Switzerland

*A Sunstar group company

www.guidor.com

REF	A11-104	3 x 1.0 ml vials, 450 - 1000 µm granules
	A11-105	3 x 2.0 ml vials, 450 - 1000 µm granules

CE 0297	CE Marking - Notified body: DQS Medizinprodukte GmbH
REF	Catalogue number
	Do not re-use
LOT	Batch code
	Use-by date
	Consult instructions for use
STERILE R	Sterilized using irradiation
	Do not use if package is damaged
	Manufacturer

CE 0297

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