CevOss

TISSUE PACKAGE INSERT

COMPOSITION

CevOss is a natural bone mineral of bovine origin. The highly purified osteoconductive mineral structure is produced from natural bone in a multi-stage purification process, manufactured following strict safety regulations. CevOss is available as granules of cancellous bone matrix. Because of its natural origin, CevOss is both chemically and structurally comparable to the mineralized human bone (nanocrystalline natural apatite). Sterilization of CevOss is carried out by gamma radiation.

PROPERTIES/EFFECTS

The mineral bone matrix of CevOss has a macro- and micro-porous structure similar to human cancellous bone. Due to the large interconnecting pore volume and the natural composition, the formation and growth of new bone at the implantation site is promoted. Over time, CevOss is partially remodeled by osteoclasts and osteoblasts (physiological remodeling). Due to its properties, CevOss is an effective alternative to autologous bone in suitable defects.

INSTRUCTIONS

CevOss granules are recommended for filling of bone defects and bone augmentation cases, such as:

- Augmentation/reconstruction of alveolar ridges
- Filling of extraction sockets
- Implantology:
  - -preparation of implant sites
  - -filling of bone dehiscence
  - -sinus floor augmentation
- Periodontology:
  - -filling of bone defects
  - -support of the membrane during guided tissue regeneration (GTR).

INSTRUCTIONS FOR USE

The sterile handling and patient medication general principles must be followed when using CevOss.

- Complete removal of granulation tissue following exposure of the defect
- Mixing of CevOss with the patient's blood or physiological saline solution before implantation.

APPLICATION:

- CevOss is placed into the defect, using sterile instruments (spatula, spoon or syringe).
- In situ modelling may be performed with a sterile spatula or other suitable instrument
- Covering CevOss with a barrier membrane is highly recommended
- When closing the wound, the soft tissue flap must completely cover the implanted CevOss, and must be fixed by suture.
- If primary wound closure cannot be fully achieved, further mobilization of the flap (incision through the periosteum) should be performed or wound covering should be achieved with a barrier membrane.

SPECIAL INSTRUCTIONS FOR USE IN PERIODONTOLOGY:

- A basic requirement for successful periodontal treatment includes control of any bacterial infection as well as thorough oral hygiene. Therefore, a hygiene phase including adequate instructions for the patient is strongly recommended before the surgical intervention. A post-operative maintenance phase can ensure long-term therapeutic success.
- Besides plaque control, the filling of periodontal defects with CevOss requires successful local treatment of the periodontal defect (root planning), prior to the implantation. The defect should be covered with a membrane for optimal tissue regeneration.

RESTRICTIONS ON USE / PRECAUTIONS:

Contraindications:

CevOss should not be used in the presence of infected wounds.

Precautions:

CevOss should only be used by trained dentists in patients with:

- Acute or chronic infection (e.g., osteomyelitis) at the surgical site
- Uncontrolled metabolic disorders (e.g., diabetes, osteomalacia, thyroid disorder, severe renal or hepatic disorder)
- Long-term corticosteroid therapy
- Autoimmune disease
- Radiotherapy
- Heavy smoking.

In order to ensure bone regeneration, CevOss should only be implanted in vital bone tissue, in direct contact

with the host bone (if necessary, with microfracture of the bone surface).
For larger defects, the addition of autologous cancellous bone may improve the regeneration process. Mobility by mechanical loading (compression loading) or insertion of implants (two-stage procedure) in the augmented area should be avoided until several weeks after the insertion of CevOss. Mechanical loading (compression loading) in areas augmented with CevOss is possible only after 6 months. The appropriate timing for dental implant insertion usually depends on the residual local bone volume.
Side effects: Incompatibility reactions with CevOss cannot be fully excluded. Possible complications which may occur after any surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.
Pregnancy/Lactation: There is no information available regarding the use of the product during pregnancy or lactation. For safety reasons: Pregnant or breast-feeding women should not be treated with CevOss. CevOss' safety and efficiency have not been researched in children before skeletal maturity.

LABELING SYMBOLS:

Symbols may be used on some international package labeling for easy identification.

	Do Not Resterilize
STERILE R	Sterilization using irradiation
	Do Not Use if Package is Damaged
	Consult Instructions for Use
	Do Not Re-use
	Temperature Limitation
	Use by date
LOT	Lot number
REF	Catalog number
	Date of manufacture
	Manufacturer

Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed physician or dentist.

BONE GRAFTING

CEVOSS

Bovine Bone Particulates

CITAGENIX
The Regen Company

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