Instructions for use CoreGraft® Products Bio-implants

Anorganic Bovine Matrix

Read this entire package insert and product description form carefully prior to use.

Note:

- This Xenograft product is derived from bovine tissue
- Intended for single patient use only, in a single operation only
- Restricted to use by a licensed physician, surgeon or dentist
- Use sterile techniques to transfer contents of inner package to the sterile surgical field

Composition

CoreGraft® is a natural bone mineral of bovine origin. The highly purified osteoconductive mineral structure is produced from natural bone through a multi-stage purification process, manufactured in accordance with strict safety regulations. CoreGraft® is available as granules of cancellous bone matrix. CoreGraft® is supplied in sterile, single-use vials in different particulate sizes. It is also available in a syringe-type package for easier handling. This syringe helps the physician hydrate the bone matrix and prevent granule loss.

Properties/ Effects

The mineral bone matrix of CoreGraft® 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, it is partially remodeled by osteoclasts and osteoblasts (physiological remodeling). Due to its properties, CoreGraft® is an effective alternative to autologous bone in suitable defects.

Indications

CoreGraft® is intended for use in:

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

Instructions for use

The general principles of sterile handling and patient medication must be followed when using CoreGraft®.

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

Application

- CoreGraft® 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 it with a barrier membrane is highly recommended
- When closing the wound, the soft tissue flap must completely cover the implanted CoreGraft® 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. It is therefore advised that, preceding the surgical intervention, there must be a hygiene phase, which would include proper instruction for the patient. A postoperative maintenance phase can ensure long-term therapeutic success.

- Besides plaque control, the filling of periodontal defects with **CoreGraft®** requires successful local treatment of the periodontal lesion (root planning, debridement), prior to the implantation. The defect should be covered with a membrane for optimal tissue regeneration.

Restrictions on use / Precautions

Contraindications

- CoreGraft® should not be used in the presence of infected wounds.

Precautions

- CoreGraft® effect on pediatric patients is not known
- CoreGraft® should only be used by dentists and surgeons trained in this field.
- CoreGraft® should be used with particular caution in patients with:
- Acute or chronic (eg, osteomyelitis) at the surgical site
- Metabolic diseases such as uncontrolled diabetes, osteomalacia, thyroid disorder, neuropathy, or severe liver disease.
- Long-term corticosteroid therapy
- Autoimmune Diseases
- Radiotherapy
- Heavy smoking.

To ensure regeneration of bone, CoreGraft® 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 CoreGraft®. Mechanical loading (compression loading) in areas augmented with CoreGraft® 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 CoreGraft® cannot be fully excluded. Possible complications that 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 breastfeeding women should not be treated with CoreGraft®. 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

	Use-by date
LOT#	Batch code
REF	Catalog number
	Date of manufacture
	manufacture
STERILE R	Sterilized using irradiation
	Do not resterilize
	Do not re-use
	Do not use if package is damaged or opened
	Temperature limit
	Consult instructions for use

CoreGraft® PRODUCT RANGE

Granule presentation:

Ref No.	Volume	Weight	Granule Size
CGB-250-05	0.5 cc	0.25 gr	250-1000
CGB-350-05	0.5 cc	0.25 gr	350-840
CGB-840-05	0.5 cc	0.25 gr	840-2000
CGB-1000-05	0.5 cc	0.25 gr	1000-2000
CGB-250-10	1.00 cc	0.50 gr	250-1000
CGB-350-10	1.00 cc	0.50 gr	350-840
CGB-840-10	1.00 cc	0.50 gr	840-2000
CGB-1000-10	1.00 cc	0.50 gr	1000-2000
CGB-250-20	2.00 cc	1.00 gr	250-1000
CGB-350-20	2.00 cc	1.00 gr	350-840
CGB-840-20	2.00 cc	1.00 gr	840-2000
CGB-1000-20	2.00 cc	1.00 gr	1000-2000
CGB-250-40	4.00 cc	2.00 gr	250-1000
CGB-350-40	4.00 cc	2.00 gr	350-840
CGB-840-40	4.00 cc	2.00 gr	840-2000
CGB-1000-40	4.00 cc	2.00 gr	1000-2000
5CCBO	5.00 cc	2.50 gr	840-2000
HU5CC	5.00 cc	2.50 gr	1000-4000
10CCBO	10.00 cc	5.00 gr	840-2000
HU10CC	10.00 cc	5.00 gr	1000-4000
HU20CC	20.00 cc	10.00 gr	1000-4000
HU30CC	30.00 cc	15.00 gr	1000-4000

Moldable putty bovine matrix:

Ref No.	Weight	Granule Size
CGP-10	1.00 gr	350-840
CGP-20	2.00 gr	350-840

Prefilled Syringes:

	Ref No.	Volume	Weight	Granule Size
Curved Syringe	CGSY-350-10	1.00 cc	0.50gr	350-840
	CGSY-840-10	1.00 cc	0.50gr	840-2000
Straight Syringe	CGSY-1400-10	1.50 cc	0.75gr	350-1400
	CGSY-840-20	2.00 cc	1.00gr	840-2000

Original Manufacturer:
Odontit S.A., Necochea 852/854
Buenos Aires City, Argentina, 1158

Legal Manufacturer: Total-Core Biomedical Manufacturing LLC
Warehouse E-P1, Block D, Unit 15-WH, Dubai Industrial City (DIC),
Mohammad Bin Zayed Road, Dubai, UAE
Head Office: Unit 807, Onyx Tower 1, Sheikh Zayed Road,
The Greens,Dubai, UAE
P.O.Box: 117503
Tel: +971 4 332 7389 www.total-core.ae
Fax: +971 4 332 7773 info@total-core.ae

Total-Core
Core value builder
Total-Core Biomedical Manufacturing