ZCORE™

Porcine Xenograft Particulate

INSTRUCTIONS FOR USE
A sterile, biocompatible anorganic porous bone mineral for use in periodontal, oral and maxillofacial surgery.

DESCRIPTION
ZCORE™ is a porous bone mineral matrix consisting predominantly of calcium phosphate. It is produced by removal of the organic components from porcine cancellous bone. *ZCORE*™ is sterilized by gamma irradiation. The product is available in granular form, non-pyrogenic and for single use only.

PROPERTIES/ACTIONS
The anorganic bone matrix of *ZCORE*™ has interconnecting macro- and microscopic porous structure that supports the formation and ingrowth of new bone at the implantation site. The use of *ZCORE*™ may be considered when autogenous bone is not indicated, or insufficient in quantity to fulfill the needs of the proposed surgical procedure.

INDICATIONS AND USAGE
ZCORE™ is indicated for:
- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

INSTRUCTIONS FOR USE
- After exposure of the bony defect with a mucoperiosteal flap, all granulation tissue must be carefully removed.
- Mix *ZCORE*™ with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. If large maxillofacial defects are present, *ZCORE*™ should be mixed with autogenous bone in a ratio of approximately 1:1.
- In order to assure the formation of new bone, *ZCORE*™ should only be placed in direct contact with well vascularized bone. Cortical bone should be mechanically perforated.
- Loosely pack *ZCORE*™ into osseous defect using a sterile instrument. Use of excessive force will result in compression of the particles and loss of trabecular architecture.
- Overfilling of the defects should be avoided.
- The mucoperiosteal flaps should be sutured to achieve primary closure, if possible. A surgical dressing may be placed over the wound for one to two weeks.
- If primary wound closure can not be achieved completely, further immobilization of the flap (e.g., by incision through the periosteum) should be performed and/or a bioabsobable membrane (e.g. Resorbable Collagen Membrane) should be placed over the bone graft site.

CONTRAINDICATIONS
Contraindications customary to the use of bone grafts should be observed. *ZCORE*™ should not be used in patients with:
- Acute or chronic infection (osteomyelitis) at the surgical site
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Severe renal dysfunction, severe liver disease
- High dose corticosteroid therapy
- Vascular impairment at the implant site
- Osteoporosis
- Known allergy or hypersensitivity to porcine-derived implantable materials

WARNINGS
The device should be secured to prevent motion and migration, use in areas where the graft can be adequately contained.

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

ZCORE™ cannot be re-sterilized or re-used. Open, unused product must be discarded. In vivo stability may be adversely affected if re-sterilized. Cross-contamination and infection may occur if re-used.

PRECAUTIONS
In order to facilitate the formation of new bone *ZCORE*™ should only be implanted in direct contact with a well vascularized bony tissue. Drilling may be recommended to facilitate bleeding from cortical bone.

In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.

Implantology
Generally, in augmented areas, the placement of titanium fixtures should take place once the bone has sufficient strength and integrity for dental implant placement, which is typically greater than 6 months after implantation of a bone graft material. For sinus floor elevation, typically 9-12 months should be allowed after implantation of bone graft material before placement of the titanium fixtures. X-rays should be taken to confirm the bone integrity prior to dental implant placement.

Periodontology
The filling of periodontal defects with *ZCORE*™ requires (along with plaque control) the successful local treatment of the periodontal lesion (e.g. root planing, debridement of granular tissue) prior to implantation.

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

ADVERSE REACTIONS
Possible complications that may occur with any dental surgery include swelling at the surgical site, flap sloughing, bleeding, local inflammation, bone loss, infection or pain.

HOW SUPPLIED
ZCORE™ is supplied sterile, non-pyrogenic, and for single use only.

Catalogue Number	Particle Size	Volume
ZS050 ZS100 ZS200 ZS400	0.25 – 1.0 mm	0.5 cc 1.0 cc 2.0 cc 4.0 cc
ZL100 ZL200	1.0 – 2.0 mm	1.0 cc 2.0 cc

STORAGE
Store at room temperature (15˚C/59˚F - 30˚C/86˚F).

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

	Caution, See Instructions For Use
	Use By
	Do Not Reuse
LOT	Lot Number
STERILE R	Sterilized Using Irradiation
REF	Catalog Number
R_X ONLY	Federal (USA) law restricts this device to sale by or on the order of physician
	Manufacturer
	Do not use if the product sterilization barrier or its packaging is compromised
	Temperature Limitation

Manufacturer
Collagen Matrix, Inc.
15 Thornton Road
Oakland, New Jersey 07436 USA

Distributed by:
Osteogenics Biomedical, Inc.
4620 71st Street, Bldg 78-79
Lubbock, TX 79424 USA
www.osteogenics.com
888-796-1923