INSTRUCTIONS FOR USE

Description:
ZCORE™ Form is an osteoconductive bone mineral with collagen composite for bone grafting in periodontal, oral and maxillofacial surgery. The device is composed of 90% anorganic bone mineral granules derived from porcine cancellous bone and 10% collagen from porcine Achilles tendon in a composite matrix. The product is supplied sterile, non-pyrogenic and for single use only.

Properties/Actions
The anorganic bone mineral matrix has an interconnecting macro- and microscopic porous structure that supports the formation and ingrowth of new bone at the implantation site. The collagen facilitates handling of the graft particles and acts to maintain the graft material in the defect site. The moldable consistency of the device allows it to take the shape of the defect. The use of ZCORE™ Form 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™ Form 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).

Aseptic Opening/Presentation:
ZCORE™ Form products are packaged in a single layer blister tray. To ensure sterility is maintained, do not open the blister package until ready for implantation. Caution should be taken during opening, removal and implantation to make sure that the product does not come in contact with any non-sterile surfaces.

1. To open:
   a. Hold the blister tray in one hand with the top lid opening (square corner) away from you.
   b. Pull the top lid back towards you.

2. To remove:
   a. Hold the flap away from both the contents of the package and the sterile field.
   b. Drop the product onto the sterile field or if assisting with the procedure hold the exposed sterile item toward the clinician so he/she can grasp with a sterile instrument (e.g., forceps) or sterile gloves.
3. To implant:
   a. Prepare the device for implantation in accordance with the instructions for use below. Transfer the device from the sterile field to the patient defect area using a sterile instrument (e.g., forceps).

Instructions for Use:
- After exposure of the bony defect with a mucoperiosteal flap, all granulation tissue must be carefully removed.
- Mix ZCORE™ Form with patient's blood or sterile normal saline.
- In order to assure the formation of new bone, ZCORE™ Form should only be placed in direct contact with well vascularized bone. Cortical bone should be mechanically perforated.
- Loosely pack ZCORE™ Form 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 cannot be achieved completely, further immobilization of the flap (e.g., by incision through the periosteum) should be performed and/or a bioabsorbable membrane (e.g. Resorbable Collagen Membrane) should be placed over the bone graft site.
- Pre- and post-operative considerations: A basic requirement for successful periodontal treatment includes control of any bacterial infection as well as through oral hygiene. It is advised that, preceding the surgical intervention, there be a hygiene phase, which would include proper instruction for the patient. A postoperative maintenance phase can ensure long-term therapeutic success.

Contraindications:
Contraindications customary to the use of bone grafts should be observed. ZCORE™ Form 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 allergies to collagen or hypersensitivity to materials of porcine origin.

Precautions:
In order to facilitate the formation of new bone, ZCORE™ Form should only be implanted in direct contact with a well vascularized bony tissue. Drilling may be recommended to facilitate bleeding from cortical bone. The use of ZCORE™ Form has not been evaluated in children.

ZCORE™ Form cannot be re-sterilized. Open, unused ZCORE™ Form must be discarded. *In vivo* stability may be adversely affected if re-sterilized.

Cross-contamination and infection may occur if re-used. Do not use if the product sterilization barrier or its packaging is compromised.

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™ Form requires (along with plaque control) the successful local treatment of the periodontal lesion (e.g. root planning, debridement of granular tissue) prior to implantation.

Warning:
ZCORE™ Form in the block form is not intended for load bearing applications. The block shape of the anorganic bone mineral and collagen composite is intended for ease of handling.

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

Adverse Reactions:
Due to the collagen component, ZCORE™ Form allergic reactions cannot be totally excluded. 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™ Form is supplied sterile, non-pyrogenic, and for single use only. The device is available in three different sizes, 0.5 cc, 1.0 cc, and 2.0 cc.

Storage:
The product should be stored at room temperature (15˚C/59˚F - 30˚C/86˚F). Avoid excessive heat and humidity.

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

⚠	Caution
⌛	Use By
⊗	Do Not Reuse
LOT	Lot Number
STERILE R	Sterilized Using Irradiation
	Temperature Limitation
REF	Catalog Number
R_X Only	Federal (USA) law restricts this device to sale by or on the order of a physician or dentist
🏭	Manufacturer
	Do not use if the product sterilization barrier or its packaging is compromised.

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