ZMATRIX™
PORCINE PERITONEUM COLLAGEN MEMBRANE

DESCRIPTION
ZMATRIX is a non-pyrogenic porcine derived dental barrier membrane. ZMATRIX is resorbable, eliminating the need for a second surgical procedure normally required to remove a non-resorbable membrane.

INDICATIONS
ZMATRIX is indicated for:

- simultaneous use of GBR-membrane and implants.
- augmentation around implants placed in immediate extraction sockets.
- augmentation around implants placed in delayed extraction sockets.
- localized ridge augmentation for later implantation.
- alveolar ridge reconstruction for prosthetic treatment.
- filling of bone defects after root resection, cystectomy, removal of retained teeth.
- guided bone regeneration in dehiscence defects.
- guided tissue regeneration procedures in periodontal defects.

CONTRAINDICATIONS
ZMATRIX is contraindicated in patients who have:

- acute infection or contaminated wounds in the oral cavity.
- known allergy to porcine derived products.
- clinically significant renal, hepatic, cardiac, endocrine, hematologic, autoimmune or systemic disease which, in the physician's judgment, will prevent safe implantation or likely healing.

WARNING
Clinicians should use extra care in screening patients for any known allergies to porcine derived products. Hypersensitivity reactions have been noted with the use of other animal derived products; therefore, the possibility exists of developing a local sensitivity response to ZMATRIX.

PRECAUTIONS

- Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
- Single patient use only. **Do not resterilize**. Discard all open and unused portions of the membrane.
- Rinse surgical gloves with sterile fluid to remove any glove powder prior to handling the membrane.
- Resorption time may be accelerated if the membrane is exposed during the healing phase.

- Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.
- Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury or illness.

ADVERSE REACTIONS

Possible complications that can occur with any dental surgery include infections, swelling of the intraoral tissue, thermal sensitivity, gingival recession, excessive gingival bleeding, flap sloughing, resorption or ankylosis, with loss of crestal bone height, abscess, inflammation, graft rejection, fistula formation, flap dehiscence, pain, or complication associated with the use of anesthesia. Minor discomfort may occur for a few days.

INSTRUCTIONS FOR USE

Preparation

1. Follow general principles of sterile handling and patient medication when using ZMATRIX. The device is packaged in double sterile pouches. Open the outer pouch carefully and place the inner pouch onto the sterile field. Remove the membrane from the inner pouch using sterile gloves or instruments.
2. Create a mucoperiosteal flap to expose the periodontal or bone defect and execute basic surgical procedures (e.g. curettage). Perform thorough debridement and defect planning. Fill the defect using space-making material such as autologous bone, demineralized bone matrix or ceramic materials. Preserve as much tissue as possible to allow for primary wound closure and correct flap positioning.

Hydration and Placement Procedure

1. If hydrating prior to implantation, hydrate the membrane in an excess of sterile saline for approximately 5 minutes prior to final placement. Otherwise, implant the membrane dry, allowing for hydration with blood from the surgical site.
2. If needed, trim the membrane in the dry or hydrated state to the size and shape of the defect using sharp, sterile scissors.
3. The membrane should overlap the walls of the defect by at least 2 mm to allow complete bone contact and prevent gingival connective tissue invasion below the material.
4. If desired, fix the membrane to avoid displacement due to loading or mobilization using absorbable sutures and a non-cutting needle. Suture the mucoperiosteal flap over the porcine membrane and close the wound completely to avoid accelerated resorption due to membrane exposure.

Postoperative Procedure

1. ZMATRIX is completely resorbable and should not need to be removed. To minimize bacterial contamination, the patient should rinse with an antimicrobial agent such as

chlorhexidine gluconate (Peridex) twice daily for 4 weeks following surgery.

2. The patient should refrain from brushing for 2 weeks following surgery. After this period, the patient may be instructed to gently brush the area with a soft toothbrush. Dental floss should not be used prior to 4 weeks following surgery. Coronal scaling and prophylaxis can be performed at follow-up visits, if indicated.
3. The patient should be seen 7 to 10 days following surgery for wound reevaluation and removal of any closing sutures or periodontal packing. These follow-up visits should be repeated every 2 weeks thereafter, up to 8 weeks following surgery.
4. Probing and subgingival scaling should not be performed prior to 6 months following surgery to prevent damage to immature tissues, at which time the membrane should be resorbed. Other assessments of clinical health may be repeated, including plaque, bleeding, and tooth mobility indices.

HOW SUPPLIED

ZMATRIX is supplied in a pouch-in-pouch configuration, with one membrane per package. ZMATRIX is sterilized by ethylene oxide and is for single use only.

STORAGE

Store in a clean, dry location at room temperature.

CAUTION

Federal (U.S.A) Law restricts this product to sale by or on the order of a dentist or physician.

DSM

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