

Vitala®

Porcine Derived Collagen Membrane

INSTRUCTIONS FOR USE

INTRODUCTION

The user of Osteogenics Biomedical products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Osteogenics Biomedical disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive, or other damages, arising out of or in connection with any errors in professional judgment or practice in the use or installation of Osteogenics Biomedical products.

IMPORTANT: Read this entirely and follow all instructions carefully. Improper handling, preparation, surgical technique, or postoperative care may adversely affect the safety and/or performance of the membrane.

DESCRIPTION

Vitala® is a natural collagen membrane for use in periodontal and/or dental surgical procedures. The membrane is manufactured using a standardized, controlled, multistage process. The pre-slaughter origin of all animals is the United States of America and the source collagen is extracted from veterinary-certified pigs sacrificed in a USDA-inspected facility. The membrane is terminally sterilized in double blister packs by electron beam irradiation. The contents of the unopened, undamaged inner package are sterile.

MODE OF ACTION

Vitala® functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually remodeled and resorbed and replaced by host tissue. Animal studies have shown that *Vitala*® is substantially resorbed by 26 weeks.

INDICATIONS FOR USE

Vitala® is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for:

- Simultaneous use with 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, or removal of retained teeth;
- Over the window in lateral window sinus elevation procedures;
- Furcation defects in multirrooted teeth;
- Treatment of recession defects, together with a coronally positioned flap;
- In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection;
- Guided bone regeneration of dehiscence defects; and
- Guided tissue regeneration procedures in periodontal defects
- Alveolar ridge preservation consequent to tooth extraction

CONSIDERATIONS

Pre-Operative Considerations

- Store the sterile membrane observing the temperature range printed on the outer label in a clean, dry place protected from direct sunlight.
- Patients should be screened prior to implantation for a history of hypersensitivity to porcine (pig) collagen or porcine products.
- Do not use the membrane unless package integrity can be verified, proper storage has been assured, and the expiration date has been verified.
- The membrane is a sterile, single-use device. Unused portions of the device must be discarded and not reused. Do not use a single membrane on more than one patient, or in more than one surgical procedure.
- Do not remove the membrane from the sterile inner package until just prior to implantation. After opening, keep the membrane in the sterile blister pack. Avoid contact between the membrane and surgical drapes or cotton gauze to avoid contamination with fibers from those materials.
- When handling the membrane, sterile, talc-free gloves should be used to avoid contamination with particulate material from the gloves.
- Do not resterilize the membrane in any fashion.
- Improper storage or handling of the membrane may damage and/or contaminate the membrane and affect the sterility, handling characteristics, resorption characteristics, and/or physical integrity of the device.

IMPORTANT: Strict adherence to sterile protocol must be followed during the implantation of this device.

Intra-Operative Considerations

- If the membrane is contaminated during the course of the surgical procedure, it must be discarded.
- Preoperative patient assessment and preparation, including careful evaluation of the past medical history, is essential. Appropriate antimicrobial therapy, if indicated, should be prescribed at the discretion of the treating clinician.
- The bone defect is exposed by a mucoperiosteal flap and basic surgical procedures (e.g. curettage, debridement) are completed.
- The resulting bone defect is filled with a space-making material such as allograft bone, autogenous bone, xenogenic bone, or synthetic bone substitute at the discretion of the treating clinician. The defect should not be over-filled, and all stray graft particles should be removed.
- Prior to rehydration, trim the membrane with sterile scissors to fit the defect. A piece of sterile foil may be used as a template for membrane sizing and trimming. It is recommended that the membrane overlap the walls of the defect by at least 2.0 mm. The free edges of the membrane should be smooth and round with no sharp corners. The edges of the membrane should be well covered with soft tissue and should not protrude from the defect. Proper sizing and placement are essential to prevent gingival connective tissue or epithelial invasion below the membrane.

- After sizing, place in 0.9% sterile saline or the patient's blood or plasma until the membrane becomes soft and flexible.
- When transferring the membrane to the defect, the surgeon should take care to avoid touching the membrane on the lips, teeth, or any part of the oral cavity to avoid bacterial contamination from these surfaces.
- The membrane may be secured in place with sutures, tacks, or by means of sufficient contact with the mucoperiosteal flap to avoid displacement and micromotion during healing. If sutures or tacks are used to secure the membrane, they should be placed 2 to 3 mm from the free edge of the membrane when possible.
- To facilitate proper healing, ensure that there is tension-free primary closure of the soft tissue flap covering the membrane.
- If there is an overlying prosthesis, it should be adjusted to prevent compression of the soft tissue overlying and adjacent to the membrane.

Post-Operative Considerations

- Patients should be monitored closely and instructed to inform the implanting clinician of any adverse reactions.
- The clinician should inform the patient to refrain from any activity that could cause the membrane to be disturbed.
- In the event of dehiscence and membrane exposure, if there is no evidence of infection it may not be necessary to remove the membrane; however, the clinician may recommend the patient use an antibacterial mouth rinse until the wound is closed to reduce the risk of contamination.
- In general, to allow sufficient time for bone maturation to occur under the membrane, 4 to 6 months is necessary prior to surgical exposure.

CONTRAINDICATIONS

- Known hypersensitivity to porcine collagen.
- Active or latent infection at or around the wound site.
- Any systemic disorder or disease that involves an unacceptable increase in the postoperative risk for complications.
- This product has not been tested on pregnant women.

PRECAUTIONS

- *Vitala*[®] is provided sterile and is intended for single use only.
- Do not resterilize or reuse in more than one surgical case or on more than one patient.
- In case of early exposure of the membrane, resorption time may be accelerated.
- If the product, labeling, or packaging is compromised in any way, do not use the membrane. Notify your source of purchase.

ADVERSE REACTIONS













In very rare cases, local reaction can occur in patients without a history of hypersensitivity to porcine collagen. The following potential side effects may be observed after surgical intervention: dehiscence with early membrane exposure, hematoma, swelling, increased sensitivity or pain, local redness, and inflammation.


CAUTION

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

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

	Manufacturer
	Use By
	Do Not Reuse
	Caution
	Lot Number
	Catalog Number
	Temperature Limit 15 - 30°C (59 – 86°F)
	Method of Sterilization Using Irradiation
	Keep Away from Sunlight
	Do Not Use if Package is Damaged
	Do Not Resterilize
	Consult Instructions for Use

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