Instruction for Use for POWERBONE Barrier Membrane

Classification

POWERBONE Barrier Membrane is a medical device (Class III), not a drug.

Material

POWERBONE Barrier Membrane consist of PLA based polymer which is degrade to CO_2 and H_2O via respiratory metabolic pathway.

Product Components of POWERBONE Barrier Membrane:

1.) Poly(DL-lactide) polymer –PDL45
2.) Choloform (evaporates during production process)
3.) N-Methyl-2-pyrrolidone (NMP)
4.) Tween 80

Intended Use:

POWERBONE Barrier Membrane is a periodontal Membrane that aids regeneration of the periodontal attachment apparatus, augmentation around implants placed in immediate extraction sockets, augmentation of insufficient ridges for later implantation; and treatment of alveolar ridge deficiencies**.**

General Description

POWERBONE Barrier Membrane is a bioresorbable polymer synthesized from PLA based polymer. Its unique, open-cell architecture is a matrix of incomplete void spaces, randomly sized and shaped, which have multiple communications with neighboring void spaces.

The polymer of the POWERBONE Barrier Membrane is of the metabolite lactic acid and is degrade to CO_2 and H_2O. The basic polymer has a long history of sale medical use. Barrier Membrane is flexible, hydrophilic and initially exhibits a vigorous uptake of fluid blood when placed on the wound. Surface tension of the fluid blood that invests in the barrier dressing promotes and improves the adherence of the barrier/tooth surface interface.

Indications

POWERBONE Barrier Membrane is indicated for use as an adjunct to periodontal restorative surgeries in the treatment of periodontal defects following established surgical procedures.

POWERBONE Barrier Membrane is a periodontal Membrane that aids: regeneration of the periodontal attachment apparatus, augmentation around implants placed in immediate extraction sockets, augmentation of insufficient ridges for later implantation; and treatment of alveolar ridge deficiencies.

- Barrier Membrane is a bioabsorbable implantable material intended to aid in the healing of periodontal defects. It may also be used as a membrane for bone graft containment.

- Barrier Membrane may be used for augmentation around immediately placed endosseous implants or existing endosseous implants (e.g. dehiscence and fenestration)

- Barrier Membrane can be used for ridge augmentation with future implantation of end osseous implants and for sinus procedures (e.g. sinus window, sinus lift)

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Contraindications

Use of POWERBONE Barrier Membrane is contraindicated in the presence of active infection where purulence is produced.

How It Works

Clinical investigations have revealed that, once implanted in the body, Barrier Membrane functions to support the initial blood clot and maintain competence of collateral circulation. It provides a unique density-gradient three-dimensional construction designed to attract, trap and retain fibroblasts and epithelial cells while maintaining space around teeth for development of bone and periodontal support tissues.

Unlike passive or defensive barriers, Barrier Membrane organizes fibroblasts and epithelial cells to help arrest epithelial migration during the later phases of healing. Barrier Membrane maintains its architecture and structural integrity for 10-12 weeks after implantation with complete bioresorption occurring between 6-12 months.

Opening the Package

Open the package and gently remove the barrier using a sterile surgical tong Place the device in the surgical sterile field in preparation for the procedure.

Directions for Use

Preparation for implant- After the patient has achieved anesthesia a full-thickness mucoperiosteal flap is elevated. The flap should extend at least one tooth anterior and posterior to the defect(s). The defects should be thoroughly debrided of granulation tissue and the roots property scaled and root-planed to remove calculus and diseased cementum.

After sufficient area preparation, the inner package (4A sterilization roll) is immersed in 60 ºC hot water. It should be exposed to hot water for 30 seconds. Then, enough Membrane material should be cut with scissors or scalpel to cover the application area or used as the size it came out of the package.

Application:
Once the material has been trimmed properly, orient the embossed side facing away from the tooth's surface and toward the gingiva, leaving the fat side of the Membrane to closely approximate the tooth surface.

Stabilizing Suture Placement:
Although employment of a stabilizing suture to secure the barrier is not necessary for most situations, the use and type of suture is at the discretion of the clinician.

The use of bone grafts or bone graft substitutes in conjunction with POWERBONE Barrier Membrane is at the discretion of the clinician.

- thoroughly prepare surgical site
- It should be exposed to 60 ºC hot water for 30 seconds
- trim Membrane material to size
- orient embossed side facing toward the gingiva
- replace flaps
- provide patient with detailed instructions for past-operative care

Post-Operative Reminders

Patients are instructed to rinse with an anti-microbial mouth rinse between meals for two weeks post-surgery to control anaerobic bacteria. Patients should not brush or floss teeth in and around the treated area until the clinician feels sufficient healing has occurred.

Patients should return at one week post-surgery for evaluation and adjustments in oral hygiene instruction.
Patients should be monitored on a regular basis for evaluation, oral hygiene instructions, and coronal scaling and rubber cup polishing for the first eight weeks.

In the event of lap recession where the material becomes exposed, Barrier Membrane will remain functional and should not be disturbed. In such cases, oral hygiene to control anaerobic bacteria should be intensified.

Possible Adverse Effects

Any periodontal surgery may result in the following complications: thermal sensitivity, gingival recession, flap sloughing. flap inflammation, resorption an ankylosis of the treated root some loss of alveolar crest, perforation or abscess formation, infection, irregular gingival formation in the healing process. Complications associated with the use of anesthesia are possible.

Warnings

Single use only. Discard unused portions of the device. POWERBONE Barrier Membrane products are being used adults whom are over 18 years old. The effect of the products on patients with the following conditions is unknown:

- Pregnancy and nursing
- Radiation bone therapy
- Metabolic bone disease
- Documented renal disease

Reuse, reprocessing, or re-sterilization 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.

Storage

Store POWERBONE Barrier Membrane in a cool, dry location, Keep Barrier Membrane away from heat, sunlight, office autoclave, and cabinets associated with hot lighting fixtures or hot plumbing. Optimal storage conditions: +17ºC - +27ºC temperature and 40-60%Rh humidity.

Shelf Life and Disposal

The expiration date is 3 years and printed on the label. DO NOT USE AFTER THE EXPIRATION DATE. POWERBONE Barrier Membrane is environment-friendly. No special disposal is necessary. The used injector should be disposed of as clinical waste.

Packaging

POWERBONE Barrier Membrane are delivered in sterile packages. Barrier Membrane are delivered in sterile packages. Gama radiation sterilization method is used. Packaged products must be stored unopened in their original packaging. Damaged products and packages must not be used and they must be returned to Bonegraft Biyolojik Malzemeler San. Tic. ve A.Ş. The implants are single-use. A removed Barrier Membrane must never be implanted again.

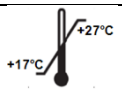
Sterility:

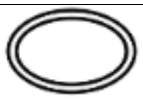
POWERBONE Barrier Membrane is sterilized by exposure to gamma radiation, using a validated process to ensure a SAL of 10^{-6}. Do not re-sterilize Sterility is guaranteed unless blister package is opened or damaged.

Further Information:

For further information on the product and its uses, please contact Bonegraft Biyolojik Malzemeler San. Tic. ve A.Ş. . The address is printed on this information sheet.

Pictogram for Product

Pictogram	Explanation
	Expire Date
	Sign of Conformity
	Do Not Use If Damaged
	Sterilization by Gamma Radiation
	Consult Instruction for use
	Temperature Limit
	Humidity Limit
	Manufacturer
	Batch Code
	Do Not Reuse
	Do not Re-Sterilize

	Catalog Number
	Date of Manufacture Country of Manufacture
	Warnings
	Keep Away From Sunlight
	Keep Dry
	Double Sterile Barrier
	Medical Device
	Unique Device Identification
	QR Codes

PLEASE READ BEFORE USE.

BONEGRAFT BİYOLOJİK MALZEMELER SAN. VE TİC. A.Ş.

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