Instructions for Use

Description

The **OsseoSeal™** (Resorbable collagen membrane) is made of purified collagen without cross-linking or chemical treatment. The collagen is extracted from veterinary certified pigs and is carefully purified to avoid antigenic reactions. The **OsseoSeal™** is a collagen membrane obtained by a standardized controlled manufacturing process. The **OsseoSeal™** has a porous and fibrous microstructure that prevents the ingrowth of fibrous tissue into the bone defect.

The **OsseoSeal™** is packed by a packaging material composed of a transparent side and an aluminum side and is easy to use by open system of easy peel type. It is easy to check the **OsseoSeal™** because one side of packaging is transparent closed by double packing system in order to protect **OsseoSeal™** from microbial formation and moisture penetration. Then this packaged **OsseoSeal™** is sterilized by gamma irradiation. The packaging contains the **OsseoSeal™** and one Template for Tyvek material.

The **OsseoSeal™** is available to the United States market in 3 sizes as shown below. They are supplied sterile and intended for single use only.

Model No.	Size	Packaging (ea/box)
OS1520	15mm x 20mm	1 membrane, 1 template
OS2030	20mm x 30mm	1 membrane, 1 template
OS3040	30mm x 40mm	1 membrane, 1 template

Mode of Action

OsseoSeal™ functions as a barrier when applied between bone graft material and soft tissue. The membrane serves as a bioresorbable scaffold that is eventually resorbed and replaced by host tissue. **OsseoSeal™** is substantially resorbed within 24 weeks after implantation.

Indications for Use

OsseoSeal™ is recommended for:

- Simultaneoususe of GBR-membrane (**OsseoSeal™**) 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
- Aid regeneration of bone defects after root resection, cystectomy, removal of retained teeth
- Guided bone regeneration in dehiscence defects

Direction for Use or Procedure

Preparation of Surgical Site

- The wound site of patient should be rinsed with antimicrobial agent or sterilized saline solution.
- The bone defect is exposed by a mucoperiosteal flap and basic surgical procedures (e.g., curettage) are undertaken.
- The bone defect is filled with a space-making material, autologous bone or bone grafting material, whenever possible.
- The defect should not be overfilled.

Instructions for Use

1. Peel outer pouch, choose **OsseoSeal™** to fit the wound area and trim it to fit the size of the defect. **OsseoSeal™** should overlap walls of the defect by at least 2 mm to allow complete bone contact and to prevent connective tissue ingrowth lateral to the material.
2. The template is a convenience item to assist in shaping the **OsseoSeal™** and not implantable, which is must be discarded following modification. In order to distinguish between the membrane and the template, the template is marked with the word "TEMPLATE".
3. The **OsseoSeal™** can be used regardless of front and back side.
4. The **OsseoSeal™** can be used in dry or hydrated conditions. If the clinician prefers the handling state of the hydrated condition, the membrane can be hydrated in sterile water or sterilized saline solution for at least 3 minutes prior to use.
5. The **OsseoSeal™** is applied over the defect and held in place with moderate pressure. Adhesion to the bone surface is facilitated by the hydrophilic properties of the membrane.
6. Fixation of the **OsseoSeal™** is possible due to its high tensile strength. Fixation may be indicated to avoid membrane displacement due to shear loading or mobilization.
7. The mucoperiosteal flap is sutured over the membrane securely and without tension. In general, the wound should be closed completely to avoid possible accelerated absorption of the exposed membrane.

Postoperative patient care

- After the operation, wound site must be treated carefully in order not to be pressured and should be managed in accordance with a prescription of a surgeon.
- The **OsseoSeal™** is fully resorbable and should not be removed.

Contraindications

- **OsseoSeal™** is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.
- **OsseoSeal™** is not to be used in patients with a known collagen allergy.
- **OsseoSeal™** should not be used in the presence of infected wounds.
- **OsseoSeal™** should not be used in patients suffering from autoimmune disease and connective tissue disease, such as: systemic lupus erythematosus, dermatomyositis etc.

OsseoSeal™

Precautions

1. Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
2. Do not re-sterilize. Discard all open and unused portions of **OsseoSeal™**.
3. The device must be used prior to the expiration date.
4. Discard device if mishandling has caused possible damage or contamination.
5. Do not reuse. Sterility and function no longer guaranteed in the event of reuse. Cross contamination and infection may occur if reused.
6. **OsseoSeal™** should only be used by trained dentists and surgeons.
7. **OsseoSeal™** should be used with special caution in patients with acute or chronic infection at the surgical site, uncontrolled metabolic diseases, prolonged corticosteroid therapy, autoimmune diseases, radiotherapy and heavy smoking.
8. If there are any changes in the performance of the membrane (such as infection, pain, any other unusual symptoms), clinician has the responsibility to inform the patient on all proper contraindications, side effects, and precautions. When these conditions occur, clinician should be instructed to see a well-trained dental specialist immediately.
9. Effects on pediatric patients is not known.
10. Effects on women who are pregnant or breastfeeding is not known.

Warnings

1. In using the **OsseoSeal™**, it must be complied with the general principle of sterile handling and patient medication.
2. MR Statement: The **OsseoSeal™** has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of **OsseoSeal™** in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
3. Rx Only
4. Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed dentist.
5. Due to the adherence to the bone tissue and the elasticity of **OsseoSeal™**, the use of bone augmentation material is recommended to create and maintain space for bone regeneration.
6. In the case of membrane exposure during the healing phase the resorption time may be accelerated.

Adverse Reactions

1. As **OsseoSeal™** is a collagen product, in very rare cases allergic reactions may occur.
2. Due to the special physical properties and the prolonged absorption time, an inflammatory reaction may occur in rare cases.
3. Possible complications which may occur with any surgery include swelling at the surgical site, flap sloughing, bleeding, dehiscence, hematoma, increased sensitivity and pain, bone loss, redness, and local inflammation.

Storage Conditions

- Store at use only between 1 and 30℃.
- Keep away from heat.
- Keep dry.

Disposal

The product can be disposed of with normal clinical waste, but local regulations must also be observed.

Symbols on the Label

	Do not re-use
	Do not resterilize
	Do not use if package is damaged
	Caution (See instructions for use)
	Manufacturer
STERILE R	Sterilized using irradiation
	Temperature limit
LOT	Batch code
	Use-by date
	Date of manufacture
	Keep away from sunlight
	Keep dry

HYUNDAI BIOLAND Co., Ltd.
162, Gwahaksaneop 3-ro, Ochang-eup, Cheongwon-gu,
Cheongju-si, Chungcheongbuk-do, 28125, Republic of Korea
Tel. +82-43-240-8633, 8636 Fax. +82-43-240-8699
www.hyundaibioland.co.kr

Distributed by KB Dental Products Inc
1205 N. Tustin Ave. Anaheim, CA 92807
Tel. +1-714-591-5851
www.kbdentalusa.com