SHELTER® F / SHELTER® S

BOVINE PERICARDIUM MEMBRANE
(sterile disposable device).

UBGEN SPECIALISTS OF BONE SURGERY IN DENTISTRY

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Intended use

SHELTER® membranes are intended for use in oro maxillo facial surgery, implant surgery, periodontics, oral and endodontic surgery for the support of guided bone and tissue regeneration, for the protection of implants, and for the regeneration of periodontal tissue.
They are obtained from cattle inspected by the Veterinarian Service, are scrupulously purified, defatted, dehydrated, and sterilized by means of treatment with ionizing radiation.
Their low antigenicity and excellent bio-compatibility allow them to be used safely and easily in oro maxillo facial surgery, implant surgery, periodontics, oral surgery, and endodontics.
The membranes are integrated into the surrounding soft tissue. The time needed for complete transformation depends on anatomical variables (the relationship between the living surfaces and the volume of the grafted site) and individual factors varying from patient to patient. They function as a barrier when applied between the material used for the bone graft and the soft tissue. The membrane forms a biological scaffold that is replaced by newly created connective tissue.
SHELTER® F and SHELTER® S membranes differ in the time needed for reabsorption of the device: based on clinical application of the membrane it is possible to choose between a membrane with fast reabsorption (SHELTER® F, 4 weeks) and a membrane with slow reabsorption (SHELTER®S,3-6 months).

Assortment

Device	Trade Name	Code	Measurements
Bovine pericardium membrane	SHELTER® F (fast reabsorption)	BMFpshelter04A	Pericardium membrane 15x20x0,2 mm
		BMFpshelter04B	Pericardium membrane 30x25x0,2 mm
		BMFpshelter04C	Pericardium membrane 50x30x0,2 mm
		BMFpshelter04D	Pericardium membrane 15x20x0,4 mm
		BMFpshelter04E	Pericardium membrane 30x25x0,4 mm
		BMFpshelter04F	Pericardium membrane 50x30x0,4 mm
		BMFpshelter04G	Pericardium membrane 15x20x0,8 mm
		BMFpshelter04H	Pericardium membrane 30x25x0,8 mm
		BMFpshelter04I	Pericardium membrane 50x30x0,8 mm
		BMFpshelter04J	Pericardium membrane 15x20x1 mm
		BMFpshelter04K	Pericardium membrane 30x25x1 mm
		BMFpshelter04L	Pericardium membrane 50x30x1 mm
	SHELTER® S (slow reabsorption)	BMSpshelter05A	Pericardium membrane 15x20x0,2 mm
		BMSpshelter05B	Pericardium membrane 30x25x0,2 mm
		BMSpshelter05C	Pericardium membrane 50x30x0,2 mm
		BMSpshelter05D	Pericardium membrane 15x20x0,4 mm
		BMSpshelter05E	Pericardium membrane 30x25x0,4 mm
		BMSpshelter05F	Pericardium membrane 50x30x0,4 mm
		BMSpshelter05G	Pericardium membrane 15x20x0,8 mm
		BMSpshelter05H	Pericardium membrane 30x25x0,8 mm
		BMSpshelter05I	Pericardium membrane 50x30x0,8 mm
		BMSpshelter05J	Pericardium membrane 15x20x1 mm
		BMSpshelter05K	Pericardium membrane 30x25x1 mm
		BMSpshelter05L	Pericardium membrane 50x30x1 mm

Therapeutic indications

SHELTER® membranes can be used on their own or in combination with bone substitute RE-BONE® during periodontal and/or dental surgical procedures, including:

- for the maintenance of the alveolus and the alveolar ridge
- for surgery of the bony socket with lateral and ridge access
- for horizontal augmentation in 2-wall defects
- for vertical augmentation in 2-wall defects
- for dehiscence and fenestration in peri-implant lesions
- for periodontal regeneration in gingival recession and in 2-wall intraosseous defects

Instructions for use

SHELTER® membranes should be used only by practitioners with appropriate professional training and therefore experts in the techniques of guided regeneration of bone and tissue.
During their application, general principles of sterilization and of medication of the patient should be observed. Prepare the graft site properly, remove any residue of fibrous tissue, and if necessary perforate the recipient tissue to enhance the initial phase of regeneration.
The product can be moistened with a physiological solution or with APG® (Autologous Platelet Gel) which can be obtained from the GFONE ® product line.

- Measure the defect with a periodontal probe.
- Cut the membrane in its dried state to the desired form and size with sterile scissors.
- Apply the rough side of the membrane to the defect.
- Moisten the membrane in situ with the blood present in the defect.
- To isolate the bone cavity from the gingival tissue and adequately support regeneration, the membrane must exceed the edges of the bone defect by at least 2 mm.
- Cover the bone defect with the membrane, exert moderate pressure for the time needed to stop the bleeding.
- The membrane can be sutured or fixated with tacks, but in most cases this is not necessary thanks to its evident hydrophilic and adhesive properties. It is recommended placing the sutures at 2-3 mm from the implant, when possible.
- It is important to guarantee that the wound is closed without tension and no saliva enters it.
- The patient should follow the instructions provided by the surgeon for proper oral hygiene.

Contraindications and warnings

The practitioner must of course ascertain the overall clinical status of the patient, evaluating whether there are any contraindications to the treatment. From the point of view of general health the following conditions should be screened for: cardiovascular and/or respiratory insufficiency, tumors, poorly-controlled diabetes, etc. It is also important to evaluate conditions of the actual surgical site.
Do not use SHELTER® membranes with patients with:

- acute infections of the oral cavity or acute or chronic inflammation of the implant site.
- systemic pathological conditions for which oro maxillo facial surgery, implant surgery, periodontics, endodontics, or other oral surgical interventions are precluded
- known hypersensitivity to membranes of bovine origin

Do not use the membranes in clinical application in neurosurgery or ophthalmology: the product is not suitable for contact with the CNS of the patient, or with the eyes.
Studies have not been done on the use of membranes of bovine origin during pregnancy or nursing, nor on their influence on the human reproductive system. For that reason, before implanting SHELTER® membranes the treating dentist must carry out an individual evaluation of the benefits for the mother and possible risks for the child.
Information is not available regarding the necessity of adopting of particular measures based on the age of the patients being treated.

Side effects

- In rare cases allergic reactions or intolerance to membranes of bovine origin cannot be ruled out.
- In rare cases there can be inflammatory tissue reaction.
- As with any foreign material, possible pre-existing local infections be exacerbated due to implantation of the membrane.
- Possible generic complications can arise also following surgical procedure, for example gum recession, severe bleeding of the gums, swelling of the soft tissue, sensibility to warmth, desquamation of the gingival epithelium in the area of the flap, reabsorption or ankylosis of the root being treated, some loss in height of the crest bone, infections, pain, or complications related to the use of anesthetics.

Interactions with other products and methods

- The efficacy of SHELTER® membranes can be reduced by platelet aggregation inhibitors and by anti-coagulant medications, as these products can prevent the formation of blood coagulation.
- No interactions with MRI have been observed and, taking into consideration the biochemical composition of the membranes, no such interactions are foreseen.

Warnings and precautionary measures

- SHELTER® membranes are used exclusively in the areas described above. The devices have not been tested on patients with particularly grave surgical defects, implant surgery, endodontics and periodontics.
- Patients must be informed of possible contraindications, side effects, and necessary precautionary measures within the scope of practice of the treating dentist. In the case of post-operative complications, among them pain, infection, or other isolated symptoms, the patient must immediately contact the referring dentist.
- Patients with serious systemic conditions (for example poorly-controlled diabetes mellitus, severe hypertension, severe PAD, malignant tumors, or auto-immune disease), or patients who for example are undergoing long-term treatment with corticosteroids or anticoagulant therapy, are to be managed with particular caution, as is the case in all surgical procedures.
- It is necessary to report any serious accident occurring in relation to this medical device to the manufacturer and the competent authority.

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Legend of symbols

UDI	UNIQUE IDENTIFICATION OF THE DEVICE
REF	PRODUCT CODE
LOT	LOT NUMBER
MD	MEDICAL DEVICE
	MANUFACTURING DATE
	EXPIRATION DATE
STERILE R	GAMMA IRRADIATION STERILIZATION PROCESS
	STORAGE TEMPERATURE 5°C - 30°C
	KEEP DRY
	KEEP AWAY FROM DIRECT SUNLIGHT
	CAREFULLY READ THE INSTRUCTIONS BEFORE USING AVAILABLE AT THE LINK: https://www.ubgen.com/client/area-download.html
	DO NOT USE IF THE PACKAGING IS DAMAGED
	SINGLE USE
	DO NOT RE-STERILIZE

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