UBGEN®
OPERATIONAL MANUAL SHELTER®

UBGEN

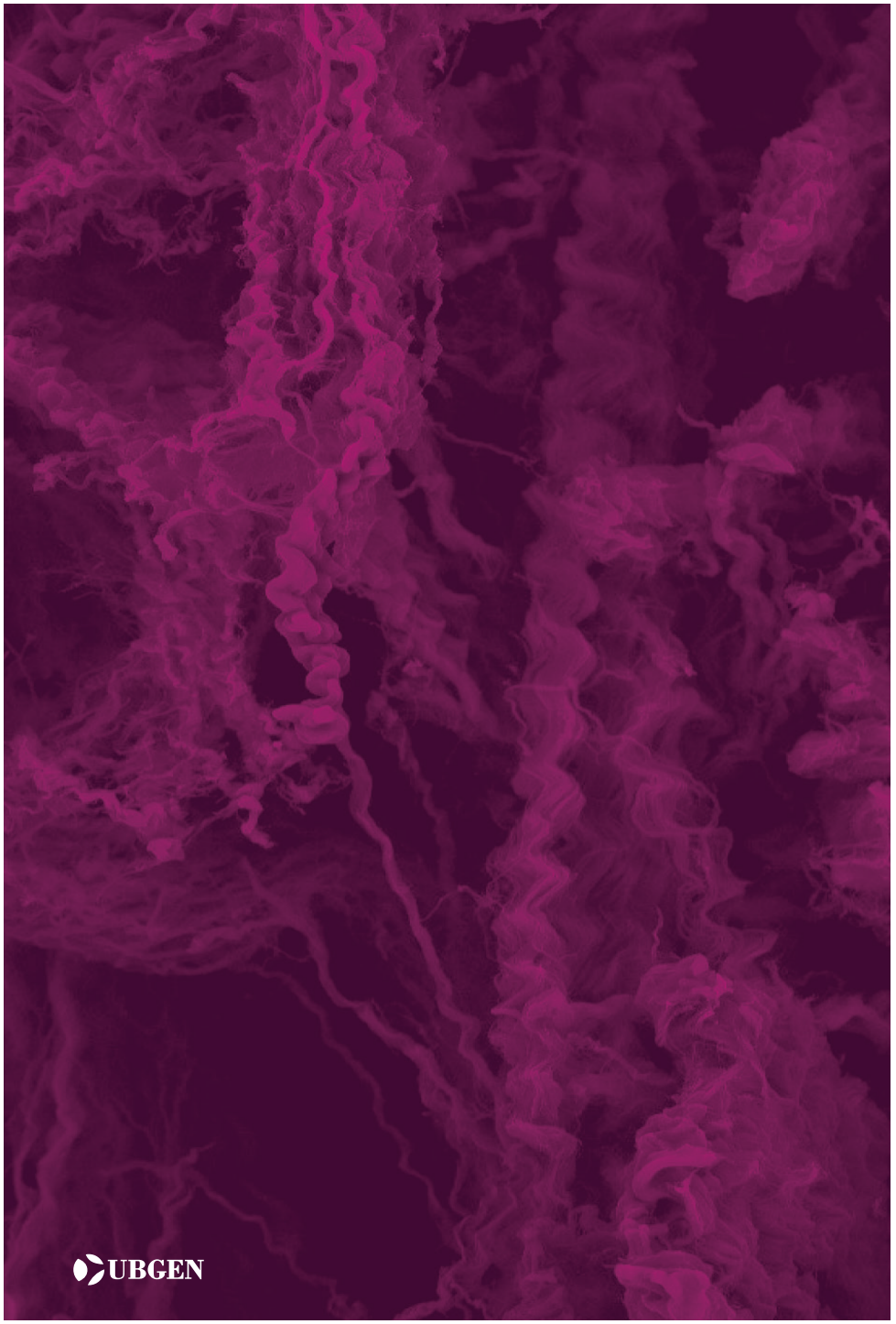
UBGEN®
OPERATIONAL MANUAL SHELTER®

INTRODUCTION

Welcome to the operational manual for SHELTER®.
This document has been created to assist dentists in the optimal use of the SHELTER® bovine pericardium membranes manufactured by UBGEN®.

It does not replace the official Instructions for Use (IFU), which can be consulted online on UBGEN®'s website. We recommend referring to the IFU for complete and detailed product information.

The primary purpose is to ensure patient well-being while supporting dentists in their daily clinical practice.



DESCRIZIONE DEL PRODOTTO

SHELTER® membranes are intended for use in oral and maxillofacial surgery, implantology, periodontology, oral surgery, and endodontics to support guided bone and tissue regeneration, protect implants, and regenerate periodontal tissue.
They are obtained from Italian cattle monitored by the Veterinary Service, meticulously purified, defatted, dehydrated, and sterilized through ionizing radiation treatment.
Their low antigenicity and excellent biocompatibility allow for safe and easy use in oral and maxillofacial surgery, implantology, periodontology, oral surgery, and endodontics.

The membranes integrate into the surrounding soft tissue. The time required for complete transformation depends on anatomical variables (the ratio between vital surface and the volume of the grafted site) and individual factors that vary from patient to patient.

They act as a barrier when applied between the bone graft material and soft tissue. The membrane forms a biological scaffold that is gradually replaced by newly formed connective tissue.
SHELTER® Fast and SHELTER® Slow membranes differ in their resorption time: depending on the clinical application, one can choose between a fast-resorbing membrane (SHELTER® F, 4 weeks) and a slow-resorbing membrane (SHELTER® S, 3-6 months).

THERAPEUTIC INDICATIONS

SHELTER® membranes are indicated for use either alone or in combination with RE-BONE® bone substitute during periodontal and/or dental surgical procedures, such as:

- Maintenance of the socket and alveolar ridge;
- Sinus surgery with lateral or crestal access;
- Horizontal augmentation in two-wall defects;
- Vertical augmentation in two-wall defects;
- Dehiscences and fenestrations in peri-implant lesions;
- Periodontal regeneration in gingival recessions and two-wall intraosseous defects.

PRE-OPERATIVE PREPARATION

SHELTER® membranes are designed to be used exclusively by medical professionals with the appropriate training and expertise in guided bone and tissue regeneration techniques.

When performing guided bone regeneration (GBR) procedures using bone substitutes and membranes that provide a barrier effect, it is essential to adopt specific surgical precautions to ensure the success of the operation and the long-term health of the regenerated tissue. Here are some pre-operative considerations for GBR procedures:

i) **Thorough pre-operative evaluation:** Before surgery, detailed planning is essential, including accurate diagnosis and a thorough medical history analysis of the patient (identifying any factors that may compromise the regenerative process).

ii) **Planning:** Radiographic images or CBCT scans are crucial for evaluating the quantity and quality of available bone and identifying anatomical structures near the surgical site.

iii) **Selection of appropriate material:** Select the appropriate type of bone substitute based on the characteristics of the recipient site and the surgical objectives. Bone substitutes with osteoinductive, osteoconductive, and osteogenic properties are the optimal choice. Depending on the extent of the procedure and the specific case requirements, choose the most suitable format of bone substitute. The choice of membranes to provide an effective barrier effect also plays a fundamental role. Resorbable membranes, which provide effective barrier properties and support angiogenesis and tissue regeneration, are often preferable. The choice of membrane format must be adapted to the size of the area to be treated and the specifics of the surgical procedure.

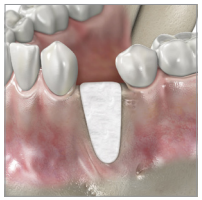
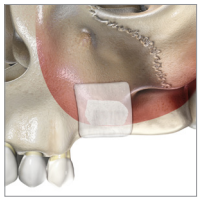
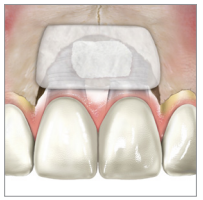
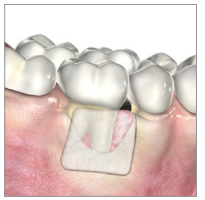
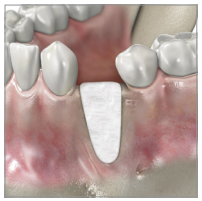
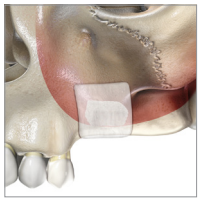
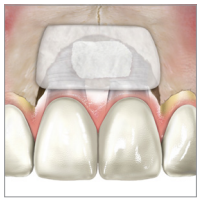
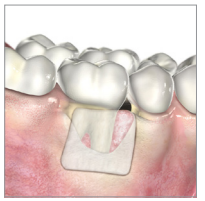
SHELTER® bovine pericardium membranes are available in two formats: SHELTER® Fast (barrier effect for approximately 4 weeks), SHELTER® Slow (barrier effect for approximately 3-6 months).

Per ciascuna tipologia, sono disponibili differenti dimensioni / spessori:

Device	Commercial Name	Code	Dimensions
Bovine Pericardium Membrane	SHELTER® F (fast resorption)	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 resorption)	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

You can refer to the application table for SHELTER® pericardium membranes to determine which format is most suitable for each type of procedure.

SHELTER® - CLINICAL APPLICATIONS

	Maintenance of the socket and alveolar ridge.	Sinus lift surgery.	Horizontal augmentation in two-wall defects.	Vertical augmentation in two-wall defects.	Dehiscences and fenestrations in peri-implant lesions.	Periodontal regeneration in intraosseous defects and two- to three-wall furcation defects.
Membrane FAST 						
Membrane SLOW 						

TYPE OF INTERVENTION	MEMBRANE	
	Slow Resorption	
	Thickness 0,2 mm	Thickness 0,4 mm
Periodontal defect (small or difficult-to-access defects)		
Periodontal defect (intraosseous defects with 1-3 walls or Class I or II furcation)	Alternative / Optional	
Peri-implant defect (up to 3 exposed threads)		
Peri-implant defect (more than 3 exposed threads)		
Post-extraction socket (preservation)	Alternative / Optional	
Sinus lift (in the main techniques, including large sinus lift, Summers, crestal or lateral approach, etc.)		Alternative / Optional
Horizontal and vertical ridge augmentation (onlay, inlay, block technique)		Recom-mended
Horizontal augmentation (split crest)		Recom-mended

MEMBRANE					
Slow Resorption		Fast Resorption			
Thickness 0,8 mm	Thickness 1 mm	Thickness 0,2 mm	Thickness 0,4 mm	Thickness 0,8 mm	Thickness 1 mm
		Recom-mended	Alternative / Optional		
		Recom-mended	Alternative / Optional		
		Alternative / Optional	Recom-mended		
		Alternative / Optional	Recom-mended		
			Recom-mended		
			Recom-mended	Alternative / Optional	Alternative / Optional
Alternative / Optional	Alternative / Optional			Alternative / Optional	Alternative / Optional
Alternative / Optional	Alternative / Optional				

OPERATIVE PROCEDURES

i) **Product Inspection Before Use:** Inspect the packaging for any damage that may compromise the sterility of the product. Use only products with intact packaging. UBGEN® Srl guarantees optimal performance of the medical device, provided it is stored according to the instructions on the packaging. Please note that any storage method not in accordance with these instructions may compromise its performance. Check the expiration date printed on the package. Do not use the product beyond this date to avoid risks of inefficacy or post-operative complications.

ii) **Strict Asepsis:** Maintain a sterile surgical field to prevent infections. The use of gloves, masks, head covers, and, when necessary, sterile barriers, is essential.

iii) **Preparation of the recipient site (debridement):** Ensure proper exposure of the surgical site for clear and clean visual access. Use soft retractors to minimize trauma to the surrounding soft tissues. Ensure that the bone bed is adequately prepared, removing fibrous tissue remnants and any infected or necrotic soft tissues.
Smooth the bone surfaces to promote better adhesion and integration of the material. This may require curettage or decortication to enhance the biological response to the graft. Perform light decortication to expose bleeding bone, which promotes osteointegration, improves the adhesion of the graft material to the host tissue, and stimulates the initial phases of regeneration.

NOTE: *Pay particular attention to this step, as it is crucial for reducing the risk of infection and promoting an optimal healing environment.*

iv) Hydration of the Material: The rehydration of bone substitute material is a critical step in the preparation process for guided bone regeneration (GBR) surgery. For proper hydration management of the bone substitute, please refer to the Operational Manual for the use of RE-BONE® bone substitute.

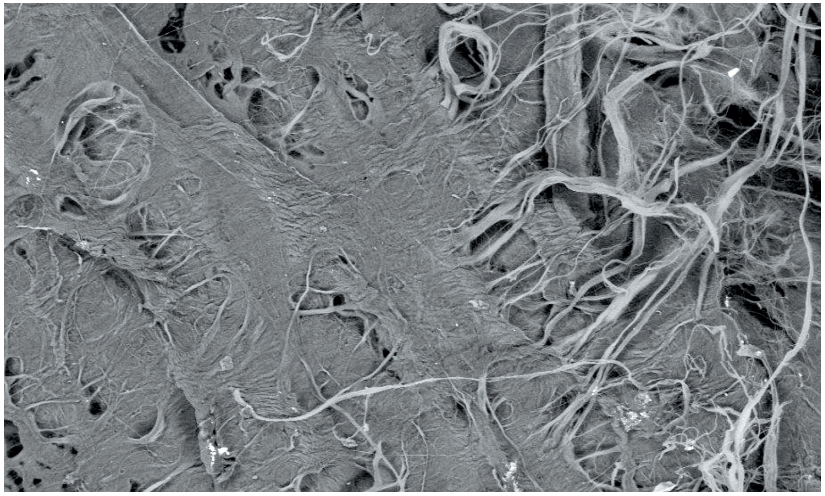
Rehydrating the membranes used in the surgical procedure is also a critical step, essential for the success of the surgery. This process ensures that the pericardium membrane has the optimal consistency and biological properties to facilitate tissue regeneration.

1. Initial Preparation:
   - Before starting rehydration, it is essential to ensure that the working area is sterile to prevent contamination of the material.
   - Prepare all necessary instruments and materials, including sterile gloves, rehydration solutions, and sterile containers.

2. Choice of Rehydration Solution:
   - The choice of rehydration solution can vary depending on the type of membrane and the specific instructions from the manufacturer.
   - UBGEN® recommends rehydrating the SHELTER® membranes preferably using the patient's whole blood or platelet concentrates, which can be obtained using the APG® vials and the GF ONE® Plus blood phase separator.
   - Alternatively, it is advisable to use a solution that enhances the chemotactic and angiogenic properties of the pericardium membrane, such as a hyaluronic acid solution, which can help promote tissue regeneration in the post-operative phases.

3. Rehydration of the Pericardium Membrane:

- Remove the membrane from its original packaging while maintaining sterile conditions.
- Immerse the membrane in the prepared rehydration liquid in a sterile container. It is advisable to follow the manufacturer's instructions regarding the incubation time.
- During the rehydration process, handle the material gently to avoid damaging it. Due to their natural structure, SHELTER® membranes maintain high tensile strength and manageability.
- It is important to ensure that the membrane is fully rehydrated to achieve the best mechanical and biological properties: check that it is soft and malleable, without dry or hard areas.



PRACTICAL ADVICE
for Proper Rehydration of SHELTER®

- The use of bioactive solutions for rehydration can further enhance the effectiveness of the membrane, promoting tissue growth and accelerating the healing process.
- Sometimes, it is also possible to place the membrane in the surgical site without prior rehydration. In such cases, it is important to ensure the membrane fully adheres to the positioning site, allowing it to absorb the blood it comes into contact with.
- Once the membrane is adequately rehydrated, it is ready to be applied to the surgical site. If not used immediately, it should be stored in sterile conditions to maintain its sterility and structural integrity.

NOTE: *SHELTER® pericardium membranes are sterile, single-use medical devices. It is recommended not to use any leftover membrane after the package has been opened.*

v) Placement of the Membrane in the Surgical Site:

1. Expose the bone defect by making a precise incision to reveal the bone while preserving the soft tissues as much as possible to facilitate suturing and subsequent healing.
2. Remove the granulation tissue, as described in the surgical site preparation procedure.
3. Remove the device from its sealed blister packaging and place it in the graft site.

NOTE: *Follow the procedures outlined in the Operational Manual for the use of RE-BONE® bone substitute.*

4. Remove the membrane from its double sterile packaging. Then follow the procedure below:
   - Measure the defect with a periodontal probe.
   - Cut the dry membrane into the desired shape and size with sterile scissors.

     NOTE: *As previously mentioned, the membrane can be placed in the surgical site without prior rehydration. In this case, it will need to be secured using appropriate tools.*

   - Hydrate the membrane using the rehydration solutions recommended by UBGEN®. Before use, ensure that the membrane is fully rehydrated and free of dry areas.
   - Once rehydrated, gently place the membrane over the graft in the surgical site. The bone defect must be completely covered by the membrane.

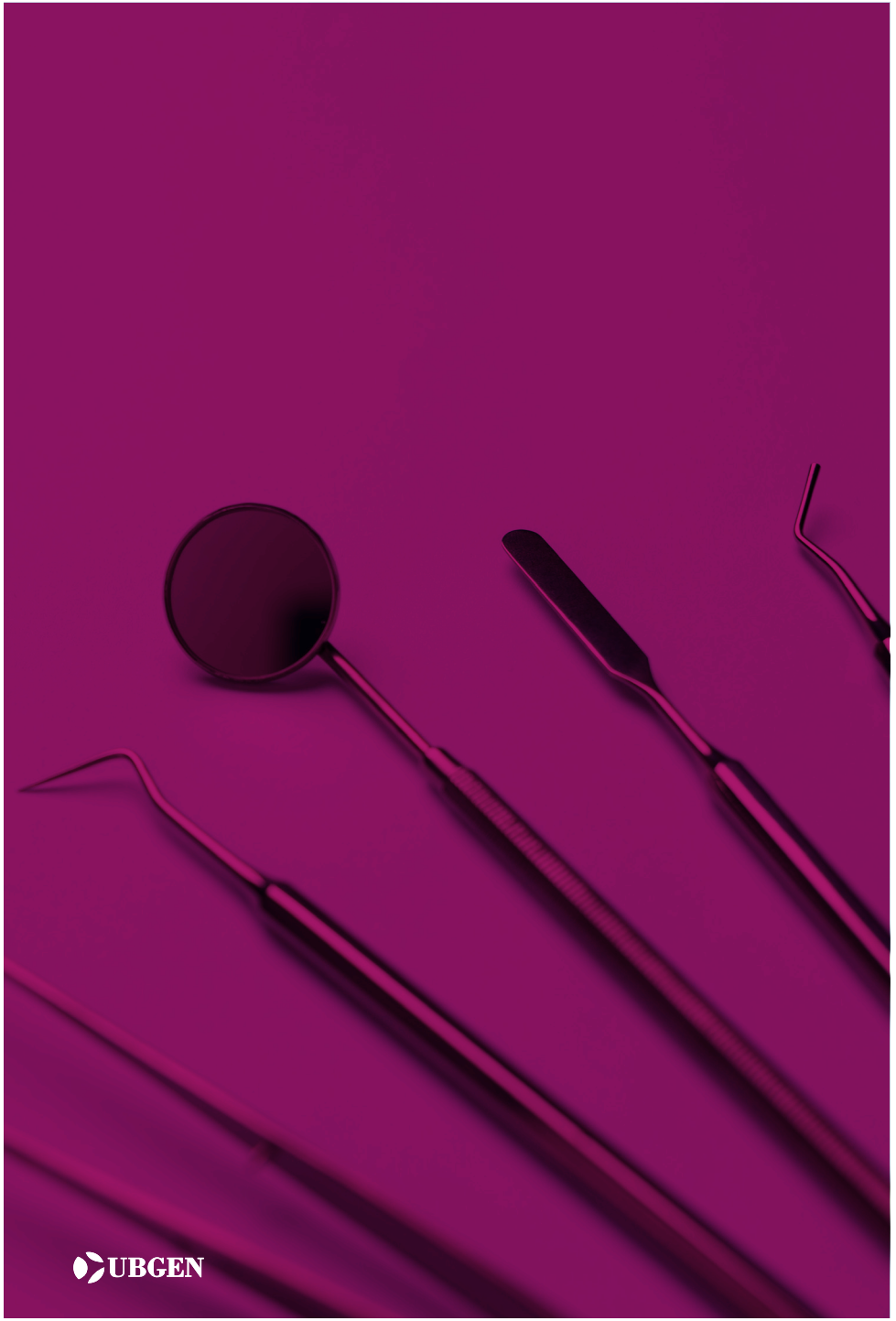
     NOTE: *The pericardium membrane, due to its natural structure, does not have a specific application side.*

   - Apply moderate pressure for the time needed to stop the bleeding.
   - The membrane can easily be sutured or fixed with appropriate pins, but in most cases, this is unnecessary due to the marked hydrophilicity and adhesive properties of SHELTER® membranes.
   - In cases of large defects, it may be helpful to use SHELTER® membranes in combination with autologous connective tissue grafts for improved regeneration.
   - To ensure a tension-free wound closure, it is essential to avoid overfilling the surgical site.

     NOTE: *Correctly selecting the size/thickness of the membrane based on the patient's anatomical characteristics is crucial.*

PRACTICAL ADVICE
for Proper Handling of SHELTER®:

- Gentle Handling: Avoid excessive handling of the membrane to prevent compromising its structure and functionality. Use delicate instruments to position the material in the desired area.
- Proper Placement Technique: Apply the material ensuring direct contact between the membrane and the site to be covered. The use of resorbable SHELTER® Fast or Slow membranes is essential to support the stabilization of the bone substitute in the correct position throughout the healing process. It is recommended to place the suture 2-3 mm away from the implant where possible.
- Intraoperative Evaluation: Assessing the consistency of the membrane during the surgical procedure can provide immediate feedback on the barrier effect it provides.
- Fixation Techniques: SHELTER® membranes, due to their elastic nature, can be easily secured using various methods: surgical sutures or fixation pins. Pay particular attention to the fixation methods: it is recommended to place the suture or sterile fixation pins 2-3 mm away from the implant, where possible.



vi) Closure of the Surgical Site

Proper management of the surgical site is crucial to ensure that the wound is closed without tension and does not allow saliva penetration.

- Ensure that the sutures are placed in a way that protects the graft and the membrane placed over it, reducing tension on the wounds and facilitating healing.
- Perform precise sutures to ensure that the membrane and graft material are completely covered by the soft tissue flaps, promoting better healing and reducing the risk of material exposure.

NOTE: *SHELTER® membranes provide a barrier effect even in cases of small exposures (1-2mm). However, complete coverage of the membrane is highly recommended.*

- Use suturing techniques that evenly distribute tension and maintain flap stability, protecting the graft site and minimizing the risk of material exposure.
- Make sure the soft tissue flaps are closed without excessive tension over the grafted area to prevent flap dehiscence.

POST-OPERATIVE MANAGEMENT

- Provide the patient with detailed post-operative instructions, including recommendations for oral hygiene, the use of antibiotics if indicated, and avoiding chewing pressure on the treated area.
- Inform the patient about potential risks and signs of post-operative complications, such as infections, excessive swelling, or persistent pain, instructing them to contact the doctor immediately if any of these events occur.
- Properly manage post-operative pain and inflammation to improve patient comfort and reduce the risk of complications.
- Emphasize the importance of attending follow-up visits to monitor healing progress and intervene promptly if complications arise.
- Follow-up: Schedule regular check-ups to monitor the surgical site through periodic visits. Assess the healing and integration of the bone substitute and identify early signs of complications. Use imaging techniques such as radiography or CBCT (Cone Beam Computed Tomography) to monitor regeneration and identify potential issues early.

Complication Management

- Generic complications may arise during or after the procedure, such as gingival recession, severe gingival bleeding, soft tissue edema, sensitivity to heat, gingival epithelial desquamation in the flap area, root resorption or ankylosis, slight loss of crestal bone height, infections, pain, or complications related to the use of anesthetic drugs.
- Frequent and periodic monitoring of the graft site can reduce the occurrence of hard-to-diagnose complications. In the event of significant adverse reactions, the specialist will evaluate the need for additional treatments or modifications to the treatment plan.

FOCUS ON PRACTICAL BENEFITS

Reduction of Healing Time

SHELTER® offers a significant reduction in healing time due to its ability to act as an effective barrier for tissue regeneration, both in the Fast and Slow versions.

The membrane not only provides a protected environment for the graft material but also promotes tissue regeneration through its angiogenic properties. Additionally, the availability of two versions (Fast and Slow) allows the clinician to choose the most suitable option based on clinical needs, thereby reducing the risks of complications and accelerating patient recovery times.

Increase in Predictability of Results

Thanks to the advanced purification process of bovine pericardium and the membrane's ability to withstand various clinical conditions, SHELTER® ensures highly predictable results, even in complex cases. The membrane is designed to be easily adaptable and offers excellent adhesion, often eliminating the need for fixation in most cases.

This reduces the risk of material exposure and facilitates the regeneration process, providing greater safety and reliability in clinical practice. Furthermore, the range of available thicknesses and sizes allows for a customized approach depending on the type of bone defect, further improving the precision and effectiveness of the treatment.

CONCLUSION

Adopting a standardized procedure for using SHELTER® will significantly improve clinical outcomes and patient satisfaction. Every step outlined in this manual is essential to ensure treatment success and patient safety.

By following these guidelines, dentists can maximize the performance of SHELTER® pericardium membranes in their clinical practice, reducing healing times and increasing the probability of successful dental implants, thereby improving patient satisfaction.

Viale del Lavoro, 14
35010 Vigonza (PD) Italy
T +39 049 628630
info@ubgen.com
ubgen.com

LEARN MORE ABOUT HOW SHELTER®
CAN IMPROVE YOUR CLINICAL RESULTS.

REQUEST OUR SCIENTIFIC BOOK
WITH CLINICAL CASES
MARKETING@UBGEN.COM

UBGEN