UBGEN®
OPERATIONAL MANUAL
RE-BONE®

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OPERATIONAL MANUAL RE-BONE®

INTRODUCTION

Welcome to the operational manual for RE-BONE®.
This document has been created to assist dentists in the optimal use of RE-BONE®, a bovine-derived bone substitute 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 information about the product.

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

PRODUCT DESCRIPTION

RE-BONE® bone substitute is designed for use in oral and maxillofacial surgery, implantology, periodontology, oral surgery, and endodontics to support guided bone and tissue regeneration, to protect implants, and to regenerate periodontal tissue.

RE-BONE® is produced from bovine bone through a standardized and controlled purification process. The raw material used for the production of RE-BONE®, obtained from cattle born and raised in Italy under the supervision of the Veterinary Service, is meticulously purified, degreased, lyophilized, and sterilized through ionizing radiation treatment.

The average resorption time depends on anatomical variables (the ratio between vital bone surface and the volume of the grafted site) and individual patient factors, and it can vary from 6 to 8 months.

THERAPEUTIC INDICATIONS

RE-BONE® is indicated for use either alone or in combination with suitable regenerative materials (e.g., autologous, allogenic, or alloplastic bone, autologous platelet gel) for guided bone and tissue regeneration in the following cases:

- In cases of surgical bone defects or bone wall defects;
- For sinus lift procedures, alveolar ridge augmentation, or reconstruction;
- In the treatment of fenestration defects;
- For periodontal bone defects (one- to three-wall defects, Class I and II furcation defects);
- In the treatment of dehiscences;
- Following apicoectomy, cystectomy, removal of impacted teeth, and resection of other bone defects;
- In post-extraction sockets following tooth extraction;
- For immediate or delayed augmentation around implants in post-extraction sockets.

PRE-OPERATIVE PLANNING

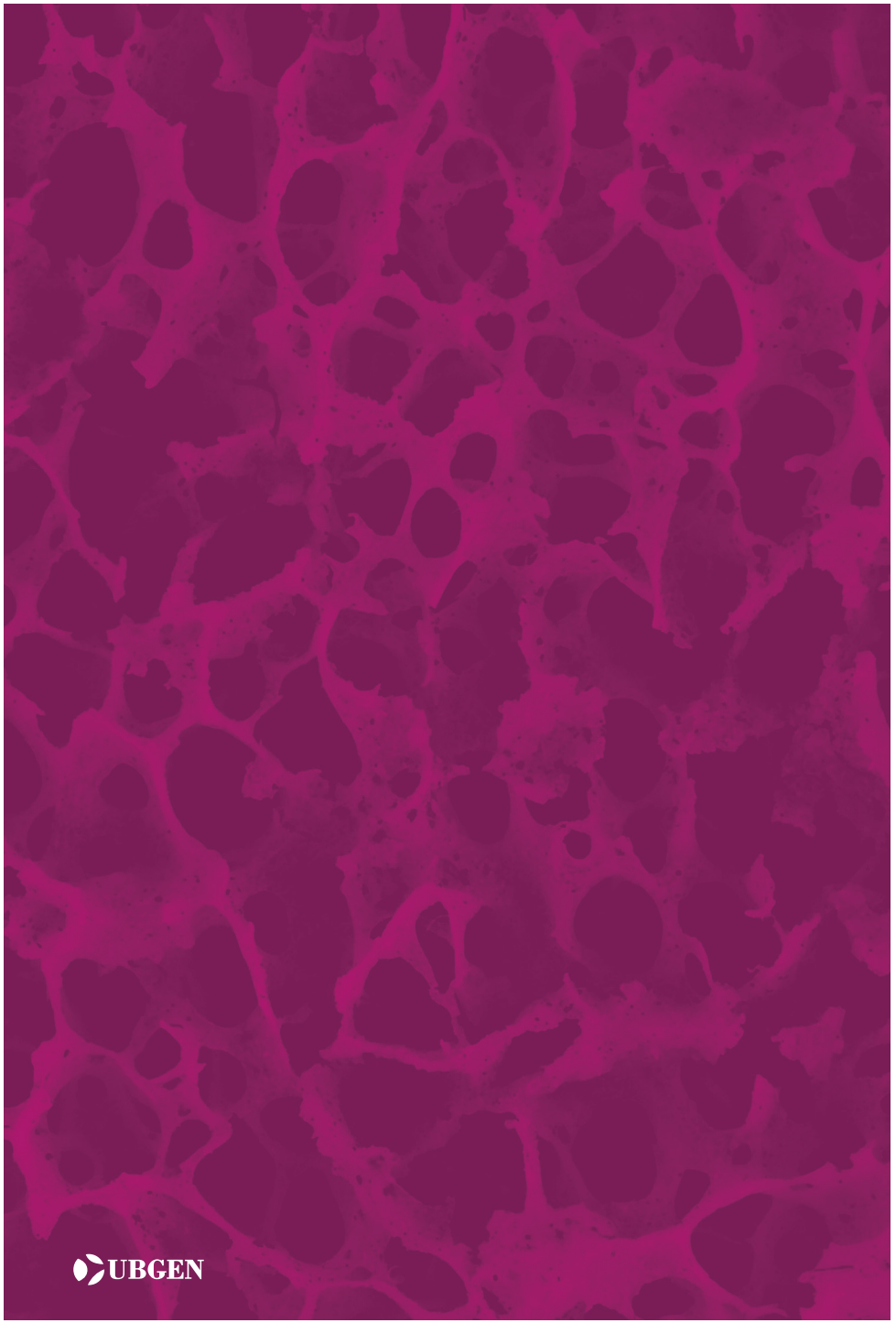
RE-BONE® is designed to be used exclusively by medical professionals with appropriate training and expertise in guided bone and tissue regeneration techniques.

When performing guided bone regeneration (GBR) using bone substitutes, 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:** Prior to 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 for identifying anatomical structures close to the surgical site.

iii) **Selection of appropriate material:** Choose the right 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 needs of the case, select the most suitable bone substitute format.



The RE-BONE® bovine-derived bone substitute is available in the following variants:

VIAL OF CORTICO-CANCELLOUS GRANULES			
BMREBONE	00A 0,25 g - < 0,25 mm	01A 0,25 g - 0,25-1,00 mm	
	00B 0,50 g - < 0,25 mm	01B 0,50 g - 0,25-1,00 mm	01E 0,50 g - 1-2 mm
	00C 1,00 g - < 0,25 mm	01C 1,00 g - 0,25-1,00 mm	01F 1,00 g - 1-2 mm
	00D 2,00 g - < 0,25 mm	01D 2,00 g - 0,25-1,00 mm	01G 2,00 g - 1-2 mm
	00DA 5,00 g - < 0,25 mm	01DA 5,00 g - 0,25-1,00 mm	01H 5,00 g - 1-2 mm

VIAL OF CANCELLOUS GRANULES			
BMREBONE	00E 0,25 g - < 0,25 mm	01I 0,25 g - 0,25-1,00 mm	
	00F 0,50 g - < 0,25 mm	01J 0,50 g - 0,25-1,00 mm	01M 0,50 g - 1-2 mm
	00G 1,00 g - < 0,25 mm	01K 1,00 g - 0,25-1,00 mm	01N 1,00 g - 1-2 mm
	00H 2,00 g - < 0,25 mm	01L 2,00 g - 0,25-1,00 mm	01O 2,00 g - 1-2 mm
	00HA 5,00 g - < 0,25 mm	01LA 5,00 g - 0,25-1,00 mm	01P 5,00 g - 1-2 mm

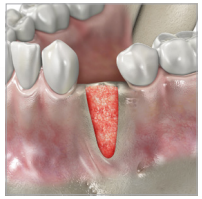
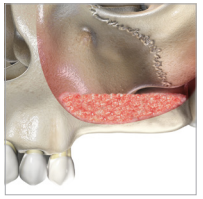
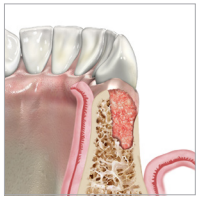
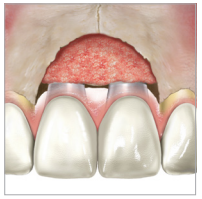
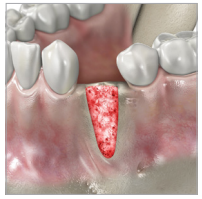
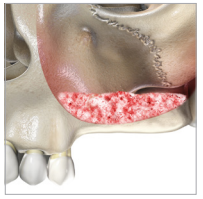
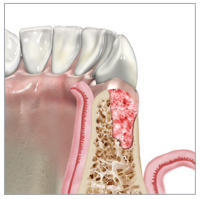
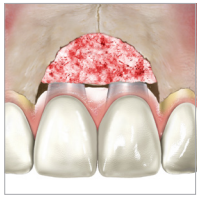
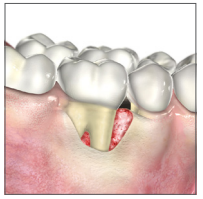
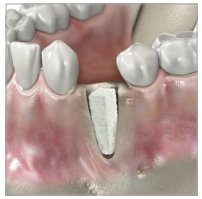
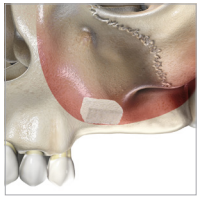
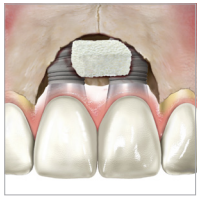
VIAL OF CORTICAL GRANULES			
BMREBONE	00I 0,25 g - < 0,25 mm	01Q 0,25 g - 0,25-1,00 mm	
	00J 0,50 g - < 0,25 mm	01R 0,50 g - 0,25-1,00 mm	01U 0,50 g - 1-2 mm
	00K 1,00 g - < 0,25 mm	01S 1,00 g - 0,25-1,00 mm	01V 1,00 g - 1-2 mm
	00L 2,00 g - < 0,25 mm	01T 2,00 g - 0,25-1,00 mm	01W 2,00 g - 1-2 mm
	00LA 5,00 g - < 0,25 mm	01TA 5,00 g - 0,25-1,00 mm	01X 5,00 g - 1-2 mm

BLOCK		
BMREBONE	02A 10x10x10 mm	
	02B 10x10x20 mm	

SYRINGE		
BMREBONE	03A 0,25 g - 0,25-1 mm	
	03B 0,5 g - 0,25-1 mm	
	03C 0,5 g - 1-2 mm	

You can refer to the RE-BONE® bone substitute application table to determine which format is most suitable for each type of procedure.

RE-BONE® - 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.
Granules 						
Syringe 						
Block 						

TYPE OF INTERVENTION	GRANULES	
	Cortico-cancellous 0,25-1 mm	**Cortico-cancellous** 1-2 mm
Periodontal defect (small or difficult-to-access defects)	Recommended	
Periodontal defect (intraosseous defects with 1-3 walls or Class I or II furcation)	Recommended	
Peri-implant defect (up to 3 exposed threads)	Alternative / Optional	
Peri-implant defect (more than 3 exposed threads)	Recommended	Alternative / Optional
Post-extraction socket (preservation)	Recommended	Alternative / Optional
Sinus lift (in the main techniques, including large sinus lift, Summers, crestal or lateral approach, etc.)	Recommended	Alternative / Optional
Horizontal and vertical ridge augmentation (onlay, inlay, block technique)		
Horizontal augmentation (split crest)	Recommended	

GRANULES		SYRINGE		BLOCKS
Cancellous 0,25-1 mm	**Cancellous** 1-2 mm	**Cortico-cancellous** 0,25-1 mm	**Cortico-cancellous** 1-2 mm	**Cancellous** 10x10x10 mm 10x10x20 mm
Alternative / Optional				
Alternative / Optional		Recommended		
Recommended		Alternative / Optional		
		Recommended		
		Alternative / Optional		
	Alternative / Optional	Recommended	Alternative / Optional	
				Recommended
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 is committed to ensuring 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 the product's 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 operative 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 to allow 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 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 the bleeding bone, promoting osteointegration, improving the adhesion of the substitute to the host tissue, and stimulating the initial phases of regeneratione.

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

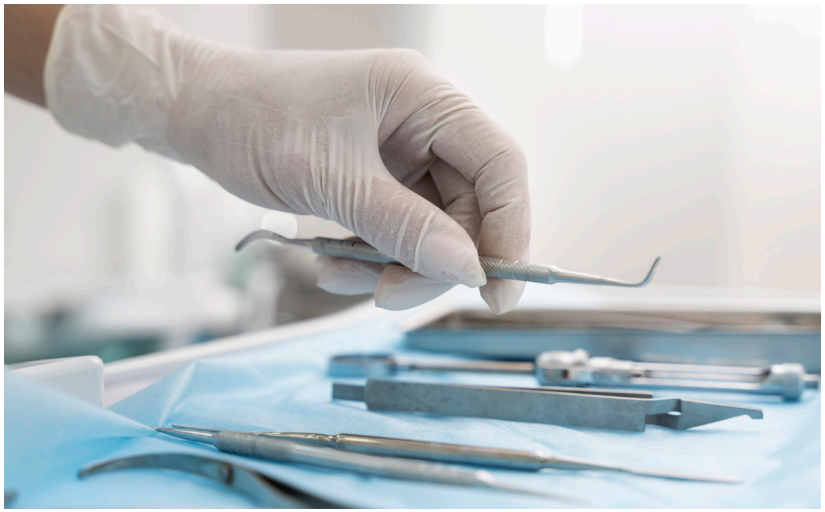
iv) **IHydration of the Material:** The rehydration of the bone substitute material is a critical step in the preparation process for guided bone regeneration (GBR) surgery. This phase ensures that the bone substitute has the optimal consistency and biological properties to facilitate new bone growth.

1. Initial Preparation:
   - Before beginning the rehydration process, 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 bone substitute and the manufacturer's specific instructions.
   - UBGEN® recommends 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, to rehydrate the RE-BONE® bone substitute. Depending on the clinical case, RE-BONE® biomaterial can be rehydrated with platelet concentrates in either liquid or gel form. The use of whole blood or platelet concentrates maximizes and optimizes the biomaterial's performance due to the intrinsic biological properties of blood.
   - Alternatively, rehydration with the ACTI-BONE® hyaluronic acid solution enhances the chemotactic and angiogenic properties of the RE-BONE® bone substitute, promoting early post-operative regeneration (anti-inflammatory effect).

3. Rehydration of the Bone Substitute:

- Remove the bone substitute from its original packaging while maintaining sterile conditions.
- Immerse the material in the prepared rehydration liquid in a sterile container.
- During the rehydration process, handle the material gently to avoid damaging or excessively compressing it.
- It is important to ensure that the material is fully rehydrated to achieve the best mechanical and biological properties: inspect the material to ensure it is soft and malleable, without dry or hard areas.
- Additionally, check that the material has maintained its structural integrity without disintegrating or becoming too soft.



PRACTICAL ADVICE
for Proper Rehydration of RE-BONE®

- Avoid excessive rehydration, as it may reduce the osteoconductive properties of the biomaterial.
- Using bioactive solutions for rehydration can further promote bone growth and healing.
- Once rehydrated, the bone substitute is ready to be placed in the surgical site. If not used immediately, it may be necessary to store it in a sterile environment to maintain its sterility and integrity.

NOTE: *RE-BONE® bone substitute is a sterile, single-use medical device: it is recommended not to use any leftover block/vial/syringe contents after opening the package.*

v) Placement of the Bone Graft 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;
4. Follow the procedures listed below, depending on whether RE-BONE® is in block, vial, or syringe format.

BLOCK

- The bone substitute block can be cut either dry or moistened, using a burr. It is essential to shape it to the appropriate size and form according to the defect being treated. The use of suitable templates can help in determining the necessary shape.
- Once rehydrated, gently place the graft into the prepared area, ensuring that it adheres well to the surrounding bone walls to prevent post-operative movement. The blocks can be secured in the surgical site using appropriate osteosynthesis screws.
- In cases of large bone defects, it may be necessary to use multiple grafts (e.g., a combination of autologous bone graft and xenograft) or combine them with other materials such as bone granules for better adaptability and stability.

GRANULES IN VIALS

- Place the bone substitute granules in a sterile container and preferably rehydrate them with the patient's blood or platelet concentrate.
- Mix the bone substitute with the rehydration solution using sterile instruments.
- Once rehydrated, gently place the graft in the surgical site, ensuring it adheres well to the surrounding bone walls to avoid post-operative movement. The bone defect should be completely filled with the granules. However, to ensure tension-free wound closure, it is essential to avoid overfilling.

NOTE: *The bone substitute should be gently compacted to avoid damaging the microscopic bone structure, which could compromise its ability to integrate with the native bone tissue. It is important to use specific instruments that allow accurate control of the applied force.*

- Remove any displaced granules from the soft tissue.
- In cases of large bone defects, it may be necessary to use multiple grafts (e.g., a combination of autologous bone graft and xenograft) for better adaptability and stability.

GRANULES IN SYRINGE

- While holding the RE-BONE® syringe steady at the liquid aspiration reducer, unscrew the outermost screw cap.
- Aspirate the rehydration liquid through the aspiration reducer.
- Hydrate the granules by moving the plunger back and forth until the granules are fully rehydrated.
- Push the plunger to compact the RE-BONE® granules and expel any excess liquid.

NOTE: *The bone substitute should be gently compacted to avoid damaging the microscopic bone structure, which could compromise its ability to integrate with the native bone tissue. It is important to use specific instruments that allow accurate control of the applied force.*

- Unscrew the liquid aspiration reducer.
- Once rehydrated, gently place the graft in the surgical site. The bone defect should be completely filled with the granules. However, to ensure tension-free wound closure, it is essential to avoid overfilling.
- Remove any displaced granules from the soft tissue.
- In cases of large bone defects, it may be necessary to use multiple grafts (e.g., a combination of autologous bone graft and xenograft) for better adaptability and stability.
- In certain circumstances, it is advisable to use a layer of autologous cancellous bone on labial and buccal applications of RE-BONE® granules, and to cover this layer with the periosteum or a membrane.

PRACTICAL ADVICE for Proper Handling of RE-BONE®

- Gentle Handling: Avoid excessive handling of the graft material to prevent compromising its structure and functionality. Use delicate instruments to position the material in the desired area.
- Proper Grafting Technique: Apply the material evenly, ensuring direct contact between the bone substitute and the surrounding bone. It is important not to overload the grafting area to avoid integration issues.
- Stabilization: It is advisable to use resorbable membranes (e.g., SHELTER® Fast or Slow) to help stabilize the bone substitute in the proper position throughout the healing process. A well-compacted graft should remain stable even under moderate pressure, indicating it is dense enough to support the surrounding structures without risk of collapse or displacement.
- Use of Appropriate Instruments: It is recommended to use instruments such as manual compactors specifically designed for this purpose to distribute pressure evenly and avoid areas of over- or under-compaction.

- Monitoring Density: During the compaction of the biomaterial, it is important to ensure the bone substitute does not become too dense. Excessive compaction can reduce the material's porosity, limiting vascularization and the colonization of cells necessary for osteointegration.
- Intraoperative Evaluation: Assessing the consistency of the graft during the surgical procedure can provide immediate feedback on the adequacy of compaction. If necessary, adjustments can be made in real-time to optimize the material's density.
- Use of Resorbable Barriers: The use of resorbable membranes is also recommended to isolate the bone substitute from the surrounding soft tissues and to concentrate the regenerative activity on the desired area. UBGEN® recommends using resorbable membranes made from bovine pericardium (SHELTER® Fast or Slow), which provide different barrier effects depending on the duration needed or desired for graft protection.

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 suturing is performed in a way that protects the graft and reduces tension on the wounds, facilitating healing.
- Make 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.
- Use suturing techniques that evenly distribute tension and maintain flap stability, protecting the graft site and minimizing the risk of material exposure.
- Ensure that 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, and instruct them to contact the doctor immediately in case of such events.
- Properly manage post-operative pain and inflammation to improve patient comfort and reduce the risk of complications.
- Emphasize the importance of compliance with follow-up visits to monitor the healing process and intervene promptly in case of any complications.
- Follow-up: Schedule regular check-ups to monitor the surgical site through periodic control visits. Assess the healing and integration of the bone substitute and identify any early signs of complications. Use imaging techniques such as X-rays or CBCT (Cone Beam Computed Tomography) to monitor the progress of regeneration and detect potential issues early on.

Complication Management

Generic complications can arise post-surgery or during the procedure, such as gingival recession, severe gingival bleeding, soft tissue edema, sensitivity to heat, 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 assess the need for additional treatments or modifications to the treatment plan.

FOCUS ON PRACTICAL BENEFITS

Reduction of Healing Time

RE-BONE® offers a significant reduction in healing time compared to other alternative solutions, thanks to its unique combination of osteoconductive and osteogenic properties. The highly porous structure of the bone substitute promotes rapid cellular colonization and vascularization, thus stimulating faster bone regeneration.

Specifically, RE-BONE®'s ability to create an optimal environment for bone cell growth and integration facilitates the early stages of healing, reducing the risk of post-operative complications and allowing for quicker patient recovery. Compared to alloplastic or synthetic solutions, RE-BONE® accelerates the regenerative process due to its natural structure that mimics human bone, enabling faster integration into the grafted site.

This reduction in healing time translates into greater patient comfort and increased operational efficiency for the dentist, who can schedule follow-up appointments sooner, reducing the overall treatment duration and improving patient satisfaction.

Increase in Predictability of Results

One of the main advantages of RE-BONE® is its exceptional reliability, even in complex clinical cases, due to the use of advanced materials and a rigorously controlled purification process. The bovine bone used as the base for RE-BONE® undergoes a meticulous process of defatting, lyophilization, and sterilization with ionizing radiation, ensuring not only the complete elimination of pathogens but also the preservation of essential osteoconductive and osteogenic properties necessary for bone regeneration.

The consistency and purity of the resulting material make RE-BONE® particularly suitable for addressing bone defects of varying complexity, offering predictable and replicable results. Thanks to its optimal biological integration characteristics, RE-BONE® reduces the risk of early resorption or complications during the healing period, increasing the likelihood of long-term success for implants and bone regeneration.

Additionally, the wide range of available formats allows for personalized treatment, facilitating better adaptability to the patient's specific defects and further improving the precision of the outcome. Thanks to the quality of the material and control processes, dentists can rely on RE-BONE® to achieve predictable and high-quality results, even in complex clinical cases where other solutions might fail.

CONCLUSION

Adopting a standardized procedure for using RE-BONE® will significantly improve clinical outcomes and patient satisfaction. Every step described in this manual is essential to ensuring treatment success and patient safety.

By following these guidelines, dentists can maximize the performance of the RE-BONE® bone substitute in their clinical practices, reducing healing times and increasing the probability of implant success, thereby enhancing patient satisfaction.

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CAN IMPROVE YOUR CLINICAL RESULTS.

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