SAFE-BONE®

CUSTOMIZED REGENERATIVE TITANIUM MEMBRANE (disposable custom device).

UBGEN SPECIALISTS OF BONE SURGERY IN DENTISTRY

ENG

Intended use

SAFE-BONE® is a customized regenerative titanium membrane intended to be employed in oral-maxillo-facial surgery, implantology, periodontology, oral surgery and endodontics in order to support the guided bone and tissue regeneration, to protect fixtures and to regenerate periodontal tissue. SAFE-BONE® is produced through laser-synthetization, using specific titanium grade 5 powders

Typical Post Heat Treatment Properties (Ti-64 G5-B, Ti-64 G23-A)

	G5-B, EOS M290	G23-A, EOS M290	Test Method
Ultimate Tensile Strength (MPa), XY/Z	1075 ± 5 / 1089 ± 4	996 ± 8 / 1008 ± 9	ASTM E8
Yield Strength (MPa), XY/Z	972 ± 4 / 1006 ± 5	889 ± 6 / 992 ± 15	ASTM E8
Elongation at break (%), XY/Z	15 ± 0.5 / 17 ± 1	17 ± 0.4 / 17.5 ± 0.4	ASTM E8
Hardness HRC	36	34	ASTM E384-17
Density, g/cc	4,3	4.3	Archimedes

Therapeutic Indications

SAFE-BONE® is intended to be used for guided bone regeneration:

- For surgical bone defects or bone walls defects;
- Within sinus lift surgery, volume augmentation or reconstruction of alveolar crest;
- In treatment of fenestration defects;
- Within parodontal bone defects (defects on one-three walls, defects of forcation class I, II);
- In treatment of dehiscence;
- Following root canal therapy, cystectomy, avulsion of impacted tooth and resection of other bone defects;
- In post-extraction sockets following tooth extraction;
- In immediate or deferred augmentation around fixture in post-extraction sockets.

Preservation

Preserve avoiding damages to the package. Do not use the device if the device may pose a risk of infection.

Precautions for use

Disposable device.
Reuse to the device may pose a risk of infection.

Warnings

Before applying, accurately clean and disinfect the device with appropriate products, dry and sterilize in autoclave at 134°C at least 10 minutes. SAFE-BONE® are intended to be used by specialized medical personnel. This medical device is compliant to the technical characteristics described in the medical prescription and to the project approved by the ordering Clinician. During its application, the general principles of sterility must be respected during application and patient medication. The reuse of the device may pose a risk of infection. UBGEN S.r.l. is not responsible for the improper usage of the device.
The medical device is considered suitable for its use only if the design of the same is completed no later than 60 days from the execution of the CT scan.

Side effects

- No pharmacological side effect have been reported since the raw material that constitutes the device are historically inert, with the exception of known allergy to grade 5 titanium.
- After surgery, the patient must follow the instructions of the treating dentist regarding oral hygiene.
- As with any foreign material, any pre-existing local infections may worsen due to the grafting of the customized regenerative membrane SAFE-BONE®.

Contraindications, cautions

The clinician shall necessarily ensure the general and local clinical status of the patient, evaluating if treatment contraindications exist.
Do not use the customized regenerative membrane SAFE-BONE® in patients with:

- Acute infections in the oral cavity or acute or chronic inflammations in the graft site;
- Systemic pathologies for whom oral-maxillo-facial, implanter, periodontal, endodontic surgeries or other oral surgeries are not allowed;
- Known hypersensitivity to grade 5 titanium.

Interactions with other products and methods

- In case of magnetic resonance, considering the composition of the SAFE-BONE® customized regenerative membrane, it is recommended the preventive notification of the medical device implantation to the authorized healthcare personnel.
- It is not-recommended any incorrect use of the device, if it is placed in contact in the oral cavity with other materials which may interact because of their chemical or physical characteristics.

Precautions

- It is recommended to employ the customized regenerative membrane SAFE-BONE® only for the uses mentioned above. The device has not been clinically tested in patients with particularly serious surgical, implant, periodontal, and endodontic defects.
- Clinicians are responsible for informing their patients about any contraindications, side effects and necessary precautionary measures. In the presence of postoperative complaints, such as pain, infection, or other unusual symptoms, the patient should immediately consult the dentist.
- It is necessary to report any serious accident occurring in relation to this medical device to the manufacturer and the local competent authority.

Legend of symbols

UDI	IUNIQUE IDENTIFICATION OF THE DEVICE
REF	PRODUCT CODE
LOT	LOT NUMBER
MD	MEDICAL DEVICE
	MANUFACTURING DATE
	EXPIRATION DATE
5°C 30°C	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

UBGEN S.r.l.
Viale del Lavoro, 14 - 35010 Vigonza (PD) Italy
ubgen.com

Rev. 00 - 01/2023