BIONER
SISTEMAS IMPLANTOLÓGICOS

INSTRUCTIONS FOR THE USE OF HEALING ABUTMENTS

1. Product description

Healing abutments are solid titanium devices with a head at one end and a thread on the other, designed to be screwed onto the implant itself or onto transepithelial connectors.

2. Planned use:

The intended use of the device is to hold the tissues open after removal of the cover screw and during the healing period (about 15 days). This epithelial opening enables connection between the implant and the over-structure.

3. Directions for use

A healing abutment is used as an auxiliary transmucosal pillar. It is placed in the implant before prosthetic restoration to simplify the formation of a soft tissue sulcus. Select the working height to ensure correct operation and prevent any transmission of chewing forces.

4. Contraindications

Allergy or hypersensitivity to the chemical components of the materials used (biocompatible Titanium).

5. Side effects and interactions

Follow the instructions for use recommended by the manufacturer. Incorrect use of the product may cause injury to the patient.

6. Cleaning, disinfection and sterilisation

Healing abutments are marketed unsterilised. The healthcare professional should clean and sterilise them before use.

Bioner SA always recommends performing previous cleaning with products commonly used in dentistry, with emphasis on ultrasonic baths or automatic cleaning and disinfection methods before proceeding with sterilisation.

Remove the product from its original packaging and place it is a suitable container before sterilisation.

Sterilisation should be performed in sterilisation bags or boxes in a wet steam autoclave at 121°C for 15 minutes or 134°C for at least 3 minutes, as per UNE-EN-ISO 17665-1:2007.

Do not use the product after sterilisation if there is any detectable deterioration of the container.

Healing abutments, as well as all accessories produced by Bioner SA, should not be reused; they are products for single use only.

7. Warnings

Before use, make sure that the material is in perfect condition and there are no loose parts to prevent the inhalation or swallowing of one or more components. Furthermore, it is highly recommended to make sure that the product is clean and disinfected and the part in contact with the patient is clean and free of any residue.

The healthcare professional using the product must have experience in using it safely and in accordance with instructions for use provided by BIONER SA, the said professional being liable for the suitability of the component to the patient's needs.

8. Precautions

It is especially important to ensure that each reference is used in combination with dimensionally compatible elements as indicated on the product label.

9. Compatibility

BIONER healing abutment family references must be used in conjunction with compatible components. Carefully examine the components available in the company product catalogue for suitability before insertion.

The dimensions ensure compatibility with the components matching each specific reference. The compatibility of each reference is guaranteed by BIONER SA in-process controls.

10. Procedure

Check the following:

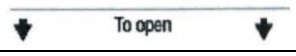
- ✓ Make sure that the platform of the implant is free of any tissue residue before placement
- ✓ Use gentle manual torque

11. Validity

These instructions for use correspond to the current version of references for the healing abutment family, as indicated at the foot of the document.

12. Storage

The elements in this family must be stored under non-extreme environmental conditions preventing prolonged exposure to sunlight.

ISO 15223 Symbol	Description
	Indicates the direction for opening the blister
BIONER SISTEMAS IMPLANTOLÓGICOS	BIONER SA logotype
REF	Catalogue reference
LOT AOFAAXXXXX	Batch code
DD/MM/YY	Date of Manufacture

	Refer to the instructions for use
	Do not use if package is damaged
Family	Product family name / additional info
Mat = Ti	General indication of the material used
q=1	Indicates the number contained in each blister
	Non-sterile
	QR code (reference and batch)
	Do not reuse
	Consult warning and precautions in instructions for use
	Manufacturer
CE 0051	EC Marking

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