INSTRUCTIONS FOR USE CLINICAL SCREWS

1. Product description

The clinical screws, also known as surgical screws, are cylindrical titanium elements, in one piece, equipped with a head at one end and a threaded part at the other, both of varying dimensions depending on the elements to be joined.

2. Intended use

The clinical screw is necessary both to fix the prosthesis to the implant and to join together the different parts that it may have.

3. Directions for use

The clinical screws are used to fix dental prostheses and auxiliary abutments on the implant or the like. Make sure the appropriate clinical screw for the system and metrology used in the reconstruction is chosen.

4. Side effects

Allergy and hypersensitivity to the chemical components of the materials used (medical grade titanium).

5. Side effects and interactions

It is advisable to follow the instructions for use recommended by the manufacturer. Improper use of the product may result in patient damage.

6. Cleaning and disinfection and sterilisation.

Clinical screws are sold without sterilisation. Before using them, the professional must perform cleaning, disinfection and proceed to sterilisation.

Bioner SA recommends to always carry out a previous cleaning with products of use in the dental sector, relying on ultrasonic baths or automatic cleaning, disinfection methods and then proceed to sterilisation.

Prior to sterilising, the products in their original packaging must be transferred to another one suitable for said purpose.

Sterilisation must be carried out in a steam autoclave at 121ºC for 15 minutes or 134ºC at a minimum of 3 minutes, according to UNE-EN-ISO 17665-1: 2007, in sterilisation bags or boxes.

Do not use the product after sterilisation if any deterioration in the package is observed.

The clinical screws, as well as all the attachments produced by Bioner SA, must not be reused; they are single-use products.

7. Warning

Before use, it must be checked that the material is in perfect condition and there are no disassembled parts, to avoid aspiration or swallowing of part or all components. Furthermore,

it is especially recommended to check that the product is clean and disinfected and that the patient connection area is clean and free of debris.
The healthcare professional who uses the reference product must have experience to use them in a safe and adequate way to the instructions provided by BIONER SA, being the responsibility of the same professional to apply this element to the needs of the patient.

8. Precautions

It must be especially taken into account that each reference must be used in combination with dimensionally compatible elements and which are indicated on the product label itself.

9. Compatibility

BIONER SA clinical screw family references must be used in conjunction with compatible components. Before fitting, it is necessary to review the components available in the company's product catalogue to make the correct choice.

The dimensions of the peaks ensure compatibility with the components with which each specific reference will be combined. The guarantee of the compatibility of each reference is based on the controls of the manufacturing process of BIONER SA.

10. Procedure

For best results, BIONER SA recommends following the following instructions:

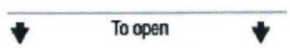
- ✓ To tighten or unscrew use the appropriate model and size of the key. It is essential to use a new clinical screw when the prosthesis is mounted for the first time and later in each revision of the prosthesis.
- ✓ In cases of immediate loading, screw on manually, avoiding excessive torque, and secure the implant so that it does not rotate when screwing.
- ✓ When transferring to the patient, do not put the same clinical screw that was used in the laboratory.
- ✓ Make sure that the clinical screw used for the case is the correct model.
- ✓ Place the patient in a safe posture to avoid aspiration in case the clinical screw falls during handling.

11. Validity

These instructions for use correspond to the current version of the clinical screw family references, indicated at the bottom of the document.

12. Storage

Elements of this family must be preserved and stored in non-extreme environmental conditions, avoiding prolonged exposure to sunlight.

ISO symbol 15223	**Description**
	Indicator of the blister opening direction
	BIONER SA logo

REF	Catalogue reference
LOT AOFAAXXXXX	Batch Code
DD/MM/YY	Manufacturing date
	See instructions for use
Don't use if package is damaged.	Do not use if package is damaged
Family	Product family name / additional info
Mat = Ti	Generic code of the construction material
q=1	Indicative of the amount contained in each blister
NON STERILE	Non-sterile
	QR code (reference and lot)
	Do not re-use
	Caution
	Manufacturer
CE 0051	EC Marking

Manufacturer information:

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