BIONER
SISTEMAS IMPLANTOLÓGICOS

INSTRUCTIONS FOR THE USE OF DENTAL TOOLS

1. Product description and planned use:

The series of dental tools available can be divided into four main groups:

- Carriers

Devices of different shapes and sizes for holding implant screws in position for either manual insertion or using a ratchet or handpiece.

- Screwdrivers

Devices of different shapes and sizes for tightening implant screws; may be used either manually or with a ratchet or handpiece.

- Ratchets

Mechanical devices whose mechanism, when fitted to a screwdriver or holder, tightens a screw or implant in only one direction.

- Other

This section includes various devices considered dental tools but which cannot be included in the previous groups.

2. Directions for use

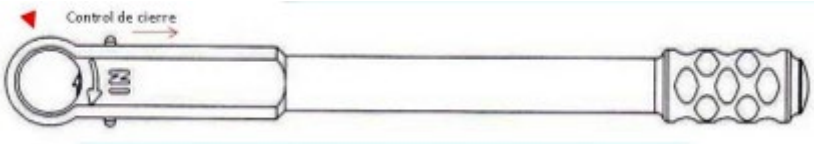
The purpose of the dental tool is to hold, position, screw, or remove implants or other prosthetic components in a laboratory or in clinical practice.

Ratchets: bear in mind

- Torque ratchet (LDR):

✓ Adjust the ratchet using the closure control as indicated in the diagram.
✓ Adjust the torque strength using the adjustment knob.
Read the adjustment level on the scale.
✓ For uncontrolled torque, turn the adjustment knob to the ∞ position.
When the ratchet reaches the set torque the handle disengages from the head. Applying more force at this point could damage the ratchet.
✓ Always store the ratchet adjusted to the minimum.

- Fixed ratchet (LCC)



3. Contraindications

Allergy or hypersensitivity to the chemical components of the materials used.

4. Side effects and interactions

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

5. Cleaning, disinfection and sterilisation

In the event of any packaging defect, the product should not be used and the manufacturer notified immediately.

All BIONER dental tools are supplied clean and suitably packed. They require sterilisation by the healthcare professional before use in the mouth.

Bioner SA always recommends performing previous cleaning of all dental tools with products commonly used in dentistry, with emphasis on ultrasound baths or automatic cleaning and disinfection methods before proceeding with sterilisation (if required).

Remove the product from its original packaging and place it in 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, under UNE-EN-ISO 17665-1:2007.

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

Ratchets: give special attention to cleaning and maintenance:

Always clean after use with a soft disinfectant brush using abundant water to eliminate any remains of blood or other residues. The tool may then be immersed in dental instrument cleaner solution. Dry the tool after cleaning. Disassemble torque wrenches/ratchets before cleaning.

▼ The areas marked on the drawings should be lubricated with special oil for dental tools.

6. Warnings

Dental tools may be reused after cleaning, disinfection and sterilisation.
Ratchets: Do not clean ratchets with metal brushes.

7. Precautions

Check compatibility with the part they are to be connected to.

8. Compatibility

BIONER dental tool family references must be used in conjunction with compatible components. Carefully examine the components available in the company product catalogue before use.

9. Validity

These instructions for use correspond to the current version of the dental tool family references indicated at the bottom of the document.

10. Storage

BIONER products do not require any special storage conditions even though it is recommended not to expose them to conditions that could affect the product, its packaging or label, such as extreme temperature and humidity, knocks, etc.

Symbols to be used with information to be supplied by the manufacturer ISO 15223-1 Fourth edition 2021-07	Description
	To open
BIONER SISTEMAS IMPLANTOLÓGICOS	BIONER SA lo type
MD	Medical D ice
Dental Tools	Product catego
REF	atalogue numbe
Mat = Titanium or Stainless steel or Al or PEEK	T of material
Q=1	Quan /blist
LOT AOFAAXXXXX	Ba h cod
DD/MM/YY	Da of Manufacture
NON STERILE	Non-sterile
	Consult instructions for use or consult electronic instructions for use
	Do not use if package is damage and consult instructions for use
0123456 (1 MMDD (10 FAA12345 **UDI datamatr and HRI**	Unique device identifier (UDI and HRI human readable information)
	Caution
	Manufacturer
CE	CE Marking
Label version	EBv0x (Ex: EBv01) x= version number

Summary of safety and clinical performance is available on website

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