

INSTRUCTIONS FOR THE USE OF DENTAL DRILLS

1. Product description

Dental drills are mechanical cutting tools made of surgical quality stainless steel. They typically have a spiral shape and are used in conjunction with a motor and a handpiece.

2. Planned use:

Dental drills are used for drilling bone in oral implantology procedures to prepare the housing for the dental implant.

Every dental drill (except lances and burs) incorporates insertion marks that enable adjusting the drill to the appropriate length for any Bioner dental implant.

3. Directions for use

Drills should be sterilised in a moist heat autoclave before use, and should not be used if any deterioration is observed. Bioner guarantees a maximum of 6 uses with the corresponding sterilisations, but the physician must make sure the tool is in good condition.

Only use dental drills with devices with a socket defined as type I in the ISO 1797-2017 standard "Dentistry. Shanks for rotary and oscillating instruments".

4. Contraindications

Allergy or hypersensitivity to the chemical components of the materials used (medical grade stainless steel), and Ti Gr5 in the case of drill stops.

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.

Any lack of irrigation during drilling may cause necrosis of the bone and adjacent tissue due to the heating effect.

6. Cleaning, disinfection and sterilisation

Drills are marketed sterilised. The healthcare professional should clean, disinfect and sterilise the devices 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.

Drill stops also require sterilisation before use.

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

When the packaging is in surgical boxes, designed for sterilisation, proceed with moist heat sterilisation under the same conditions:

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.

It should be borne in mind that the material may suffer wear during its useful life; BIONER SA therefore recommends a maximum of 6 sterilisations per element to ensure product quality.

7. Drilling sequence

Dental drills are designed for sequential use to shape a cavity of the appropriate size, both in diameter and depth, for the placement of Bioner dental implants. All dimensions have been set to meet this objective, including the insertion marks corresponding to the heights of Bioner dental implants. The drill depth will depend on the height of the dental implant to be placed and the insertion marks on the burs. Refer to the drilling guide in the BIONER catalogue.

8. Drilling stop marks

Bioner, S.A. offers a full range of drill depth stops for dental drills to ensure the drill depth does not exceed the size of the implants. Before use, make sure the selected stop corresponds to the dental drill used and the depth of the implant to be placed.

9. Warnings

Make sure the material is in perfect condition before use. Repeated use of a drill may cause loss of its characteristics.

Check the condition of the cutting edges before use.

Do not store moist dental drills after the cleaning and sterilisation process, and discard dental drills at the first signs of wear.

The healthcare professional using the product must have experience in using it safely and in accordance with instructions for use provided by BIONER SA.

10. Precaution

BIONER SA does not recommend using the product after a maximum of 6 sterilisations, with the corresponding cleaning and disinfection, to guarantee correct operation of the device.

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

In the event that the dental drill does not perforate the bone smoothly, check the drill speed and sharpness of the edges. In the event of any deficiency, discard the dental drill.

In the event of breakage during use, remove any remains, clean the wound and continue with the procedure

11. Compatibility

The compatibility of every reference is guaranteed by the stringent controls BIONER SA applies to all devices. Refer to the drilling guide in the BIONER catalogue.

12. Procedure

Check the following:

- ✓ That handpieces, turbines and contra-angles where the dental drill is connected are in perfect hygienic and operational conditions
- ✓ That the dental drill is correctly seated in the contra-angle
- ✓ Correct rotation of the dental drill
- ✓ That the drill speed is between 500-1000 rpm according to the hardness of the bone and phase
- ✓ Obtain accurate measurements of the perforation made by using calibrated measurement probes
- ✓ Use irrigation during drilling (lack of irrigation may cause necrosis of adjacent bone and tissue due to heating)








13. Validity




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

14. Storage












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

Information on the blister pack

ISO 15223 Symbol	Description
 To open	Indicates the direction for opening the blister
	BIONER SA logotype
REF	Catalogue reference
LOT A01XXXXX	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: STAINLESS STEEL	General indication of the material used
q=1	Indicates the number contained in each blister
	Non-sterile
	QR code (reference and batch)

	Precautions
	Manufacturer
	EC Marking

Information on the surgical box

ISO 15223 Symbol	Description
	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
Name of the KIT	Name identifying the KIT
Components	Description of each of the components on the box.
	Non-sterile
Sterilisation method	Sterilisation method, temperature and time
	Precautions
	Manufacturer
	EC Marking
	EC Marking Self-certification

Manufacturer details:

Name	BIONER, S.A.
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Name	BIONER, S.A.


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