BIONER
SISTEMAS IMPLANTOLÓGICOS

INSTRUCTIONS FOR THE USE OF A KIT FOR DRILL STOPS

1. Product description

BIONER SA. kits for drill stops contain machined grade 5 titanium biocompatible, reusable, cylindrical elements of different diameters and lengths, whose inside diameter is suitable for placement on the drill.

They are available on the market in kits that are appropriately identified according to their planned use.

2. Planned use:

The purpose of drill stops to ensure the drill depth does not exceed the size of the dental implant. They are for optional use by the healthcare professional.

3. Directions for use

Before use, make sure that the selected drill stops correspond to the surgical drills being used and the depth of the dental implant to be placed. They are colour-coded to ensure correct use. The colour indicates the drill diameter and the laser marks on the drill show the drill depth.

4. Contraindications

Allergy or hypersensitivity to the chemical components of the materials used; medical grade Ti.

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

Kits for drill stops are supplied unsterilised. The healthcare professional should clean, disinfect and sterilise the devices before use.

Bioner 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.

Sterilisation should be performed in sterilisation bags 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.

Remove the kit from the sterilisation bag immediately before use.

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

7. Warnings

Drill stops may be reused after cleaning, disinfection and sterilisation.

The healthcare professional using the product must have experience in using this product 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 that each reference be used in combination with dimensionally compatible elements.

9. 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.

10. Presentations

Drill stops are available in kits for procedures.

11. Validity

These instructions for use correspond to the current version of references for the kit for drill stops family as 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.

Symbols to be used with information to be supplied by the manufacturer ISO 15223-1 Fourth edition 2021-0	Description
	To open
BIONER SISTEMAS IMPLANTOLÓGICOS	Logotype
MD	Medical Device
Drill stop	Product category
	Catalogue number
Mat = Titanium	Type of material
Componen	Description of each of the components on the box.
Sterilisation method	Sterilisation method, temperature and time
LOT **AOFAAXXXXX**	Batch code
DD/MM/AA	Date 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

(01)01234567891011 (11) AAMMDD (10) AOFAA12345 **UDI datamatrix and HRI**	Unique device identifier (UDI and HRI human readable information)
	Caution
	Manufacturer
	CE Marking
Label version	EBv0x (Ex: EBv01) = version number

Summary of safety and clinical performance is available on website

Manufacturer details:

Name	BIONER, S.A.
Address	Espigolera 08960 Sant J Desvern B
Tel.	93 470 03
Fax	93 470 35 27
e-mail	ner@bio r.es
Website	www.bioner.es

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