INSTRUCTIONS FOR USE OF SLEEVES FOR GUIDED SURGERY

1. Product description

The BIONER SA family of guided surgery sleeves are machined from single use biocompatible Titanium. They are cylindrical in shape and available in different inside diameters and lengths to simplify fully guided drilling and implant placement. This product family also includes mounting pins to hold the sleeve in place during surgery.

2. Planned use

The elements included in this family are used to guide computer aided drilling and implant placement processes based on precise preoperative planning. The guided surgery sleeves define the position and three-dimensional orientation of the implants and so contribute to minimising problems during surgery.

3. Indications for use

Before use, make sure that the selected elements are suited to the surgical drills to be used and the size of the dental implant to be placed.

4. Contraindications

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

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 sterilization

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

Guided surgery sleeves are marketed as non-sterile products. They should cleaned, disinfected and sterilised by the healthcare professional 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.

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

7. Warnings

Guided surgery sleeves should not be reused; they are products for single use only, as any reuse could alter their technical specifications.

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

9. Compatibility

The references of the BIONER family of guided surgery sleeves must be used in conjunction with compatible components. Carefully examine the components available in the company product catalogue for suitability before insertion.

10. Procedure

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11. Validity

These instructions for use correspond to the current version of references of the family of guided surgery sleeves as indicated at the bottom of the document.

12. 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	Logotype
MD	Medical Device
Guided surgery sleeves	Product category
REF	Catalogue number
Mat = Titanium	Type of material
Q=1	Quantity/blister
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)
	Do not re-use
	Caution
	Manufacturer
CE	CE Marking
Label version	EBv0x (Ex: EBv01) x= version number

Summary of safety and clinical performance is available on website

Manufacturer details:

Name	BIONER, S.A.
Address	Espigolera 9, 08960 Sant Just Desvern Barcelona
Tel.	93 470 0360
Fax	93 470 35 27
e-mail	bioner@bioner.es
Website	www.bioner.es

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IFU-CCG v01/2022-EN