INSTRUCTIONS FOR THE USE OF REPLICAS

1. Product description

Replicas are machined refractory stainless steel or medical class titanium elements designed to support high temperatures in the event of welding.

2. Planned use:

They are used to replicate the transepithelial/digital implant of plaster laboratory model and so their name.

3. Directions for use

Before any manipulation, make sure that the anti-rotation and retaining parts are firmly connected.

Before tightening, make sure that the replica and the prosthesis coincide in size and connection type.

Replicas are machined with furrows or facets which, once the plaster sets, prevent any movement and fix them securely in place.

4. Contraindications

na

5. Side effects and interactions

na

6. Cleaning, disinfection and sterilisation

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

All BIONER replicas are supplied clean and appropriately packaged. As they are not inserted in the mouth and their use is restricted to the laboratory, they require no sterilisation.

7. Warnings

Do not reuse any replica, they are products for single use only; reuse could alter their connections and technical specifications.

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

BIONER replica family references 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 the replica family references 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
Replicas	Product category
REF	Catalogue number
Mat = Stainless steel or 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:

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