

INSTRUCTIONS FOR THE USE OF IMPRESSION COPINGS

1. Product description

Impression copings are divided into two large generic groups:

- ⇒ Closed tray impression copings
- ⇒ Open tray impression copings (fenestrated)

In the first group the impression copings remain in the patient's mouth after removal of the tray with the impression material already setting and must be unscrewed at a later stage. In the case of an open tray, the copings remain lodged in the impression material in the tray.

2. Planned use:

Their purpose in clinical practice is to map the exact position (height and angle) of the implant in the patient's mouth to enable precise reproduction of oral anatomy on the model.

3. Directions for use

Make sure the connection seat of the implant is clean before taking the impression. Any trace of residue or dirtiness could affect later adjustment of the prosthesis.

Loosen the cover screw, clean the connection with water and dry with air.

Closed tray: choose short screws. After tightening, block the hexagon of the screw with wax. After the impression has hardened check its stability before shipping to the laboratory.

Open tray: choose long screws. Before mixing the impression material place the tray in the mouth and check access to the screws. After hardening, dismantle all the screws and remove the tray.

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 sterilisation

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

All BIONER impression copings are supplied clean and suitably packaged. They require sterilisation by the healthcare professional before use in the mouth.

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 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, as per UNE-EN-ISO 17665-1:2007.

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

7. Warnings

Do not reuse any impression coping, they are products for single use only; reuse could alter their connections and 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

BIONER impression coping 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




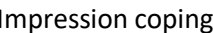

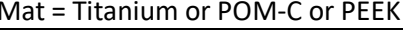

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11. Validity

These instructions for use correspond to the current version of references for the impression coping family 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 SA logotype
	Medical Device
	Product category
	Catalogue number
	Type of material
	Quantity/blister

 LOT AOFAAXXXXX	Batch code
 DD/MM/YY	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 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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