BIONER
SISTEMAS IMPLANTOLÓGICOS

INSTRUCTIONS FOR THE USE OF TRANSEPITHELIAL CONNECTORS

1. Product description

Transepithelial connectors are titanium elements which are screwed to the implant through the gum. Unlike titanium abutments, transepithelial ones are not retouched in the laboratory before placement in the mouth and the prosthesis they support will be screwed on. It is important to note that the terms *transepithelial connectors*, *transepithelial, converters and overdenture pillars*, are used indistinctly but all of them refer to the same type of product.

2. Planned use:

Transepithelial connectors are used to raise the level of the prosthetic connection in cases where the implant is very submerged, enabling work to be carried out with greater comfort and hygiene and ensuring better results at a soft tissue level.

3. Directions for use

Transepithelial connectors, placed directly on dental implants, are designed to be auxiliary transmucosal attachment points for screw-retained prosthetic rehabilitation. After placement, use periapical x-rays to check correct positioning.
In the case of straight transepithelial connectors: place an abutment that suits the dimensions and system. Tighten the abutment to 20-30 Ncm using an appropriate torque wrench. Take an impression using the routine procedure. If a temporary prosthesis is not required, put cap plugs in place.
STERILE transepithelial connectors are supplied with a disposable holding device that is only used to simplify positioning and placement.

4. Contraindications

Allergy and hypersensitivity to the chemical components of the materials used (medical grade titanium).

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

The references for the transepithelial connectors available indicate whether they are STERILE (gamma radiation) or NON-STERILE; this is also indicated on the primary packaging.
In the event of any packaging defect, the product should not be used and the manufacturer notified immediately.
STERILE transepithelial connectors are designed for single use only prior to the expiry date indicated on the label. BIONER S.A. accepts no responsibility in the event of re-sterilisation or reuse of the product by the physician.
Before being used, the healthcare professional should check which type they are and proceed with cleaning, disinfection and sterilisation as required (NON-STERILE references).
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.
Transepithelial connectors, as well as all accessories produced by Bioner SA, should not be reused; they are products for single use only.

7. Warnings

Before use, make sure that the material is in perfect condition and there are no loose parts to prevent inhalation or swallowing of one or more components. Furthermore, it is highly recommended to make sure that the product is clean and disinfected and the part in contact with the patient is clean and free of any residue.

The healthcare professional using the product must have experience in using it 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 transepithelial connector family references must be used in conjunction with compatible components. Carefully examine the components available in the company product catalogue for suitability before insertion.
The dimensions ensure compatibility with the components matching each specific reference. The compatibility of each reference is guaranteed by BIONER SA in-process controls.

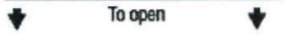
10. Validity

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

11. Storage

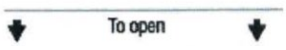
Elements of this family must be preserved and stored in non-extreme environmental conditions, avoiding prolonged exposure to sunlight.

NON-STERILE

ISO 15223 Symbol	Description
	Indicates the direction for opening the blister
BIONER SISTEMAS IMPLANTOLÓGICOS	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
Family	Product family name / additional info
Mat = Ti	General indication of the material used
q=1	Indicates the number contained in each blister
	Non-sterile
	QR code (reference and batch)
	Do not reuse
	Precautions
	Manufacturer
CE 0051	EC Marking

STERILE

ISO 15223 Symbol	**Description**
	Indicates the direction for opening the blister
BIONER SISTEMAS IMPLANTOLÓGICOS	BIONER SA logotype
REF	Catalogue reference
LOT AOFAAXXXXX	Batch code
 DD/MM/YY	Date of Manufacture
	Expiry date
STERILE R	Sterile
	Refer to the instructions for use
	Do not use if package is damaged
Family	Product family name / additional info
Mat = Ti (or Ti/PEEK or Ti/Nylon)	General indication of the material used
q=1	Indicates the number contained in each blister
	QR code (reference and batch)
	Do not reuse
	Precautions
	Manufacturer

CE 0051	EC Marking

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