BIONER
SISTEMAS IMPLANTOLÓGICOS

INSTRUCTIONS FOR THE USE OF SCANBODY

1. Product description

ScanBody is a device used to establish the virtual 3D position of the implant in relation to the mouth cavity. It is comprised of three elements: titanium base, PEEK body and titanium insertion screw.

2. Planned use:

ScanBody is placed directly on the connection of the implant or on a transepithelial element, depending on the model, and used as a reference during the intraoral CAD/CAM process, or in the laboratory for the design and machining of prosthetic restorations.

3. Directions for use

The intended use is to simplify the transmission of information between the clinic and the laboratory in relation to prosthetic restorations on implants through the use of digital technology. It enables processing scanned images and the use of specific software for the design and manufacture of structures and attachments in the laboratory, thus improving precision and reproducibility of the construction of prostheses on the implants.

4. Procedure

Check the following:

- ✓ Compatibility with the implant or corresponding transepithelial element
- ✓ Cleanliness and disinfection
- ✓ Sterilisation and later cooling to a temperature of 20-40°C
- ✓ Verification of perfect condition and assembly
- ✓ Remaining in the mouth for less than 5 minutes
- ✓ Perfect condition of the connected implant
- ✓ Scanning
- ✓ Removal of the ScanBody

5. Contraindications

Allergy or hypersensitivity to the chemical components of the materials used; PEEK and titanium alloys.

6. Side effects and interactions

Follow the instructions for use recommended by the manufacturer. Incorrect use of the product may cause injury to the patient including infections and/or swallowing of the device or incorrect results of the scanning process.

7. Cleaning, disinfection and sterilisation

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

All BIONER ScanBody are supplied clean and appropriately packaged.

The ScanBody is marketed unsterilised. The healthcare professional should clean, disinfect and sterilise the device 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.

It should be borne in mind that the material may suffer wear during its useful life; BIONER SA therefore recommends a maximum of 20 sterilisations per device to ensure product quality is maintained.

8. Warnings

Before use, make sure that the material is in perfect condition and there are no loose parts to prevent the 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.

ScanBody references can only be used with compatible digital libraries.

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.

9. Precautions

BIONER SA does not recommend using the product after a maximum of 20 sterilisations, with the corresponding cleaning and disinfection, to guarantee correct operation of the device.

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

10. Compatibility

The references of the BIONER SA. ScanBody family are available for various implant sizes as indicated on the label of each reference and in the company product catalogue.

11. Additional information

Refer to the instructions for use of the scanner

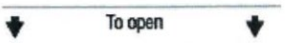
Refer to the instructions for use in BIONER SA databases

12. Validity

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

13. 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.

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	Name of the product family
Mat = Titanium/PEEK	General indication of the material used
q=1	Indicates the number contained in each blister pack
NON STERILE	Non-sterile
	QR code (reference and batch)
	Consult warnings and precautions in instructions for use
	Manufacturer
CE	EC Marking

Manufacturer details:

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