BIONER
SISTEMAS IMPLANTOLÓGICOS

INSTRUCTIONS FOR THE USE OF DENTAL IMPLANTS

1. Product description

Dental implants are biocompatible Titanium devices with an outer thread for initial fixation in bone, and an inner thread, for connection to the dental prosthesis. They are of variable length and diameter in order to cover all clinical needs. They are inserted directly into the bone using a surgical method and special tools.

The surface is chemically treated to improve osseointegration. They are presented suspended inside a polyethylene tube only in contact with a titanium ring inside the tube and which, in turn, is inside a sealed blister. The dental implant is held in place by a screw fitted to the cap of the inner tube. Dental implants include, when necessary, a cover screw located in the upper part of the inner container. Dental implants are supplied sterile. The sterilisation process uses Gamma irradiation.

2. Intended use:

A dental implant is used to replace the dental root, thus providing support for a future dental prosthesis.

- **Prior to use**: the shelf life depends on the sterilisation process and, therefore, on its expiry date. A dental implant may not be placed after its use-by date as its sterility cannot be guaranteed after this date.
- **In use**: once placed and osseointegrated, its use is permanent and will mainly depend on:
    - Good practices regarding the prosthesis and/or other procedures applied by the surgeon.
    - The hygienic coditions of the patient, mainly those applied by the patient him/herself.

3. Indications for use

BIONER implants are indicated for providing an anchor point for intraoral reconstructive prostheses in the jaw or upper maxillary and in cases of partial or total edentulism.

4. Traceability

The BIONER dental implant is accompanied by traceability labels indicating product and batch reference numbers for inclusion on the patient's dental record

5. Contraindications

No contraindications have been identified to date for BIONER SA titanium dental implants and so the contraindications are those defined in general for all oral surgery involving the placement of implants.

They are also contraindicated in case of allergy and hypersensitivity to the chemical components of the materials used in their manufacture (medical grade titanium)

- Absolute contraindications: lack of bone or insufficient bone quality, inflammation, septicaemia and osteomyelitis.
- Other diseases or conditions previous to surgery that could negatively affect the potential benefits of the procedure: presence of tumours, congenital defects, immunosuppressant diseases, increased sedimentation rate and increased leukocyte count.

All applications not included in the indications and specialised literature are contraindicated.

BIONER Dental implants are also contraindicated in the event of allergy or hypersensitivity to the chemical components of the materials used in their manufacture (biocompatible Titanium).

6. Side effects and interactions

Follow the instructions for use recommended by the manufacturer, although, even in this case side effects, interactions or complications may appear, including:

- ✓ Loss and integration failure.
- ✓ Stress Shielding: bone loss (dehiscence) requiring a bone graft.
- ✓ Perforation of the maxillary sinus, lower jaw, lingual cortical plate, palate, lips, inferior alveolar canal and the gums.
- ✓ Serious infection of the wound after the operation and tardive infections with possible systemic infection and septicaemia.
- ✓ Persistent pain, sensation of discomfort or abnormal sensations.
- ✓ Swelling, Hyperplasia, Thrombosis and Embolism.
- ✓ Damage to nerves.
- ✓ Slackening, deformation or fracture of the dental implant
- ✓ Displacement or misalignment of the dental implant with reduction of the range of movement.
- ✓ Haematoma in the wound and delayed healing of the wound.
- ✓ Temporary or prolonged functional neurological disorders.
- ✓ Tissue reactions due to allergy or reaction to foreign bodies as a result of the particle detachment.

7. Cleaning, disinfection and sterilization

Dental Implants are supplied sterile. The sterilisation process uses Gamma irradiation. In the event of any packaging defect, the product should not be used and the manufacturer notified immediately.

All dental implants are designed for a 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 surgeon.

8. Warnings

Make sure the material is in perfect condition before use.

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

It is necessary to make detailed clinical examination of the patient before any treatment with dental implants. X-ray studies are also recommended.

When prescribing therapy with dental implants it is important to consider such aspects as the degree of motivation and capacity for cooperation of the patient, the conditions of oral hygiene, addiction or excessive consumption of tobacco, alcohol or drugs, bone quality, the mastication loads the dental implants must resist, etc.

Dental implants have specific dimensional characteristics that must remain unaltered for attachment to the future prosthesis. The use of instruments and/or components that do not have the adequate size may cause damage to the dental implant and the patient's tissue, apart from jeopardising the aesthetic result of the prosthetic reconstruction.

In order to simplify the surgical technique, there is a specific range of devices for Bioner implants. Precautions should be taken during surgery to prevent patients from swallowing or choking on the components.

After placement of the dental implant, the physician should verify the initial stability to determine the convenient time for loading the prosthesis. Applying excessive force to the dental implant should be avoided during the healing period. Follow the placement instructions in the surgical protocol for Bioner implants.

10. Compatibility

The dimensions ensure compatibility with the components matching each specific reference. The compatibility of each reference is guaranteed by BIONER SA in-process controls.

11. Validity

These instructions for use correspond to the current version of the specific references set composing the dental implant family, as indicated at the foot of the document.

12. Storage

The elements in the dental implant family must be stored under non-extreme environmental conditions preventing prolonged exposure to sunlight.

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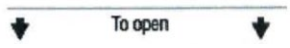
ISO 15223 Symbol	Description
	Indicates the direction for opening the blister
BIONER SISTEMAS IMPLANTOLÓGICOS	Bioner Logo
REF	Catalogue reference code
LOT AOFAAXXXXX	Batch number
DD/MM/AA	Manufacture date
DD/MM/AA	Expiry date
STERILE R	Sterile
	Refer to the instructions for use
	Do not use if package is damaged
Family	Name of the product family/ additional information
Mat = Ti	General indication of the material used
q=1	Quantity
	QR code (code and batch number)
	Do not reuse
	Precautions
	Manufacturer
CE 0051	CE mark

Manufacturer details:

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