

Bionnovation

implantes e biomateriais

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Orthodontic Mini-Implants



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BRASILEÑA

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Prazo de Validade
Fecha de Fabricación
Date of Manufacture



Mantener afastado do sol
Mantener fuera de la luz solar
Keep away from sunlight



Consulte as instruções de utilização
Consulte las instrucciones de utilización
Refer to instructions for use



Marcação CE para Comercialização na Comunidade Europeia
Marca CE para Comercialización en la Comunidad Europea
CE Mark for European Community Market



Data de Fabricação
Fecha de Fabricación
Date of Manufacture



Código do Produto
Código del Producto
Product Code



Número do Lote
Número de Partida
Batch Number



Produto esterilizado por radiação gama
Producto esterilizado por radiación gama
Product sterilized through gamma rays



Não utilizar se a embalagem
estiver danificada
No usar si el paquete está dañado
Do not use if package damaged



Fabricante
Fabricante
Manufacturer



Mantener seco
Mantenga seco
Keep dry



Não reutilizar
No reutilizar
Do not reuse



Representante europeu autorizado
Representante europeo autorizado
Authorised representative in the european community

ACTION DESCRIPTION AND RATIONALE

The Bionnovation Orthodontic Mini-Implants are small implants used during provisory periods in orthodontic treatment for anchorage in skeletal and/or dental movement, installed in the jaw and/or jaw bone tissue through surgical procedures in places which are determined by the orthodontist.

In orthodontic procedures it enables the intra-oral dental movement through dental anchorage by using springs and/or elastics. Easy installation, self-tapping, reduced diameter and length.

They are presented in a single body with BALL or BRACKET abutment, in which there is also a HOLE that allows insertion of springs or elastics, and ensures greater stability of the whole during appropriate mechanical movement for the correction of tooth position.

Bionnovation Orthodontic Mini-Implants system presents a smooth surface, that is, without surface treatment by acid etching, which makes the process of osseointegration late, and because of that, there is the possibility of use during provisory periods which are enough for functional correction of occlusion and aesthetics.

The keys to the installation of Bionnovation Orthodontic Mini-Implants for contra-angle or torque wrench (not included in the product, they are sold and registered separately), are used for direct application of torque at the top part of the implant.

These keys are attached to the notch at the top of the implant, below the abutment, in square hole. Maximum torque recommended: 32N. Besides, they allow the transportation from the package to the surgical site installation. The keys (not included in the product, they are sold and registered separately) must pass through a decontamination and sterilization process before use, under the responsibility of the professional.

Bionnovation Orthodontic Mini-Implants have slightly conical structure and the apical area is much funneled, resembling a screw. This enables self-tapping and its attachment to bone tissue, as well as facilitates its removal after treatment. Because they are threaded to the bone, they discard the use of various drills (not included in the product, they are sold and registered separately), they ensure minimum heat, less surgical time and therefore exposure of vital tissues that culminates in biological advantages of preserving both the structure and the tissue quality.

PRODUCT COMPOSITION

Bionnovation Orthodontic Mini-Implants are produced with F136 titanium, aluminum-vanadium alloy (Ti-6Al-4V).

USE INDICATIONS AND ENDS

The treatment with Bionnovation Orthodontic Mini-Implants aims to provide appropriate skeletal and/or dental anchorage for the displacement of a tooth or a block of teeth. This orthodontic movement aims at aesthetic and functional recovery of the stomatognathic system and the important aspect of reducing the need for patient cooperation. Bionnovation Orthodontic Mini-Implants system is indicated for orthodontic treatment to aesthetic and functional recovery with dental anchorage. They work as support points and allow the application of forces needed for tooth and/or skeletal movement, controlled and predetermined by the responsible professional. Due to the fact that implants are installed in bone tissue, the choice of diameter and length of the implant should respect the amount of available bone, anatomical accidents and tooth roots through previous X-ray analysis. Due to the reduced size and diameter, funneled conical shape, it is installed with minimal use of drills and possibility of self-tapping, hence highlighting the biological advantages of the product.

The indication should be based on each case and on clinical analysis, radiographic and laboratory tests, when deemed necessary in order to determine the shape of the abutment (zzz), length (yy.yy mm) and diameter (x.xx mm) of the implant to be used under the responsibility of the expert professional.

LIST OF ACCESSORIES THAT ACCOMPANY THE PRODUCT



Bushing – Anchorage of the Implant to the packing (plastic tube), support, and avoiding damages to the product.

List of exclusive optional accessories to insert the orthodontic Mini-Implant (such accessories do not accompany the product; they are sold separately and have distinct records)

ORTHODONTIC KIT

The kit components, drivers and drill devices (are sold separately and have distinct records), are exclusive and assist on the insertion and anchorage of Bionnovation Orthodontic Mini-Implants.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

1. Do not use if sterile package is opened or damaged, to avoid possible contamination. Throw away or return to the factory, the damaged packages and the device included.
2. The product may not be reused, re-sterilized or reprocessed. You must dispose it of according to the current regulation for medical waste or return the damaged packing and the device to the plant. Destroy it after use.
3. SINGLE USE – In the event it is reused the anchorage instability, fragility risk, insert driver engagement deformation, thread profile modification and quality reduction may occur. In the event of impact damages to the dimensional characteristics and the shoulder may occur.
4. DO NOT RESTERILIZE- in the event it is sterilized a surface oxidation may occur.
5. Not suitable for patients with blood disorders, such as Diabetes Mellitus and outweighed Gingivitis.
6. The abusive use of alcohol, tobacco, drugs, corticoids or lack of adequate oral hygiene can significantly jeopardize the success of the treatment.
7. All potential adverse effects such as dehiscence, inflammation, bone loss, hemorrhage, allergic reaction, fracture, or implant loss must be previously informed to the patient.
8. Do not use if packaging is broken or the expiration date of sterilization is expired.
9. Open the packing only upon its use.
10. Handle it under aseptic and sterile instrumental conditions.
11. STERILE, provided that the package integrity, period of validity and storage conditions are kept.

Note: The adhesive identification labels that accompany the product should be attached to the documentation to be delivered to the patient, medical records and on tax documentation managing the collection.

In case the subject develops any adverse event, the responsible must keep in contact with Bionnovation CSH (Customer Service Hotline) by phone 0800 707 3824 or e-mail sac@bionnovation.com.br immediately. Bionnovation Biomedical Products is responsible for notifying ANVISA (Brazilian Sanitary Surveillance Agency) on the relevant occurrences, and the procedures are described on the Quality General Procedures internal system – “Systematic to Inform Incidents to the Surveillance Authorities.”

STORAGE AND TRANSPORTATION

Transport and store away from direct sunlight, heat or humidity. Shipping must be made in the original packaging and avoid damage to it.

STERILITY

The Orthodontic Mini Implant is delivered as STERILE (Gamma Radiation 25 kGy).

FORMS OF PRESENTATION OF THE PRODUCT

They are available in the following diameters and lengths and transmucous profiles, for both Ball and Bracket shapes

Orthodontic Mini Implant with 1mm transmucous profile				
Diameters (x,xx mm)				
Ø 1,40 mm				
Ø 1,60 mm				
Ø 1,80 mm				
Ø 2,00 mm				
Lengths (yy,yy mm)	7,00 mm	7,00 mm	7,00 mm	7,00 mm
	9,00 mm	9,00 mm	9,00 mm	9,00 mm
	11,00 mm	11,00 mm	11,00 mm	11,00 mm

INSTRUCTIONS

1. PROFESSIONAL USE - Bionnovation Orthodontic Mini-Implants should be implanted only by dentists.
2. It is supplied in sterile condition and after opening it should be used in aseptic conditions. One should always work with sterile sites and instruments which are appropriate to the procedure and in good preservation conditions, in order to eliminate sources of infection and damages to components by inadequate instrumentation.
3. The orthodontic treatment should take into consideration the biomechanical characteristics, the balance of occlusal and masticatory forces, aesthetics, and factors related to the good performance of the mini implant. The information exchange between the dentist and patient is critical for the success of the treatment.
4. The Mini-implants diameters, traction under the mini-implants, angling to an specific chosen force, insertion site in the gum and clinical and radiographic assessment must be properly implemented and prior to the insertion surgery, assisting the suitable planning of the treatment. It is also necessary to determine the osseous quality and quantity, repairs and anatomical structures and teeth analysis and adjacent roots. Following the proper procedures, fractures, osseointegration, anatomic details deformation and lesion are avoided.
5. The bone region to receive the orthodontic mini-implant must be prepared (drilled) with dental milling cutters adequate to receive the chosen Mini-implant. The appropriateness of milling will depend on the professional assessment of local bone quality, especially the thickness of cortical bone.
Comments: The milling cutters must be regularly replaced in order to preserve the cutting efficiency. They do not accompany the product, are sold separately and have distinct records)
6. The surgery with the use of drills should be conducted with careful criteria regarding cooling, which should be continuously done with saline solution, gradually increasing the diameter of drills and low speeds. The high heat can cause permanent damage to the host tissue and consequent loss of the mini implants.
7. After installation, the orthodontist must make sure that all the thread is within the bone/gum tissue and must evaluate the initial stability for immediate loading. Preferably apply low intensity forces at first.
8. Suture of soft tissue, when necessary, after the professional evaluation.

Milling order for Bionnovation Orthodontic Mini-Implants				
Ø Mini Implant (mm)	Helical Milling Cutter			
	1,0 mm	1,2 mm	1,4 mm	1,6 mm
1,40 mm	x			
1,60 mm		x	x	
1,80 mm			x	
2,00 mm				x

PREOPERATIVE CARE

The implant should be used only for its intended purpose. All patients who will undergo a surgical procedure should be carefully examined and evaluated for the determination of the clinical and radiographic state as well as for bone deficit or adjacent soft tissue that may influence the final outcome of the intervention. Biomechanical Planning is essential to the success of the treatment.

POSTOPERATIVE CARE

Painkillers, antibiotics and bed rest for 24-48 hours may be prescribed varying according to the procedure and the technical and professional conduct.

CAUTIONS CONCERNING THE PRODUCT DISPOSAL

Product disposal must comply with current environmental and biosafety laws. Do not discard contaminated products with the regular garbage; they shall be discarded in proper containers, with a contaminant identification. Explanted or defective products shall be decharacterized before being disposed of.