



Bionnovation Non-Cutting Instrumentals

EC REP

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BRASILEÑA

www.bionnovation.com.br



Fabricante
Fabricante
Manufacturer



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



Manter seco
Mantenga seco
Keep dry



Data de Fabricação
Fecha de Fabricación
Date of Manufacture

REF

Código do Produto
Código del Producto
Product Code

LOT

Número do Lote
Número de Partida
Batch Number



Prazo de Validade
Fecha de Fabricación
Date of Manufacture



Mantener ao abrigo 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 para Comercialização na Comunidade Europeia
Marca ce para Comercialización em la Comunidad Europea
CE Mark for European Community Market

DESCRIPTION AND ACTION GROUNDS

Bionnovation Non-Cutting Instrumentals are auxiliary components used during treatment with dental implants.

They are presented in different models, sizes, and platforms which allows the appropriate choice and use for each surgical procedure.

The raw material with which the products are machined allows them to be constantly submitted to steam sterilization procedures, crucial for clinical intervention procedure use.

Optional components (sold separately, not included with the product)

Trays

Bionnovation Non-Cutting Instrumentals can be placed on Bionnovation Trays. These Trays offer Healthcare professionals, especially dentist surgeons, an easy and reliable system for sterilization procedures, condition and transport of materials.

Bionnovation Trays System has the purpose to provide sterilization procedures, condition and transport of materials, drills and braces, used in different clinical procedures.

PRODUCT COMPOSITION

Bionnovation Non-Cutting Instrumentals are made of stainless steel.

INDICATIONS AND USE PURPOSES

Bionnovation Non-Cutting Instrumentals Family has the purpose to assist dental procedures. These surgical instrumentals are used as facilitator devices for installing implants, and their use is limited to implants and not to bone tissue. The Professional must ensure the sterilization of such devices in order to avoid implants and implants components potential contamination, such as, for example, the implant fitter and the implant cover.

The different compatible models, sizes and platforms allow the appropriate choice and use for each procedure stage.

Keys, adapters, wrenches and parts for contra-angles are essential products for dental treatments with implants, from the settlement at the surgical bed to the final prosthesis.

The instrumentals must be submitted to the sterilization procedure, prior to its use on clinical intervention procedures, such as surgeries and dental care.

As the instrumentals are made of stainless steel, they can be constantly submitted to sterilization procedures on chemical and physical environment, preferably wet steam sterilization.

Hand-Held Driver Hexed 0,9mm – connected to hexagonal screw to installation of cover screw. Used in manual torque application.

Hand-Held Driver Hexed 1,2mm – connected to hexagonal screw to installation of prosthetic components which are accompanied of this type of screw . Used in manual torque application.

Hand-Held Driver Square – connected to square screw to instalation of prosthetic components which are accompanied of this type of screw. Used in manual torque application.

Hand-Held Driver Mini Conical and Conical Abutment – connected to prosthetics components: Mini Conical and Conical Abutments in small, regular or large platforms (SP/RP/WP). Used in component installation with manual torque application.

Hand-Held Driver Spherical Abutment – connected to prosthetic component: Spherical Abutment. Used in installation of component with manual torque application.

Latch-Type Drivers Hexed 1,2mm – connected to hexagonal screw to installation of prosthetic components which are accompanied of this type of screw. Used in torque application adapted to contra-angle.

Latch-Type Drivers Square – connected to square screw to installation of prosthetic components which are accompanied of this type of screw. Used in torque application adapted to contra-angle.

Driver Handle Slot – connected to screw or prosthetic components, used in manual torque application.

Latch-Type Drivers Mini Conical and Conical Abutment – connected to prosthetic components: Mini Conical and Conical Abutment in small, regular or large platforms (SP/RP/WP). Used in component installation adapted to contra-angle to torque application.

Latch-Type Drivers Slot – connected to screw or prosthetic components, used in torque application, adapted to contra-angle.

Drill Extender - Assists perforations between adjacent teeth. Should be adapted to drill to increase the length thereof.

Contra-Angle Driver to HI installation – connected to internal hexagonal implants (HI) MP/SP/RP/WP (small, regular or large platforms). Used as adapted to contra-angle to implant installation.

Implant Placement Adapter for Motor Driven – connected to External Hexagonal Implant Mounter (HE) MP/SP/RP/WP (small, regular or large platforms). Used to implant installation adapted to contra-angle for fixing the implant.

Surgical Torque Wrench or Ratchet Wrench Extensor – connected to External Hexagonal Implant drivers or moulder (HE) MP/SP/RP/WP (small, regular or large platforms). Used in implant installation adapted to torque wrench or ratchet wrench for fixing the implant.

Drive Lock Torque Wrench or Ratchet Wrench HI – connected to Internal Hexagonal Implants (HI) MP/SP/RP/WP (plataformas pequena, regular e larga). Used adapted to ratchet wrench or surgical-prosthetic torque wrench for implant installation.

Hexed Torque Wrench Driver 0,9mm – connected to hexagonal screw to cover screws installation. Used in applying manual torque with assists of torque wrench, ratchet wrench or manual adapter.

Hexed Torque Wrench Driver 1,2mm – connected to hexagonal screw for prosthetic components installation which are accompanied of this type of screw. Used in torque manual application with assists of torque wrench, ratchet wrench or manual adapter.

Square Torque Wrench Driver 1,3mm – connected to square screw for prosthetic components installation which are accompanied of this type of screw. Used in torque manual application with assists of torque wrench, ratchet wrench or manual adapter.

Mini Conical and Conical Abutment Torque Wrench Driver – connected to prosthetic components: Mini Conicals and Conicals Abutments in small, regular or large platforms (SP/RP/WP). Used in manual torque application with assists torque wrench, ratchet wrench or manual adapter.

Slot Torque Wrench Driver – connected to screw or prosthetic components, used in manual torque application, adapted to Driver Handle, torque wrench or ratchet wrench.

Spherical Abutment Torque Wrench Driver – connected to prosthetic component: Spherical Abutment. Used in component installation with manual torque application. Used in manual torque application with assists torque wrench, ratchet wrench or manual adapter.

Drive Lock torque wrench or ratchet wrench Orthodontic Anchor Screw – connected to mini implants, used with assists driver handle, ratchet wrench or torque wrench for implant installation.

Contra-Angle Orthodontic Anchor Screw – connected to mini implants. Used adapted to contra-angle for implant installation.

Drive Lock Torque Wrench H.E TD – connected to TD implants MP/SP/RP/WP (small, regular or large platforms). Used adapted to driver handle, ratchet wrench or torque wrench for implant installation.

Contra-Angle Driver HE TD – connected to TD Implants (TD) MP/SP/RP/WP (small, regular or large platforms). Used adapted to contra-angle for implant installation.

Driver Handle – connected to drivers to be used for torque application, installation or components, screws and implants adaptation.

Depth Gauge – it assists to check the drilling depth and implants positioning by radiographic evaluations. The depth marking is 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 and 18.0 mm.

Parallel Pin – it assists the parallel insertion of the implants, through visual inspection by inserting the pin in the surgical site made for the implant installation.

Surgical Hammer - it assists rehabilitative treatment with dental implants in the manufacture of surgical site for implant placement. Used in conjunction with the osteotome or expander creates the cavity for implantation.

Titanium Forceps – it assists the manipulation of implants and components, and prevents contamination and damage to surface of products.

Open Wrench – it assists removal implants mounter after its insertion.

Ratchet Wrench – for manual fixing of the implant. The rotation in 180° from cable provides reversal of the torque direction.

Surgical Probe – it assists instant verification of drilling depth. Has scale height of the implants with markings 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 e 18.0 mm.

Prosthetic Probe – Used to measure the height of the soft tissue, aiding the selection from the heights of the prosthetic components.

Rescue Drive – it assists the treatment with dental implants in the process of internal rectification the implant thread, to correct adaptation of prosthetic components and implant. Manual use. Available in compatible diameters with internal threads of the implant.

Screwdriver Handle – is assists the installation and manual fixing of the components and screws. Adapted to screwdrivers, functions as an extender.

Surgical-Prosthetic Torque Wrench – for installation and manual settlement of implants and prosthetic components. The stem and markings allow viewing and applying the correct torque on the installation procedure and settlement of components and implants. The inversion provides reversal of direction of torque, which enables the application of clockwise and counterclockwise rotation, or torque and detorque processes.

Tufo Driver – it assists the manual installation of components and screws with adaptation to prosthetic adapters (torque wrench or ratchet wrench).

Self-Tapping Expander – Used to make the lateral compression of the bone to receive the implant used when bone has small thickness and there is a need to increase it.

Implants Remover - Used for removal of malpositioned implants and disease patients Peri-implant. The implants remover uses the internal thread of the implant removal.

Orthodontic Anchor Screw Installation Rod – adapted to screwdriver handle is used for installation of orthodontic implant mini.

Screw Graft Installation Rod – adapted to screwdriver handle is used for installation of screw graft

Torque Wrench Orthodontic Anchor Screw – connected to Orthodontic Mini Implants, used as assists of screwdriver handle adapter, ratchet wrench for implant installation.

Torque Wrench Screw Graft and Fixation – connected to Screw Graft, used as assists of screwdriver handle adapter, ratchet wrench for implant installation.

Contra-Angle for Orthodontic Implant Mini – connected to orthodontics implant mini. Used adapted to contra-angle for implant installation.

Contra-Angle for Screw Graft and Fixation – connected to screw graft. Used adapted to contra-angle for screw installation.

Driver Handle for Orthodontic Implant Mini – connected to screwdrivers to be used for torque application, installation or adaptation of orthodontics implant mini.

Torque Wrench for CM Implant – connected in the implant is used with driver handle assists, ratchet wrench for implant installation.

Contra-Angle for CM Implants – connected in the CM Implant, is used adapted in the contra-angle for implant installation.

Contra-Angle for TD 4/5 Implant – connected to TD 4/5 Implants is adapted in the contra-angle for implant installation.

Ratchet Wrench for TD 4/5 Implant – connected in the TD 4/5 Implant. Adapted to ratchet wrench, torque wrench or driver handle for implant installation.

Torque Wrench for Unique Corps Implant – connected in the implant is used with driver handle assists, ratchet wrench for implant installation.

Contra-angle for Unique Corps Implant – connected in the Unique Corps Implant is adapted in the contra-angle for implant installation.

Straight and Curve Osteotome - active tip concave used to compress the bone laterally instead of removing it as in traditional surgery performed with drill bits.

Straight and Curve Expander – convex tip used when bone thickness is thin, performed under pressure for the bone expansion for implant placement.

Biomorse Component Height Meter - has a tapered insert compatible with the Biomorse Implants, with height reading of 0.8 to 6.0 mm from the end of the tapered insert. It is indicated to verify the gum height after installation of the implant, establishing the gum height of the component to be used and ensuring the best solution for each case

PRECAUTIONS, RESTRICTIONS AND WARNINGS

1. NON STERILE - Bionnovation Non Cutting Instrumentals are supplied non-sterile, observe the appropriate asepsis techniques.

2. PROFESSIONAL USE ONLY – Only qualified professionals with expertise in surgical techniques and procedures required for proper use of the product should make use of the instrumentals.

3. REUSABLE AND RE-STERILIZED - The product may be reused and re-sterilized, follow current biosafety guidelines for cleaning, disinfection e sterilization. The preview sterilization is from professional responsibility

4. Always sterilize the instrumentals before using them, we recommend steam sterilization preferably (autoclave). The use of instrumentals in inappropriate conditions may cause contamination and other undesirable results to the patient.

5. In all surgeries involving instrumentals please observe the appropriate asepsis and antisepsis techniques.

6. The instrumentals must only be used for the purpose it has been designed.

7. In the event of adverse events in patients, the professional in charge should contact Bionnovation Consumer Services (SCA) immediately at **0800 770 3824** or e-mail **sac@bionnovation.com.br**. Bionnovation Produtos Biomédicos is responsible for notifying ANVISA (Brazilian National Health Surveillance Agency) on the pertinent occurrences according to the techno-surveillance internal procedure.

8. The Instrumentals have been developed in order to avoid that its use might compromise patients' clinical state and safety.

9. Handle carefully, avoid dropping and harsh movements. If any product falls down and presents severe scratches, dismantling, cracks or dents that may put at risk the instrumental good functioning, the professional in charge should contact Bionnovation Consumer Services (SCA) immediately at **0800 770 3824** or e-mail **sac@bionnovation.com.br**.

10. One should always work with instrumentals in good conditions in order to avoid sources of infection and damages caused to products due to improper instrumentation. All deteriorated instrumentals or those presenting signs of corrosion must be separated and discarded, in order to prevent corrosion process spreading by contact to other components.

11. Never store clean and sterile instrumentals on stained surgical boxes or with severe scratches that might be focus of contamination for such instrumentals.

12. Do not use the instrumentals after loss marking of the heights
13. Tying the manual keys wired passerby, avoiding the risk of deglutition by the patient
14. For the installation key, not to exceed 80Ncm torque, observing the fit key on the implant should be parallel
15. Regarding to expander, follow the correct sequence recommended, of smaller diameter to a larger diameter, where the first drilling is with the lance drill.
16. If the professional exceeds the limit of time and temperature suitable for autoclaving esterilization, may occur fatigue of the alloy of the instrument and could cause fracture, deterioration, and/or discoloration.
17. The installation of Biodirect and CM Biomorse implants should be started with the contra angle only up to 2/3 of implant length, finishing the installation with Bionnovation torque wrench respecting the specified torque. In the event of the completion of the implant installation with the contra angle, there will be risk of fractures or key deformation compromising the equipment contra angle.

PRE AND POST-SURGICAL CARES

Pre-Surgical Cares

The instrumentals used during dental procedure should be clean, dry and sterilized. The determination of the necessary instrumentals during the clinic session is from professional responsibility.

Post-Surgical Cares

The instrumentals must be submitted to cleaning, decontamination and sterilization procedures. This cleaning must remove each and every organic fluid; therefore, appropriate products for this purpose must be used.

SPECIAL CONDITIONS FOR THE PRODUCT'S STORAGE AND TRANSPORTATION, CONSERVATION AND/OR HANDLING

Storage and transportation

Transport and store away from direct sunlight and sources of humidity, in a clean environment free from residues. Transport must be done in the original package in order to avoid damages or, preferably, on Bionnovation Trays System trays.

Conservation and Handling

- Any change in the characteristic of instrumental, discard a way that the product be mischaracterized according to current legislation for hospital waste or return to factory the packages damaged and the device included.
- Using chemicals suitable for cleaning and disinfection;

COMMERCIAL PRESENTATION FORMS

Bionnovation Cutting Instrumentals are packed in blisters sealed with Tyvec® and identification sticker containing the product traceability information, such as primary package, and final package, sealed heavy density cardboard casing, with 01 sticker attached. The biggest instrumentals as open wrench, surgical probe, prosthetic probe, surgical hammer, screwdriver handle, titanium forceps, prosthetic torque wrench, surgical torque wrench, tufo driver, orthodontic anchor screw installation rod, screw graft installation rod, straight and curve osteotome, straight and curve expander are packed uniformly in termoselante envelope (surgical grade paper) and are properly sealed and labeled with product identification.

They are available in different sizes and shapes in order to meet the different clinical needs.

INSTRUCTIONS FOR USE

The instrumentals are subject to sterilization and reuse and must follow strict procedures of prewash or descaling, decontamination, washing, rinsing, drying and sterilization, according to current biosafety law. However, the cleaning of instrumentals and trays must be carried out separately. They may be autoclaved together at the time sterilization only.

The following contains detailed information about the process, however, it does not substitute the reading and specific knowledge.

INFORMATION ON REUSE PROCEDURES:

Preliminary Washing or Descaling: it is the removal of organic matter from the instrument kit, without direct hand contact. It should be undertaken as soon as possible, after the use in surgeries for installation of dental implants.

- 1-The person in charge of the task should be properly vested with individual protective articles (gloves, masks, glasses, aprons, etc.);
- 2-Use enzymatic solutions in the concentration and in the time of exposure established by manufacturers;
- 3-Rinse it only once, directly with a water jet, without handling the instrument kits.

OBS.: To prevent the hardening of dirt, it is recommended that every instrument kit is cleaned immediately after the surgical procedure, according to the appropriate standardization, so as to avoid dissemination of contamination and damage to the instrument kit. It is recommended to undertake the cleaning process within 10 minutes after the surgery, because this is the best defense against the corrosion (generally by pitting) and the spots. After this time delay, keep the contaminated instrument kits damp, so as to avoid the drying of the residues.

Decontamination: it is the removal of microorganisms in a vegetative way that poses occupational risks.

- 1-The person in charge of the task should be properly vested with individual protective articles (gloves, masks, glasses, aprons, etc.);
- 2-Use phenol or ammonia based solutions in the concentration and in the time of exposure established by manufacturers;
- 3-Rinse it only once, directly with a water jet, without handling the instrument kits.

Washing: it is the removal of dirt from the surgical instrument kits through manual brushing or vibrations caused by ultrasound.

- 1-Always use deionized or demineralized distilled water for this procedure. The temperature of the water should not exceed the range of 40-45°C;
- 2-Use mild soap or detergent (pH between 6.5 - 7.5);
- 3-Never use abrasive materials for the cleaning, so as the instruments are not damaged; Always use brushes with natural soft bristles;
- 4-Do not pile up a great number of instrument kits; avoid the overlapping with each other, to prevent some damage to the small and more fragile parts;

5-When using the cleaning with ultrasound, it should be used a solution for heated washing of at least 45°C and the instrument kits should be placed in the open position. The time required for cleaning the instrument kits ranges between 3 and 5 minutes; there might be a need of brushing the serrated parts and the links.

Rinse: it is the removal of chemical residues, detergents and foams still present on the instruments.

1-Always use deionized or demineralized distilled water for this procedure. A temperatura da água não deve ultrapassar a faixa de 40-45°C;

2-Never use saline solutions, especially sodium hypochlorite and physiological saline solution, disinfectants, hydrogen peroxide or alcohol when rinsing the instruments.

OBS.: Saline substances generate fouling that in a great concentration can cause deep corrosions. This corrosion is made still worse when followed by increase of temperature, decrease of pH, very long length of time for application, rough or dull surfaces and insufficient drying.

Drying: it is the removal of wastewater and damp after the rinse procedure.

1-Always use a support when drying the instrument kit, such as a soft cloth or compressed air free of damp;

2-Never use drying chambers when drying the instrument kits.

NOTE1.: Only hinged instrument kits, such as the torque wrench, should be lubricated after the drying process. Be sure that the instrument kit is free of dirt or other residues, lubricate them with non-corrosive, non-sticky and silicone free water soluble lubricant. Follow the lubricant manufacturer instructions. The lubrication should be a regular task and should be done including when the instrument kits are not being used.

Sterilization: it is the procedure whose purpose is the total elimination of microorganisms. Use the sterilization procedure by AUTOCLAVE PRESSURE SATURATED STEAM.

1-Use deionized or demineralized distilled water so as the resulting steam is free of impurities. If required, the autoclave should have appropriate filters for the restraint of the impurities;

2-Do not open the autoclave too early, to avoid the quick condensation;

3-Do not open the autoclave quickly, allowing for the steam to escape before completing the drying cycle;

4-The instrument kit should stay for 30 minutes in a conventional autoclave, after reaching the temperature of 121°C. This length of time should be four minutes in a vacuum autoclave, after reaching a temperature of 132°C.

5-Clean the autoclave rigorously and periodically, by removing the dirt and the casual excessive build-up of rust.

NOTE1.: The sterilization should be done only after cleaning and drying the instrument kits completely. The high temperature of the autoclave will cause chemical reactions that could spot permanently the instrument kits and/or cause their yellowing.

When cleaning the trays, the organic matter of the ultrasound vats should be removed by using enzymatic soap (at least three enzymes) according to the dilution recommended by manufacturer. After washing in plain water, in case the presence of residues is observed, repeat the process. If the problem persists, remove the impurities through mechanic cleaning. For disinfection, use a 0.2%-paracetic acid solution during 10 minutes. The sterilization should be done through autoclave, at temperatures ranging from 121°C to 134°C, observing the autoclave manufacturer instructions manual. Repeat the process after each use. Keep the product in an exclusive venue, in closed cabinets, protected against dust and insects.

IMPORTANT:

- Always use distilled water when washing the kit. Tap water contains chlorine that causes rust.

- Always observe the water level in the autoclave, avoiding casual damages to the kit.

- Pus, blood and other surgical secretions cause corrosion in the instrument kits of brown-orange color due to chloride ions contained in their compositions. In case the instrument kits stay from one to four hours in contact with these residues, there will be marks and spots especially when these residues dry on the instrument kits.

Note: More information about the procedures for using surgical/prosthetic manual torque wrench see technical bulletin (BT 001-USI) available on the website www.bionnovation.com.br

CARE WHEN DISCARDING THE PRODUCT

The product's disposal must comply with the environmental and biosafety laws in force. Do not discard contaminated products in the general waste.