



Bionnovation Cutting Instrumentals



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BRASILEÑA

www.bionnovation.com.br



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



Prazo de Validade
Fecha de Fabricación
Date of Manufacture



Manter 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



Fabricante
Fabricante
Manufacturer



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



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

DESCRIPTION AND ACTION GROUNDS

Bionnovation Cutting Instrumentals are auxiliary components used during the installation of dental implants.

They are crucial for drilling bone procedure and essential for implants installation.

They present different models, sizes, and platforms which allows the appropriate and specific choice and use at each surgical procedure.

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

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

Motors to installation

Bionnovation Cutting Instrumentals must be coupled to surgical motors, which by means of rotations and specific speeds assist on bone tissue drilling and preparation of surgical bed for installation of implants.

Trays

The drills and cutters can be adequately placed on Bionnovation Trays that offer to 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 Cutting Instrumentals are made of stainless steel.

INDICATIONS AND USE PURPOSES

Bionnovation Cutting Instrumentals Family has the purpose to assist the surgical procedures.

Surgical instrumentals are used as facilitator devices for installing implants, its use is limited to boné tissue and not to implants. The professional must ensure the sterilization of such devices in order to avoid tissues, implants and implants components potential contamination.

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

The drills and cutters, coupled to surgical drill contra-angle (sold separately, is not included with the product) are crucial for dental implant, for they prepare the surgical bed, by drilling for the installation of the implant. The diameter to be used is determined by the professional based on radiography and prior clinical examinations. The choice of implants will determine the correct sequence of cutting instrumentals to be used.

The drilling depth can be monitored in accordance to the marks found on cutting instrumentals, according to the figure below, and is also related to surgical plan made by the professional in charge.

The correct sequel for bone drilling using cutting instrumentals should be of prior knowledge of the professional, and it is his responsibility to determine the alteration, either by addition or subtraction, on the use of suggested drills. However, we emphasize that such professional is answerable for the consequences.

The drills and cutters 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.

Lindman Drill – Used to mark the location of the perforations and perforate the cortical. Professional's choice criteria. Length: 30 mm.

Guide Drill (Lance Drill) - Used to mark the location of the perforations and perforate the cortical. Professional's choice criteria. Length: 30 mm.

Round Drill - Used to mark the location of the perforations and perforate the cortical. Professional's choice criteria.

Twist Drill - Determines the inclination and the drilling depth for implants with parallel body. Length: 30 mm.

Conical Drill - Determines the inclination and the drilling depth for implants with conical body. Length: 30 mm.

Pilot Drill – Used in the transition between conical or twist drill of different diameters. Length: 25 mm.

Countersink Drill – Accommodates the neck of the implant avoiding intrusive movements. Length: 22 mm.

Screw Tap – Used in high-density bone tissue to facilitate insertion of the implant. Length: 22 mm.

Tronco-conic Drill – Used to cut bone grafts. Professional's choice criteria. Professional's choice criteria.

Trefine Drill – Used to remove of the implants. Professional's choice criteria.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

1. NON STERILE - Bionnovation 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. Careful clinical and radiographic evaluations are necessary for a correct treatment planning, as well as to verify the anatomical structures that must be observed before perforation. An adequate safety margin adjacent to other teeth and vital structures must be preserved.

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

7. Abuse of alcohol, tobacco, drugs and corticosteroids or inappropriate oral hygiene may significantly compromise the success of treatment.

8. An incorrect surgical technique may lead to discomfort, such as a painful sensation, hypoesthesia and edema.

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

10. The surgeon shall evaluate its indication to patients diagnosed with diseases or that use a medication that might change the reparation metabolism

11. 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.

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

13. Handle carefully, avoid dropping and harsh movements. If any product falls down and presents severe scratches, 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.

14. 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.

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

16. Ensure the constant cooling of drills during surgeries, preferably with physiologic saline, to prevent bone tissue heating and potential superficial necrosis.

17. Use of drills and cutters compatible to bone diameters and characteristics and to implant system. Competitor drills may not be compatible with the implants external format. Therefore, observe the compatibility between the systems. We suggest the use of Bionnovation Cutting Instrumentals for Bionnovation Dental Implant System.

18. Do not use the instrumentals after loss marking of the heights and cutting.

19. 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, discoloration and/or loss of the cut.

CONTRA INDICATIONS

- Instrumentals should not be placed in an existing active infection or in any other degenerative disease that might affect the implants' placement.
- They should not be used in patients that are not able, under the clinical point of view, to be submitted to an odontological intervention. Such as, for example, in patients suffering blood disorders, such as Diabetes Melitus and uncompensated periodontal disease.

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;
- Regarding surgical drills, in addition to sterilization, the professional should concern with the replacement of these parts of 20 and 30 surgeries, depending on the drilling wear in accordance to the drilled bone type and the amount of installed implants. Critical analysis of surgical drills is from professional responsibility.

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.

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.

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.

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.