






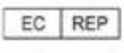


SYMBOLS	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO LEJOS DE LA LUZ SOLAR
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NO LO UTILICE SI EL ENVOLTORIO ESTÁ DAÑADO
	ATENÇÃO	CAUTION	PRECAUCIÓN
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDADE EUROPEA
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTE DISPOSITIVO POR OU POR ORDEM DE UM PROFISSIONAL DE SAÚDE LICENCIADO.	CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER.	PRECAUCIÓN: LAS LEYES FEDERALES (USA) RESTRINGEN LA VENTA DE ESTE DISPOSITIVO POR O EN EL ORDEN DE UN PROFESIONAL DE LA SALUD LICENCIADO.

DEVELOPED AND MANUFACTURED BY:

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PRODUCT:

S.I.N. Dental Kit - KOR

Anvisa Registration: 80108910063

CE

The S.I.N. Dental Kit – KOR is intended for specialized procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional’s training. The use of the product must be performed in a surgical environment and in appropriate conditions for the patient’s health and safety.



PRODUCT DESCRIPTION

The S.I.N. Dental Kit - KOR is a kit consisting of fasteners and cutters required for the installation of Dental mini-implants.

INDICATIONS OF USE

The S.I.N. Dental Kit - KOR is indicated to aid in the installation of the SIN Dental mini-implant family.

OPERATION PRINCIPLE

The instruments contained in the S.I.N. Dental Kit - KOR, base their principle of operation on mechanical action. All instruments are indicated for use in the placement of Dental mini-implants and must be used following appropriate dental techniques.

HOW TO USE

The form of use is inherent to the training of the professional who will use the material. It can only be used and/or applied by a specialized dental surgeon.

1. Select the instruments to be used and ensure they are properly sterilized at the time of initiation of procedures (see sterilization conditions in this instructions manual).
2. Open the package and start the procedure.

CONTRAINDICATIONS

The S.I.N. Dental Kit - KOR do not present contraindications since they follow their recommendations correctly and used by specialized professionals.

ADVERSE EFFECTS

The SIN Dental Kit - KOR is used to aid in the installation of implants, so adverse effects will occur only if the choice of instruments is inappropriate.

PRECAUTIONS AND RECOMMENDATIONS

To use the S.I.N. Dental Kit we recommend that the professional have a specialization course in the area of Dental Implant or Orthodontics. The professional must submit the patient to a detailed anamnesis and definition of the treatment plan for a correct indication and use of the S.I.N. Dental Kit. Excessive use of instrumentation, improper positioning, and added leverage during use may compromise the active end of the keys and the milling cutters or fractured deformation of mini-implants. The professional should be aware of the force applied when using the product, in order not to cause harm to the patient and the product. Before using the S.I.N. Dental Kit , the professional should sterilize it, in accordance with the recommendations contained in this instruction manual.

For milling cutters, it is recommended to use up to 20 to 30 perforations, which are:

- 20 drillings in high-density bone;
- 30 drillings in low density bones.

Do not stick labels, tapes, as well as write, or mark the surface of the product.

It is recommended to immediately wash and sterilize the kit and its components after use.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of dental instruments. All items may appear a natural wear due use and they should be replaced whenever the professional identifies loss of fitting capacity or accuracy of these products, as they may interfere with final work results.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches for traceability, which promotes greater safety for the professional qualified to the procedure. Through this batch number it is possible to know the entire history of the product from the manufacturing process until the moment of distribution

STORAGE

The S.I.N. Dental Kit - KOR must be stored in a cool and dry place and away from sunlight.

TRANSPORTATION

The S.I.N. Dental Kit - KOR must be transported in room temperature, away from direct sunlight, avoiding places where large variations of temperature and humidity occur. The transportation must be carried out properly to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

Once sterilized, instruments should be handled only in a sterile environment by properly trained professionals and in appropriate gowning at the time of surgery to install dental mini-implants. Risks, creases or indentations of the instruments should be avoided as such factors may increase the possibility of corrosion of the products.

ADDITIONAL INFORMATION

Multiple use product. Exclusive for dental use.
Reprocessing Allowed.
Refer to the cleaning and sterilization conditions contained in these Instructions.

CLEANING INSTRUCTIONS

1. Pre-cleaning or De-embedding

- Remove the organic matter from the instruments without hand contact.
- Begin cleaning or de-embed quickly after surgical use.

Recommendations

- Wear appropriate gowning (gloves, masks, goggles, caps, etc.).
- Use enzyme solutions at the concentration and time of exposure determined by the manufacturer of these chemical solutions
- Perform a single rinse, directly in a water jet, without the handling of the instruments

2. Decontamination

- The cleaning of microorganisms in vegetative form
- This type of cleaning offers occupational hazards.

Recommendations

- Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- Never use saline solutions, especially sodium hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

3. Cleaning

- It is the removal of dirt from surgical instruments by manual brushing or ultrasonic vibrations.

Recommendations

- Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- Use neutral soap at 1% or neutral detergent, both at pH 7.0.
- Always use brushes with natural or Nylon bristles for cleaning racks, serrations and fittings.

- d. Never use steel straws or sponges and abrasive products not to damage the instruments.
- e. Do not accumulate instruments in large quantities on top of one another to avoid deformation of minor and delicate parts.

Try to handle a few parts at a time.

Ultrasonic cleaning, if used, should have the washing solution heated to at least 45°C and the instruments should be placed in the open position for 3 to 5 minutes of immersion at a frequency of 35 KHz.

There may also be the need to brush the serrated parts and joints.

4. Rinse

- a. It is the removal of chemical residues, detergents and foams still present in the instruments.

Recommendations

- a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- b. Never use saline solutions, especially sodium hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

5. Drying

- a. It is the removal of residual water and moisture after the rinsing procedure.

Recommendations

- a. Never let the instrument dry naturally.
- b. Always use soft, absorbent fabric (e.g. compresses) or moisture-free compressed air.
- c. Never use dry heaters to dry the S.I.N. Instruments.

STERILIZATION

It is the procedure that aims at the total elimination of microorganisms (viruses, bacteria, microorganisms and fungi), either in vegetative or sporulated form.

Recommendations

- a. Dry all instruments before the steam sterilization cycle.
- b. Use mechanical and chemical indicators (place the internal chemical indicator between instruments or materials to be sterilized) for each sterilization cycle.
- c. Allow instruments to dry and cool in the sterilizer before handling to prevent contamination and oxidation of materials.
- d. The autoclavable case can be sterilized at 121°C at 1 ATM pressure for 30 minutes or at a temperature of 134°C at 2 ATM pressure for 20 minutes.
- e. Always place the case in an autoclave on a flat surface and away from the walls of the unit.
- f. Never overlap objects or even other cases.
- g. Chemical sterilization is not recommended as some products may cause discoloration and damage to the case.

DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

EXPIRATION DATE

Indicated on the label.