

The S.I.N Orthodontic Kit offers practicality and versatility of use for those seeking excellence in clinical results.



PRODUCT DESCRIPTION

The Orthodontic Kit is a set of instruments made of drivers and drills made of stainless steel and organizer box for carry.

INDICATIONS OS USE

Intended to be used during orthodontic screws installation, the Orthodontic Kit has all necessary instrumentals for orthodontic screws instalation. Some items of Kit as drivers and drills require contra-angle and surgical motor for operation.

APPLICATIONS

The purpose of assisting the installation of orthodontic screws, thus enable the orthodontic anchor.

The kit pieces should be selected according the surgical planning for installation of mini orthodontic implant. It is necessary adjust the rotation and motor torque according to the recommendation of the implant/ component to be installed.

Select the instrument to be used and ensure that are properly sterilized before to start the procedures (check conditions of sterilization presented in this Instruction for Use). Open the pack to start the surgical procedure.



ATTENTION

The Orthodontic Kit is destined to specialized procedures, that must be performed by qualified professionals in Implantology. The use of product must be performed in surgical enviromental under properly conditions for health and safety of patient.

PRECAUTION

- The professional must submit the patient to a thorough anamnese to define the treatment definition for correct use and indication of S.I.N Orthodontic Kit.
- The excessive use of the instruments, bad position, adding the efforce of adding to the lever effort caused during the use can compromise the active tip of the drivers and drills or deformation with risk of fracture of the mini implants.
- The professional must be aware of the force exerted at the time of use of the product to avoid causing harm to the patient and the product.
- Do not stick labels, tape, write or demarcate the surface of the product.
- It is recommended that after use, all parts of kits and kit items should be washed and sterilized immediately.

RECOMMENDATIONS

To use the S.I.N. Orthodontic Kit we recommend that the professional have a specialization course in the area of Dental Implant or Orthodontics.

Before using the S.I.N. Dental Kit, the professional should sterilize the kit, in accordance to the recommendations contained in this instruction manual.

For drills 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.

CONTRAINDICATIONS

The use for purposes other than the installation of orthodontic mini-implants.

SIDE EFFECTS

The S.I.N. Orthodontic Kit – KOR is used to assist the installations of orthodontic mini-implants, so the side effects will occur only if the choice of instruments is inadequate.

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. Orthodontic Kit - KOR must be stored in a cool and dry place, at a maximum temperature of 35°C and protected from direct sunlight.

HANDLING

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.

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.

COMPLEMENTARY INFORMATIONS

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

CLEANING INSTRUCTIONS

1. Pre-cleaning or De-embedding

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

Recommendations

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

2. Descontamination

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

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.

3. Cleaning

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

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. Use neutral soap at 1% or neutral detergent, both at pH 7.0.
- c. 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. Enxágue

- 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. Secagem

- 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.













Recommendation


- 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.

	CONSULTAR AS 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 COMUNIDAD EUROPEA
	LIMITE SUPERIOR DE TEMPERATURA	UPPER LIMIT OF TEMPERATURE	LÍMITE SUPERIOR DE TEMPERATURA
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.
	FABRICANTE	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VIDA ÚTIL
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA

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PRODUCT:

S.I.N Orthodontic Kit - KOR

ANVISA REGISTRATION: 80108910063

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