

The S.I.N. Orthodontic Kit - KOR presents practicality and versatility of use for those who seek excellence in clinical results.



PRODUCT DESCRIPTION

The S.I.N. Orthodontic Kit - KOR is a set of instruments composed of surgical steel keys and cutters, and has an organizer box.

INDICATIONS OF USE

Intended to be used in the installation of orthodontic screws, the S.I.N. Orthodontic Kit - KOR has all the necessary instruments for the installation of orthodontic screws. Some items of the kit, such as cutters and wrenches, require a counter angle and surgical motor for operation.

OPERATION PRINCIPLE

The instruments contained in the S.I.N. Orthodontic Kit - KOR are based on mechanical action. All instruments are indicated for use in the placement of orthodontic mini-implants and must be used following the appropriate dental techniques.

HOW TO USE

It is intended to assist in the installation of orthodontic screws and thus enable orthodontic anchorage. The kit parts must be selected according to the surgical planning for installation of the orthodontic mini-implant. It is necessary to adjust the rotation and torque of the motor according to the recommendation of the implant/component that will be installed.

1. Select the instruments to be used and make sure they are properly sterilized when you start the procedures (see sterilization conditions contained in this instruction for use).
2. Open the package and start the procedure.



ATTENTION

The S.I.N. Orthodontic Kit - KOR is intended for specialized procedures, which must be performed by qualified professionals in Implant Dentistry. The use of the product must be performed in a surgical environment and under adequate conditions for the health and safety of the patient.

PRECAUTIONS

- The professional should submit the patient to a thorough anamnesis and definition of the treatment plan for a correct indication and use of the S.I.N. Orthodontic Kit - KOR.
- Excessive use of the Instruments, bad positioning, added to the lever effort caused during use, can compromise the active tip of the braces and cutters, or deformation with risk of fracture of the mini implants. The professional must be aware of the force exerted when using the product in order not to cause damage to the patient and to the product.
- Do not stick labels, adhesive tapes, write or mark the product surface.
- It is recommended that after use, the kit and its components be washed and sterilized immediately.

RECOMMENDATIONS

For the use of the S.I.N. Orthodontic Kit - KOR it is recommended that the professional has a specialization course in implant dentistry or orthodontics. Before using the S.I.N. Orthodontic Kit - KOR, the professional should sterilize it, according to the recommendations contained in this Instruction of Use. For the cutters, it is recommended the maximum use of 20 to 30 perforations, being:

- 20 perforations in high density bones;
- 30 perforations in bones of low density.

CONTRAINDICATIONS

Use for purposes other than installing or removing orthodontic mini implants.

SIDE EFFECTS

The S.I.N. Orthodontic Kit - KOR is used to assist in the installation of the mini implant orthodontic family, thus adverse effects will only occur if the choice of instrumentation is inadequate.

WARNING

Do not use the instruments if you notice cracks, wear or oxidation/corrosion spots. This may cause problems in the functioning of the instruments. All items may present natural wear and tear generated by use and must be replaced whenever the professional identifies loss of fitting capacity or precision of these products, as they may interfere in the final result of the work.

TRACEABILITY

All S.I.N. products - Implant System - have sequential lots that allow traceability, thus providing greater security to the professional who is qualified for the procedure. Through this lot number it is possible to know the entire history of the product from the manufacturing process to the moment of distribution.

STORAGE

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

HANDLING

Once sterilized, the instruments must be handled only in a sterile environment by properly dressed professionals in appropriate attire at the time of surgery for installation of orthodontic mini-implants. Scratching, bending or notching of the instruments must be avoided, since these factors may increase the possibility of corrosion of the products.

DISPOSAL OF MATERIAL

The disposal of materials must be done according to hospital standards and local legislation in force.

TRANSPORTATION

The Orthodontic Kit must be transported in a proper way to avoid falling and stored under the maximum temperature of 35°C, sheltered from heat and humidity. The transportation must be done in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for Odontological use. Passible of Reprocessing. See cleaning and sterilization conditions contained in this Use Instruction. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplante.com.br or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Remove manually all surgical instruments from the kit. Remove the kit box parts (lid, tray and bottom).
2. Prepare the enzymatic detergent, according to manufacturer's recommendation.
3. Immerse the trays into the prepared detergent solution and keep in contact for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove trays from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
5. Visual inspection of each part for cleaning process residue or organic waste from product use.
6. If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
7. Dry with a soft, clean, dry cloth or disposable paper.

RECOMMENDATIONS

- a. Use the proper PPEs (gloves, masks, goggles, caps, etc.).
- b. Start the cleaning right after the surgical use.
- c. Never let the instruments dry with organic waste after the surgical use.
- d. Never let the instrument dry naturally after cleaning.
- e. Never use saline solutions, include sodium hypochlorite, disinfectant, hydrogen peroxide or alcohol to cleaning or rinsing the surgical instruments and kits.
- f. Never use steel wool and abrasive products, so that the instruments are not damaged.
- g. Do not stack the instruments in lots to avoid the deformation of smaller and delicate pieces.

STERILIZATION

Reusable product and provided non-sterile. It must be clean and sterilized in autoclave before use.

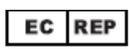
1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed in a steam sterilizable wrap.
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave over a plane surface and away of device walls.
5. Never stack objects or other cases.

RECOMMENDATIONS

- a. Sterilize the products in the same day or one day earlier the procedure.
- b. The chemical sterilization is not recommended, once some products may cause the discoloration and damages to the case.
- c. Do not use temperature higher than 60°C to drying process.
- d. Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N. - Implant System.

LIFE TIME

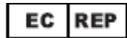
The S.I.N. Orthodontic Kit - KOR can be reprocessed, depending on proper handling, cleaning, and sterilization, up to 250 times.

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|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
|  | NÃO ESTÉRIL | NON-ESTERILE | NO ESTÉRIL |
|  | 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 | MANUFACTURE | FABRICANTE |
|  | DATA DE FABRICAÇÃO | DATE OF MANUFACTURE | FECHA DE FABRICACIÓN |
|  | CÓDIGO DE REFERÊNCIA | REFERENCE CODE | CÓDIGO DE REFERENCIA |
|  | DISPOSITIVO MÉDICO | MEDICAL DEVICE | DISPOSITIVO MEDICO |
|  | IDENTIFICADOR ÚNICO DO DISPOSITIVO | UNIQUE DEVICE IDENTIFIER | IDENTIFICADOR DE DISPOSITIVO ÚNICO |
|  | IMPORTADOR | IMPORTER | IMPORTADOR |
|  | DISTRIBUIDOR | DISTRIBUTOR | DISTRIBUIDOR |
|  | PAÍS DE FABRICAÇÃO | COUNTRY OF MANUFACTURE | PAÍS DE FABRICACIÓN |
|  | LOTE | BATCH CODE | LOTE |
|  | EMBALAGEM RECICLÁVEL | RECYCLABLE PACKAGING | EMBALAJE RECICLABLE |

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