

S.I.N. Prosthetic Kit - KTMEC 02

The S.I.N. Prosthetic Kit - KTMEC 02 is intended for specialized procedures, which must be performed by qualified professionals. The form of use of the product and surgical techniques are inherent to the formation of the professional. The use of the product must be performed in a surgical environment and under adequate conditions for the health and safety of the patient.



PRODUCT DESCRIPTION

The S.I.N. Prosthetic Kit - KTMEC 02 is a kit composed by hexagonal, square, digital and angular wrenches, accompanied by a prosthetic torque wrench.

INDICATIONS OF USE

The S.I.N. Prosthetic Kit - KTMEC 02 is indicated to adequately fix and remove prosthesis and prosthetic devices over dental implants.

OPERATION PRINCIPLE

The instruments contained in the S.I.N. Prosthetic Kit - KTMEC 02, are based in mechanical action. All the instruments are indicated for use in the installation or removal of prosthetic components and must be handled according to the appropriate dental techniques.

HOW TO USE

Wrenches: The wrenches should be used according to their respective connections (e.g.: square wrench for screws with square connections), and should be positioned along the screw shaft and handled carefully, respecting the torque limit indicated in the instruction of use of the screws and prosthetic components.

Torque meter: Initially the professional must select the torque level to be applied (10, 20 or 32 Ncm). After selecting the torque, the professional must couple the ratchet wrench to the torque wrench and start the process of tightening the screw/prosthesis on the implant.

Observe the maximum torque limit supported by each screw so that the connection is not damaged or the screw fracture does not occur.

ATTENTION

The S.I.N. Prosthetic Kit - KTMEC 02, is intended for specialized procedures, which must be performed by qualified professionals in dentistry. The use of the product must be performed in surgical environment and under appropriate conditions for the health and safety of the patient.

PRECAUTIONS

Excessive use of the wrench, bad positioning of the wrench on the components head, added to the lever effort of the digital adapter or torque wrench, out of the long axis of the screw, can lead to stripping the screw head connections, and can even compromise the active tip of the wrenches. 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. Incorrect use of the torque wrench may alter the torque reference. Before using the S.I.N. Prosthetic Kit, the professional should sterilize it and after use, follow the Cleaning instructions contained in this Instruction for Use. The professional should inform the patient of the adequate way of cleaning, the need for periodic monitoring and to avoid physical efforts after the application. Do not stick labels, adhesive tapes, write or mark the surface of the product. It is recommended that after use, the kit and its components be washed and sterilized immediately.

RECOMMENDATIONS

For using the S.I.N. Prosthetic Kit - KTMEC 02 it is recommended that the professional must have taken a specialization course in Implant Dentistry or Prosthesis. Previously to the clinical use, the instruments must pass through a meticulous visual inspection to diagnose the cases mentioned above in the warnings.

CONTRAINDICATIONS

The S.I.N. Prosthetic Kit - KTMEC 02 does not present contraindications as long as its recommendations are correctly followed and used by a specialized professional, who will be responsible for the adequate planning of the procedure in which the Kit will be used.

SIDE EFFECTS

The S.I.N. Prosthetic Kit - KTMEC 02 is used to assist in the installation of prosthetic components on dental implants, thus adverse effects will occur only if the choice or use of the instruments 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 Rotary Expander. 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 with the final result of the work.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches that allow for 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 S.I.N. Prosthetic Kit - KTMEC 02 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 should be handled only in a sterile environment by properly dressed professionals in appropriate attire at the time of implant installation surgery.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

The S.I.N. Prosthetic Kit - KTMEC 02 should be transported in a proper way to avoid falls and stored at a maximum temperature of 35°C, protected 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. In case of any incident caused by the product, the professional must inform the manufacturer immediately. 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.

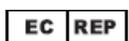
1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed in a steam sterilizable wrap.
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave 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. Prosthetic Kit - KTMEC 02 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 |

DEVELOPED AND MANUFACTURED BY:

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PRODUCTO: Kit Protético S.I.N. – KTMEC 02

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