

SURGICAL KIT

Prosthetic Kit S.I.N. - KTMEC 02

Prosthetic Kit S.I.N. - KTMEC 02 are intended for surgical procedures for installing dental implants, which must be performed by qualified professionals. The way of using the product is used and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in conditions suitable for the health and safety of the patient.



PRODUCT DESCRIPTION

The Prosthetic Kit S.I.N. - KTMEC 02 is a kit composed by hexagonal, square, digital and angular drivers, accompanied by a Prosthetic Torque Ratchet. The instruments of the Kit are manufactured in:

Stainless steel

Drivers and Prosthetic Torque Ratchet.

Udel Polysulfone

Box.

Drivers: Indicate for installing implants and prosthetic components, assist in the surgical procedure or in fixing/removal of implants and components.

Prosthetic Torque Ratchet: Used to tighten the screw of the prosthetic component with torque grading of 10N.cm, 20N.cm and 32N.cm.

Box: Support for storing, transporting and sterilizing all kit items.

INDICATIONS OF USE

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

PURPOSE AND OPERATION PRINCIPLE

The instruments contained in the Prosthetic Kit S.I.N. - KTMEC 02 base their operating principle on mechanical action. All instruments are indicated for use in the placement of Strong SW and Strong SW Plus implants and must be used following appropriate dental techniques.

HOW TO USE THE INSTRUMENT

Drivers: The drivers should be used according to their respective connections (e.g.: square driver 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.

Prosthetic Torque Ratchet: 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 driver to the Prosthetic Torque Ratchet 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

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

PRECAUTIONS

Excessive use of the drivers, bad positioning of the drivers on the components head, added to the lever effort of the digital adapter or torque driver, 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 driver. 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 Prosthetic Torque Ratchet may alter the torque reference. Before using the Prosthetic Kit S.I.N. - KTMEC 02, 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 Prosthetic Kit S.I.N. - 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.

CONTRAINDICATION

The Prosthetic Kit S.I.N. - 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 Prosthetic Kit S.I.N. - KTMEC 02 is used to assist in the installation of prosthetic components on dental implants, thus side effects will occur only if the choice or use of the instruments is inadequate.

WARNING

Do not use the instrument if you notice cracks, wear or spots of oxidation/corrosion. This may cause problems in the operation of the instruments. All items may exhibit natural wear and tear and should be replaced whenever the professional identifies loss of fit or accuracy of these products as they may interfere with the end result of the work.

TRACEABILITY

All S.I.N. products have sequential batches that allow traceability, thus promoting greater safety for professionals skilled for the procedure. Through this lot number it is possible to know all product history from the manufacturing process to the time of distribution.

STORAGE

The Prosthetic Kit S.I.N. - KTMEC 02 should be stored in a cool dry place at a temperature of 15°C to 25°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

Once sterilized, the instruments should be handled in a sterile environment by properly attired professionals and in appropriate clothing at the time of surgery to install implants. Scratches or notches of the instruments should be avoided as such factors can increase the possibility of corrosion of the products.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

The Prosthetic Kit S.I.N. - KTMEC 02 must be transported adequately to avoid falling and stored at a maximum temperature of 25°C, protected from heat and moisture. Transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for dental use. Reprocessing allowed. Refer to the cleaning and sterilization conditions contained in this instruction for use. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplantsystem.com or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Manually remove all surgical instruments from the kit. Wash the kit trays separately.
2. Prepare the enzymatic detergent according to the detergent manufacturer's recommendation.
3. Immerse all parts of the product into the prepared detergent solution and leave for 5 minutes. Then, using a soft bristle brush, scrub the parts for at least 2 minutes until complete remove organic matter from the products.
4. Remove the parts from the detergent solution and rinse with tap water for 1 minute until the residue is completely removed. Repeat the rinse two more times.
5. Visually inspect each part to check for process residues or organic residues from the used of the product.
6. If residue in detect 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. Wear appropriate clothing (gloves, masks, glasses, hats, etc.).
- b. Begin cleaning immediately after surgical use.
- c. Never let the instrument dry containing organic residues after surgical use.
- d. Never let the instrument dry naturally after cleaning.
- e. Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide or alcohol to clean or rinse surgical instruments and Kit trays.
- f. Never use steel wool or sponges or abrasive products, so that the instruments are not damaged.
- g. Do not accumulate instruments in large quantities on top of each other to avoid deformation of smaller and delicate pieces.

TORQUE RATCHET CLEANING INSTRUCTIONS

Cleaning must be carried out immediately after using the Torque Ratchet. To clean it, the Torque Ratchet must be disassembled; the use of tools is not necessary.

1. Pull the steering reversing rod back.
2. Remove the ratchet from the socket with your head.
3. Rotate the fixing door counterclockwise.
4. Remove the central shaft of the Torque Ratchet.
5. Remove the torque grading rod.
6. Prepare the enzymatic detergent according to the manufacturer's instructions.

7. Immerse all parts of the product in the prepared detergent solution and leave for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
8. Remove the pieces from the detergent solution and rinse with running water for 1 minute, repeat the rinse two more times, totaling 3 rinses of 1 minute each.
9. Visually inspect each piece to check whether there is residue from the cleaning process or organic residues from the use of the product.
10. If the presence of residue on the product is confirmed, repeat the cleaning process until the residue is completely removed.
11. Dry with a soft, clean, dry cloth or disposable paper.

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 Prosthetic Kit S.I.N. - KTMEC 02 can be used as below depending on proper handling, cleaning and sterilization.

Drivers and Prosthetic Torque Ratchet: use up to 250 times.

Box: can be cleaned and sterilized up to 250 times.

	NÃO ESTÉRIL	NON-STERILE	NON STÉRILE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTER LE MODE D'EMPLOI
	MARCAÇÃO CE	CE MARK	CE MARQUE
	MANTENHA SECO	KEEP DRY	GARDER AU SEC
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	TENIR À L'ABRI DE LA LUMIÈRE DU SOLEIL
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NE PAS UTILISER SI L'EMBALLAGE ENDOMMAGÉ
	ATENÇÃO	CAUTION	ATTENTION
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRÉSENTANT AUTORISÉ DANS LA COMMUNAUTÉ EUROPÉENNE
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LIMITE DE TEMPÉRATURE
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.	ATTENTION: LES LOIS FÉDÉRALES (AMÉRICAINES) LIMITENT LA VENTE DE CET APPAREIL PAR OU SUR ORDRE D'UN PROFESSIONNEL DE LA SANTÉ AGRÉÉ.
	FABRICANTE	MANUFACTURER	FABRICANT
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	DATE DE FABRICATION
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CODE DE RÉFÉRENCE
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIF MÉDICAL
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICATEUR UNIQUE DE L'APPAREIL
	IMPORTADOR	IMPORTER	IMPORTATEUR
	DISTRIBUIDOR	DESTRIIBUTOR	DISTRIBUTEUR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAYS DE FABRICATION
	LOTE	BATCH CODE	CODE DE LOT
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALLAGE RECYCLABLE
DESCRIPTION ON THE LABEL	CONTÉM: 1 UNIDADE	CONTENT: 1 UNIT	CONTENU: 1 UNITÉ

DESCRIPTION ON THE LABEL	PRODUTO NÃO ESTÉRIL	NON STERILE PRODUCT	PRODUIT NON STÉRILE
DESCRIPTION ON THE LABEL	KIT CIRÚRGICO	SURGICAL KIT	KIT CHIRURGICAL

**MANUFACTURER****S.I.N. Implant System LTDA.**

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74

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SYSTEM

Prosthetic Kit

MDL LICENSE CANADA

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