

SURGICAL KIT

Surgical Kit Epikut - KCSE 02I

Surgical Kit Epikut - KCSE 02I 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 Surgical Kit Epikut - KCSE 02I is composed of materials necessary for the installation of Epikut and Epikut Plus implant line. The instruments of the Kit are manufactured in:

Stainless steel

Drivers, Drills and Torque Ratchet.

Titanium Grade 5

Direction Indicator, Gingival Height and Depth Probe.

Udel Polysulfone

Box.

Lance Drill: Used to mark the location where the implant will be installed, promoting the rupture of the cortical bone, facilitating the insertion of other drills.

Conic Drill: Used in sequence to enlarge the perforation in progressive diameter until the final dimension is suitable for installing the implant following the surgical planning.

Countersink Drill: Used to increase the diameter in the cervical region of the implant. The purpose of this drill is to make space for a correct seating of the implant platform.

Helical Drill: Used to deepen and direct the perforation into the bone according to the surgical plan.

Direction Indicator: Used to assist and guide correct drilling.

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

Gingival Height: Indicated for determining the height parameter between the implant and the gingival tissue, enabling the correct selection of the height of the components.

Torque Ratchet: Used to install the implant with torque grading of 30N.cm, 45N.cm, 60N.cm and 80N.cm.

Depth Probe: Used to assist and guide correct drilling.

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

INDICATIONS OF USE

The Surgical Kit Epikut - KCSE 02I is indicated for the installation of maxilla and mandible implants in surgical procedures with late and immediate loading and for single and multiple implants.

PURPOSE AND OPERATION PRINCIPLE

The instruments contained in the Surgical Kit Epikut - KCSE 02I base their operating principle on mechanical action. All instruments are indicated for use in the placement of Epikut and Epikut Plus implants and must be used following appropriate dental techniques.

HOW TO USE THE KIT

The Surgical Kit Epikut - KCSE 02I must be used in accordance with the surgical planning programmed by a qualified dental professional. Each instrument included in the kit has a mode of use, which can be accessed on the website: www.sinimplantsystem.com



ATTENTION

Surgical Kit Epikut - KCSE 02I 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

The product should only be used by qualified dental professionals who already have all the scientific information necessary for the correct use of the product. Always clean and sterilize as recommended before the surgical procedure. Before drilling, make sure the cutter fits into the contra-angle and adjusts the motor in relation to rotation, torque and irrigation. During drilling, pressure should not be excessive, and intermittent movements should be made with constant irrigation. The drills cannot be sharpened and using them without cutting can cause undue bone heating, compromising the success of the procedure. The use of inappropriate cutters or sequence of cutters may compromise the performance of the implant, resulting in system failures, such as loss or fracture of the Implant. Care must be taken in cases of patients who show signs of allergy or hypersensitivity to stainless steel. For drills, it is recommended to use a maximum of 20 to 30 perforations, being: 20 perforations in high-density bones and 30 perforations in low-density bones. Do not stick labels, tape, write or mark the surface of the product.

RECOMMENDATIONS

Before each procedure, check the condition of the instruments, always respecting their useful life. It is necessary to replace the instruments in case of damage, erased markings, compromised sharpening, deformations and wear.

CONTRAINDICATION

Use of drills without irrigation, which can cause bone necrosis. Use for purposes other than installing an Epikut and Epikut Plus implant.

SIDE EFFECTS

They will not occur as long as surgical planning and handling is carried out in accordance with the instructions for use.

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 Surgical Kit Epikut - KCSE 02I 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 Surgical Kit Epikut - KCSE 02I 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 INFORMATION

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 instructions.
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 Surgical Kit Epikut - KCSE 02I can be used as below depending on proper handling, cleaning and sterilization.

Drills: 20 perforations in high-density bones; 30 perforations in low-density bones.

Direction Indicator, Drivers, Torque Ratchet, Gengival Height and Depth Probe: use up to 250 times.

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

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|---|--|--|--|
|  | 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 | DESTRIUTOR | 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

Epikut Surgical Kit

MDL LICENSE CANADA

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