






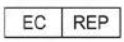


SIMBOLOGIA	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO 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
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTES 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.



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PRODUCT

KCSU 03 – UNITITE Surgical Kit

Anvisa Registration: 80108910086



The KCSU 03 – UNITITE Surgical Kit intended to specialized procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and under conditions suitable for the health and safety of the patient.



PRODUCT DESCRIPTION

The KCSU 03 – UNITITE Surgical Kit is a Kit composed by a full line of instruments such as Fasteners, Cutters, Cylinders, and other instruments required for the installation of the implants of the UNITITE Line, also offering the Surgical Torque Wrench.

Manufactured in:

Fasteners and Cutters: Made in stainless steel.

Male Thread and Depth Rod. : Made in Titanium

Measurer: Made of Titanium (stem) and polyacetal (bushing)

Direction Indicator: Made of Titanium

Organizer Box: Made of Polycarbonate/ Polyetherimide.

Torque Fastener : Made in stainless steel

Fasteners/ Keys: They help in the fixation or removal of components and implants.

Cutter: Indicated to perform the perforation of the bone tissue for implant installation.

Thread Cutter/ Male Thread: indicated for making the thread in the bone tissue before implant placement.

Rod and Cylinders: It is indicated to assist and guide a correct drilling.

Measurer: It is indicated to determine the height parameter between the implant and the gingival tissue, allowing the selection of the correct component height.

Torque Fixer: It has the function of assisting the installation of implants in the surgical procedure, or installing the prosthetic component with the appropriate torque.

INDICATIONS OF USE

The KCSU 03 - UNITITE Surgical Kit is exclusively indicated to assist in the installation of implants of the S.I.N UNITITE family and is not compatible with other lines and systems of other manufacturers.

OPERATION PRINCIPLE

The instruments contained in the KCSU 03 - UNITITE Surgical Kit base their working principle on mechanical action. All instruments are indicated for use in implant placement of the Unitite family and should be used following appropriate dental techniques.

DIRECTIONS

The form of use is inherent to the training of the professional responsible for using the material. It can only be used and/or applied by dental surgeon specialized in implant surgery.

CONTRAINDICATIONS

The KCSU 03 - UNITITE Surgical Kit does not present contraindications since its recommendations are followed correctly, as directed in this Instructions for Use and used by a specialized professional, who will be responsible for the adequate planning of the surgical procedure in which the Kit will be used.

SIDE EFFECTS

KCSU 03 - UNITITE Surgical Kit is used to aid in the installation of dental implants, so adverse effects will occur only if the choice of instruments is inadequate.

PRECAUTIONS AND RECOMMENDATIONS

The KCSU 03 - UNITITE Surgical Kit requires specialized surgical procedures, only to be used by qualified dental surgeons, including: diagnosis, preoperative planning and surgical protocol. The use of the product without knowledge of the proper techniques and / or inadequate procedures and conditions may harm the patient leading to unsatisfactory results.

For milling cutters, it is recommended to use up to 20 to 30 perforations, which are:

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

Do not stick labels, tapes, as well as write, or mark the surface of the product.

It is recommended to immediately wash and sterilize the kit and its components after use.

WARNING

Do not use the instruments if you notice cracks, wear or oxidation/ corrosion points. This may cause problems in the operation of the products, installation of the implants and in the postoperative period.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches that allow 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

KCSU 03 - UNITITE Surgical Kit should be stored in a dry, cool, ventilated place away from direct sunlight;

TRANSPORTATION

The KCSU 03 - UNITITE Surgical Kit must be transported at room temperature, away from direct sunlight, avoiding places with greater variations in temperature and humidity. The transportation must be carried out properly to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

Once sterilized, instruments should be handled only in a sterile environment by properly trained professionals and wearing appropriate gowning at the time of surgery to install dental implants. Risks, creases or indentations of the surgical instruments should be avoided as such factors may increase the possibility of corrosion of the products.

COMPLEMENTARY INFORMATION

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

CLEANING INSTRUCTIONS

- Step 1: Remove the part (if applicable).
For torque wrenches, refer to the specific instructions contained in this Instructions for Use.
- Step 2: Take to the ultrasound and immerse the piece with distilled water and neutral detergent, for at least 5 minutes.
- Step 3: Remove the organic matter from the instruments using soft bristle brush.
- Step 4: Rinse with plenty of running water until the residue is completely removed.
- Step 5: Dry with a soft, clean, dry cloth or disposable paper.
- Step 6: Perform visual inspection, observing if there are flaws in the cleaning process. (If there is dirt, the piece should be immersed again in detergent - 2nd step. Repeat the rinse and drying sequence).
- Step 7: Send to the sterilization process.

RECOMENDATIONS

Wear appropriate gloves (gloves, masks, glasses, caps, etc.)
Start cleaning immediately after surgical use.

Never let the instrument dry containing organic waste after use.

Never let the instrument dry naturally after cleaning.

Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide or alcohol for cleaning or rinsing surgical instruments.

Never use steel wool or abrasive sponges and products, so that the instruments are not damaged.

Do not accumulate instruments in large quantities on top of each other to avoid deformation of minor and delicate parts.

CLEANING INSTRUCTIONS TORQUE WRENCH

Cleaning must be carried out immediately after use of the torque wrench. For cleaning, the torque wrench must be dismantled, so it is not necessary to use tools.

1. Pull the inverter rod back.
2. Remove the ratchet from the connection with the head.
3. Rotate the securing door counterclockwise.
4. Remove the central axis of the torque wrench.
5. Remove the rod with torque graduation
6. Start the washing procedure by: Immersing the parts in detergent aqueous solutions with neutral or enzymatic pH and place them on ultrasound for 30 minutes. Then, clean the parts using a brush with soft bristles, detergent and running water, wiping carefully.

STERILIZATION

Product supplied non-sterile and must be sterilized by autoclaving before use.

Use packaging compatible with the sterilization process.

Sterilize the steam in cycles of 121° C to 1 ATM pressure for 30 minutes or at 134° C to 2 ATM pressure for 20 minutes.

Always place the products in an autoclave on a flat surface and away from the walls of the appliance.

Never overlap objects or even other cases.

RECOMENDATIONS

Sterilize on the day before or on the day of the procedure.

Chemical sterilization is not recommended as certain products may cause discoloration and damage to the case.

Do not use temperature above 60 ° C for drying the products.

Never use dry heat ovens for sterilization of instruments and kits S.I.N.

DISPOSAL OF MATERIAL

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