KCSU 02 - UNITITE SURGICAL SET

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
CE	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
EC REP	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 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.

DEVELOPED AND MANUFACTURED BY:

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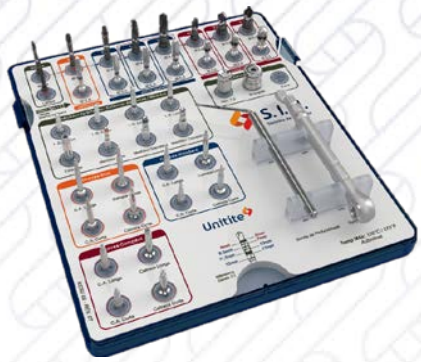
PRODUCT:

KCSU 02 - Unitite Surgical Set

Anvisa Registration: 80108910055

CE

The KCSU 02 - UNITITE Surgical Set is intended for expert 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 in proper conditions for the health and safety of the patient.



PRODUCT DESCRIPTION

The KCSU 02 - UNITITE Surgical Set is a Kit composed by the complete line of instruments such as Cutters, Wrenches, Male Threads, and other instruments required for the installation of the implants of the UNITITE Line, also offering the Surgical Torque Wrench.

INDICATIONS OF USE

The KCSU 02 - UNITITE Surgical Set is indicated to assist in the installation of implants of the UNITITE family.

OPERATION PRINCIPLE

The instruments contained in the KCSU 02 - UNITITE Surgical Set base their working principle on mechanical action. All instruments are intended for use in the placement of implants of the Unitite family and must be handled in accordance with appropriate dental techniques.

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

Cutter: It is indicated to perform the perforation of the bone tissue for implant installation.

Male thread: It is indicated for making the thread in the bone tissue before implant placement.

Direction indicators: 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.

DIRECTIONS

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

CONTRAINDICATIONS

The KCSU 02 - UNITITE Surgical Set does not present contraindications if its recommendations are correctly followed and used by a specialized professional, who will be responsible for the appropriate planning of the surgical procedure in which the Kit will be used.

SIDE EFFECTS

The KCSU 02 - UNITITE Surgical Set is used to assist in the installation of dental implants, thus adverse effects may occur only if the instrument choice is inappropriate.

PRECAUTIONS AND RECOMMENDATIONS

The KCSU 02 - UNITITE Surgical Set requires specialized surgical procedures, and must only be used by qualified dental surgeons, including: diagnosis, preoperative planning, and surgical protocol. The use of the product without knowledge on the appropriate 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

The KCSU 02 - UNITITE Surgical Set must be stored in a dry, fresh, and welll-ventilated place away from direct sunlight;

TRANSPORTATION

The KCSU 02 - UNITITE Surgical Set 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: Disassemble the parts (if applicable).
Step 2: Take to the ultrasound and emerge the piece with distilled water and neutral detergent, for at least 5 minutes.
Step 3: Remove the organic material from the instruments using soft bristle brush.
Step 4: Rinse thoroughly with plenty of water until the residue is completely removed.
Step 5: Dry with a soft, clean and dry cloth or disposable paper.
Step 6: Perform visual inspection, observing if there are failures 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.

RECOMMENDATIONS

Wear appropriate paramentation (gloves, masks, glasses, caps, etc.)
Begin cleaning immediately after surgical use.
Never let the instrument dry containing organic material after surgical 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 straws or sponges and abrasive products, so that the instruments are not damaged.
Do not accumulate the instruments in large quantities on top of each other to avoid deformation of minor and delicate parts.

DISMANTLE INSTRUCTIONS FOR THE TORQUE WRENCH

For the torque wrench dismantle, follow the steps below:

1. Rotate the torque wrench drum counterclockwise until it is fully loosened.
2. After releasing the drum remove the body and the head of the torque wrench.
3. Start the cleaning procedure according to the information contained in this instruction for use.
4. After complete the cleaning procedure, mount the Torque wrench following the same disassembly procedures in reverse order.

STERILIZATION

1. Product provided non-sterile and must be autoclaved prior to use.
2. Dry all instruments before the steam sterilization cycle.
3. Use packaging compatible with the sterilization process.
4. Sterilize by steam autoclaving in cycles of 121 ° C to 1 ATM pressure for 30 minutes or at 134 ° C to 2 ATM pressure for 20 minutes.
5. Always place the products in an autoclave on a flat surface and away from the walls of the device.
6. Never overlap objects or even other cases.

RECOMMENDATIONS

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 stoves for sterilization of instruments and assemblies S.I.N.

DISPOSAL OF MATERIAL

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

EXPIRATION DATE

Indicated on the label.