SURGICAL KIT

Unitite Guided Surgery Kit - KCSUG 02

The Unitite Guided Surgery Kit - KCSUG 02 is intended for 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 adequate conditions for the health and safety of the patient.

PRODUCT DESCRITION

The Unitite Guided Surgery Kit is indicated to assist the installation of the Unitite implant family. It is composed of the complete line of instruments such as cutters, keys, thread taps and other instruments necessary for the installation of the implants, and also offers a surgical torque wrench.

INDICATIONS OF USE

All the instruments are indicated to assist the placement of the Unitite family implants and must be used following the appropriate dental techniques.

Cutters: Their purpose is to deepen the perforation in the bone tissue according to the procedure performed by the professional.

Thread Milling Cutter: Instrument used in cases of high bone density to facilitate insertion of the implant, ensuring the ideal recommended torque.

Fixators: Instruments that help in the fixation or removal of a component or implant.

Depth Probe: Instrumental indicated to help and guide a correct drilling, at the right depth and angles.

Keys: Instruments that help in the installation of implants, cover-implants or prosthetic components.

Cutter Guides: Instrumental that helps in the correct insertion and angulation of the cutter inside the surgical guide for the guided surgery technique.

Organizing Box: Accommodates the surgical instruments in an organized manner.

Connectors: Instrumental that has as function the coupling of the torque wrenches to the fixator.

Mucosa Extractors: Instrument used to make the incision in the mucosa in a circular shape to start the milling procedure.

Safe Drill Limiters: Instrument that helps in drilling the alveolus, limiting the desired depth.

Torque Fixator: Has the function of assisting the installation of implants in the surgical procedure, or installing the prosthetic component with the proper torque.

OPERATION PRINCIPLE

The instruments contained in the Unitite Guided Surgery Kit are based on mechanical action. All instruments are indicated for use in the Unitite Line of implants and must be used following the appropriate dental techniques.

HOW TO USE

The form of use 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 a specialized dental surgeon, for implant surgery.

UNITITE PRIME, COMPACT AND SLIM IMPLANT INSTALLATION:

- Remove the blister from the outer cartridge.
- Retain the accompanying traceability labels.
- On a sterile surgical field and after breaking the sterility seal of the blister, grasp the primary packaging (sleeve) with your non-dominant hand and open the lid.
- The implant will be exposed inside the tube for key capture;
- For motorized installation, use the key for counter-angle.
- Capture the implant keeping the key still and slightly rotating the internal support, seeking the perfect fit between the Connection and the Implant. Press the wrench over the implant to have a better fixation.
- Transport the Implant to the bone bed.
- In the surgical motor, use maximum torque of 35 N.cm and rotation between 20-40 RPM.
- Perform the implantation according to the planned procedure for guided surgery previously defined.
- Preferably, complete the implant installation with the Surgical Torque Wrench.
- The maximum recommended installation torque is 80N.cm.
- The choice between implant cover, healer or prosthetic component installation is at the discretion of the professional.

Note: While making the socket, avoid bending the cutters laterally and use abundant and uninterrupted irrigation. The transport of the implant from the package to the insertion in the alveolus must be done through the keys with fitting for counter-angle.

ATTENTION

The Unitite Guided Surgery Kit is intended for specialized procedures, which must be performed by qualified dental professionals. The use of the product must be performed in a surgical environment and under adequate conditions for the health and safety of the patient.

PRECAUTIONS

The Unitite Guided Surgery Kit requires specialized surgical procedures, should only be used by qualified dental surgeons, including: diagnosis, preoperative planning and surgical protocol. The use of the product without knowledge of the appropriate techniques and/or inappropriate procedures and conditions, may harm the final result of the treatment and the patient, leading to unsatisfactory results.

RECOMMENDATIONS

For cutters, a maximum of 20 to 30 perforations is recommended, of which:

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

Do not stick labels, adhesive tapes, write or demarcate the product's surface.
It is recommended that after use, the kit and its components be washed and sterilized immediately.

CONTRAINDICATIONS

The Unitite Guided Surgery Kit does not present contraindications as long as its recommendations are correctly followed and used by a specialized professional, who will be responsible for planning the surgical procedure in which the Kit will be used.

SIDE EFFECTS

The Unitite Guided Surgery Kit is used to assist in the installation of dental implants, so adverse effects will only occur if the choice of instrumentation is inappropriate.

WARNING

Do not use the instruments in case you notice cracks, wear or oxidation/corrosion points. This can cause problems in the functioning of the products, installation of the implants and in the post-operative period. Some items present natural wear generated by use, such as the milling cutters, and must be replaced whenever the professional identifies loss of cutting capacity or precision of these products, because they can interfere in the final result of the treatment.

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 Unitite Guided Surgery Kit - KCSUG 02 should be stored in a dry, cool, well-ventilated place away from direct sunlight.

HANDLING

Once sterilized, the instruments must be handled only in a sterile environment by properly dressed professionals in appropriate attire at the time of surgery for installation of dental implants. Scratches, bends or notches of the surgical instruments must be avoided, since such factors can increase the possibility of corrosion of the products.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

The Unitite Guided Surgery Kit - KCSUG 02 must be transported at room temperature, away from direct sunlight, avoiding places where there are great variations in temperature and humidity. The transportation must be done in an appropriate way, to avoid falling and must be done in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive of 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.

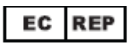
1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed in a steam sterilizable wrap.
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave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

It is estimated that the Unitite Guided Surgery Kit - KCSUG 02 can be reprocessed up to 250 times. It is necessary to verify the functionality of the instruments, fitting capacity or precision of these products after each procedure and if there is natural wear generated by use they must be replaced and discarded

	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:
S.I.N. Sistema de Implante Nacional S/A
CNPJ: 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 2445 - Vila Rio Branco CEP: 03348-060 - São Paulo - SP - Brasil

SERVICE TO PROFESSIONALS
0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com
e-mail: sin@sinimplante.com.br

EC REP

OBELIS S.A.
Bd. Général Wahis 53
1030 Brussels, Belgium

CE

RESPONSIBLE TECHNICIAN:
Alessio Di Risio
CREA-SP: 5061207169

PRODUCT: Unitite Guided Surgery Kit - KCSUG 02

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