SURGICAL KIT

Surgery Kit Unitite – KCSU 05

The Surgery Kit Unitite is intended for specialized procedures, which must be performed by qualified professionals. The way of using 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 conditions suitable for the health and safety of the patient.

PRODUCT DESCRITION

The Surgical Kit Unitite is a composite of materials necessary for installing implants in the Unitite line.

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

Helical Drill: Used to deepen and direct the drilling in bone tissue according to the planning carried out by the professional.

Pilot Drill: Used in the surgical sequence after the helical cutter and before each conical cutter to attenuate bone heating.

Conic Drill: Used in progressive diameter enlargement in the surgical site until the adequate dimension for implant installation.

Screw tap: It has the purpose of forming threads in high density bone, it is used after the use of the last cutter indicated for installation of the implant and, consequently, it reduces the final torque of installation of the dental implants in this bone density.

Transmucosal Meter: Its purpose is to assist in the selection of the prosthetic component. The meter is fitted to the installed implant to check the transmucosal height.

Direction Indicator: Its purpose is to assist in the correct drilling of the surgical alveolus.

Driver/Fixer: : Indicated for installing components and implants and has a final installation torque indicator**.**

Depht Rod: Its purpose is to assist in the correct drilling of the surgical alveolus.

Torque Ratchet: The finality is to enable the installation of dental implants and prosthetic components, through the aid in the surgical procedure.

Box: Support to store, transport and sterilize all items in the kit.

INDICATIONS OF USE

The Surgery Kit Unitite is indicated for the installation of maxilla and mandible implants in surgical procedures with late and immediate loading and for single and multiple implants.

OPERATION PRINCIPLE

The instruments contained in the Surgery Kit Unitite base their operating principle on mechanical action. All instruments are indicated for use in the placement of Unitite implants and must be used following the appropriate dental techniques.

HOW TO USE

The Surgery Kit Unitite should be used in accordance with the surgical planning programmed by a qualified dentistry professional. Each instrument included in the kit has a way of use, which can be accessed on the website: www.sinimplantsystem.com

ATTENTION

The Surgery Kit Unitite 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

1. 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.
2. Always perform cleaning and sterilization as recommended before the surgical procedure.
3. Before drilling, make sure the cutter fits into the contra-angle and the motor is adjusted for rotation, torque and irrigation.
4. During drilling the pressure must not be excessive, and intermittent movements must be made with constant irrigation.
5. The drills are not capable of sharpening and using them without cutting can generate undue bone heating, compromising the success of the procedure.
6. The use of the drills or the inappropriate cutter sequence can compromise the performance of the implant resulting in system failures, such as implant loss or fracture.
7. Care should be taken in cases of patients who show signs of allergy or hypersensitivity to stainless steel.
8. For drills, a maximum use of 20 to 30 perforations is recommended, as follows:

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

9. Do not stick labels, adhesive tapes, 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.

CONTRAINDICATIONS

Use of drills without irrigation, which can cause bone necrosis. Use for purposes other than installing a Unitite implant.

SIDE EFFECTS

It will not occur as long as the surgical planning and handling is done according to the instructions for use.

WARNING

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

TRACEABILITY

All S.I.N. - Implant System products have sequential batches that allow traceability, thus promoting greater safety to the professional skilled in 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 Surgery Kit Unitite should be stored in a cool, dry place at a maximum temperature of 35°C and protected from direct sunlight.

HANDLING

Once sterilized, the instruments should be handled only in a sterile environment by properly attired professionals and in appropriate clothing at the time of surgery to install implants.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

The Surgery Kit Unitite must be transported adequately to avoid falling and stored under a maximum temperature of 35°C, protected from heat and moisture. Carriage must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Reprocessing allowed. Refer to the cleaning and sterilization conditions contained in these instructions. In case of an incident caused by the product, the professional must immediately inform the manufacturer. 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.

TORQUE RATCHET CLEANING INSTRUCTIONS

Cleaning must be carried out immediately after using the torque wrench. For cleaning, the torque wrench must be disassembled, for this it is not necessary to use tools.

1. Pull the steering inverter rod back.
2. Remove the ratchet from the socket with the head.
3. Rotate the fixing door counterclockwise.
4. Remove the central axis from the torque wrench.
5. Remove the torque graduated rod.
6. Prepare the enzymatic detergent according to the manufacturer's instructions.
7. Dip all parts of the product in the prepared detergent solution and leave for at least 5 minutes, afterwards using a soft bristle brush, rub the parts to remove organic matter from the products.
8. Remove the parts from the detergent solution and rinse under running water for 1 minute, repeat the rinse for two more times, totaling 3 rinses of 1 minutes each.
9. Visually inspect each part to check for residue from the cleaning process or organic residues from using the product.
10. If the presence of residues in the product is confirmed, repeat the cleaning process, until the total removal of residues.
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 3. 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

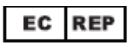
The Surgery Kit Unitite can be used as below depending on the proper handling, cleaning and sterilization.

Drill: 20 perforations in high density bones; 30 low density bone perforations.

Drive/Fixer, Direction Indicator, Transmucosal Meter, Depht Rod and Torque Ratchet: Used up to 250 times.

Screw Tap: Used up to 20 times.

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

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