SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	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
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.
	FABRICANTE	MANUFACTURER	FABRICANTE

DEVELOPED AND MANUFACTURED BY:

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TECHNICIAN RESPONSIBLE:

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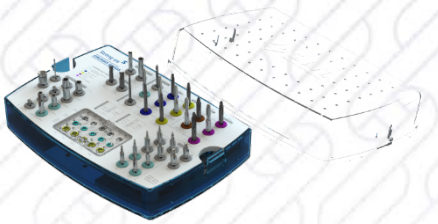
PRODUCT:

KCSWG04 - GUIDED SURGERY KIT UNITITE
Anvisa Registration: 80108910084

The Guided Surgery Kit Unitite is intended for expert procedures, which must be performed by qualified professionals in this surgical technique. 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 Guided Surgery Kit Unitite is a set of instruments required for installation of Unitite implants:

Extracting Drill: These drills have the purpose of facilitating the removal of the mucosa, so that the professional can have access to the implant to finalize the work.

Flat Drill:

Helical/ Conical/ Unitite Drill: The purpose of these Drills is the progressive extension of drilling, to promote greater control of the work performed until the final drilling dimension allows the implant to be installed.

Short Drill: Millings are indicated to perform a stepped and controlled drilling for a correct insertion of the implant.

Male Thread: Indicated for the formation of type I and II bone threads during the surgical procedure. They are suitable for all implant models.

Driver: Used for tightening, implant, screw cover, assemblers, healing abut., transfer, hexagonal retention screw, angled mini-abutment.

Surgical Torque Fixer: Used for implant installation;

Deepth Rod: Indicated to check for anatomical accidents and to check the length of the surgical alveolus.

Guide: Indicated to assist and guide a correct drilling of the surgical alveolus;

Fixer: It assist in the installation or removal of components and implants.

Safe Drill Limited: Indicated to assist in the installation of dental implants. Its function is to limit the perforation depth of the bone tissue for implant installation.

Organizer Box: Indicated to organize, store, transport and sterilize the surgical instruments that belongs to this kit.

INDICATIONS OF USE

Guided Surgery Kit Unitite are intended for pre-operative planned treatments with 3D planning software. They were developed to prepare the surgical alveolus for implants of the S.I.N Unitite system using the guided surgery technique.

It can be used and/ or applied by a specialized dental surgeon for implant surgery. The way to use is inherent in professional training, requiring accreditation for guided surgery.

OPERATION PRINCIPLE

The planning of the implant surgery is made digitally, from a tomography and a software where a surgical guide is milled or printed for the accomplishment of the surgery.

CONTRAINDICATIONS

It is contraindicated the use of the Kit without the digital planning and the surgery guide created from this planning. Use of drills without irrigation can cause bone necrosis.

OPERATION MODE

Indicated for professionals seeking for high predictability and accuracy in their clinical cases. Bringing greater safety, comfort and lower postoperative morbidity, because it is a less invasive surgical technique for the patient.

SIDE EFFECTS

The Guided Surgery Unitite is used to assist in the installation of dental implants, so side effects will occur only if the choice of instruments is inadequate.

PRECAUTIONS AND RECOMMENDATIONS

- The product should be only used by qualified dentistry professionals who already have all the scientific information necessary for the correct use of the product.
- Always perform cleaning and sterilization according to recommendations before the surgical procedure.
- Before drilling, make sure that the engagement cutter is in counter-angle and the motor is adjusted for rotation, torque and irrigation.
- The cutters must be completely inserted on the guides before starting the rotation.
- It is necessary to perform surgery with intermittent perforations, to ensure that the irrigation reaches the apex of the mills, thus avoiding on bone heating.
- During drilling the pressure should not be excessive, and the movements must be intermittent with constant irrigation.
- The cutters can not be edged and their use without cutting can generate undue bone heating, compromising the success of the procedure.
- The inappropriate use or sequence of milling cutters can compromise the performance of the implant resulting in system failure, as loss or fracture of the implant.
- Should be aware in cases of patients who show signs of allergy or hypersensitivity to stainless steel.
- Before each procedure, check the condition of the instruments, always respecting their shelf life. It is necessary to replace the instruments in case of damage, markings erased, sharp edging, deformation and wear.

WARNING

The S.I.N. warns that the information in this manual, by its self, are not enough to ensure that the professional is able to carry out installation of dental implant surgery Unitite with guided surgery technique. For proper use of the system it is necessary to have professional qualification in the dental area according to local regulations and it is recommended the qualification/ accreditation in guided surgery for the Unitite implant system.

For specific information about products supplied by third parties, please contact the respective companies directly.

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Note: Products in this manual may not be available in all markets, see your local S.I.N. for more information. 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. 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 Guided Surgery Kit Unitite must be stored in a dry, fresh and ventilated place away from direct sunlight;

TRANSPORTATION

The Guided Surgery Kit Unitite 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.
The Guided Surgery Kit Unitite are intended for surgeries that were planned in the preoperative phase with 3D planning software. They were developed to prepare the surgical alveolus for implants of the S.I.N. Unitite using guided surgery technique.
The 3D planning software enables virtual simulations of treatment plans. Software planning increases the safety of the surgical procedure and allows the predictability of the ideal implants to be used. It is possible to create surgical guides from the planning done in the software.
This software can be handled by the trained dental surgeon, or the data can be sent to one of our accredited Planning Centers.
The planning should be made on software approved for use in conjunction with the Guided Surgery Kit Unitite.

CLEANING INSTRUCTIONS

1. Preliminary Cleaning or Disinfecting

a.Take to the ultrasound and emerge the piece with distilled water and neutral detergent, for at least 5 minutes

b.Remove the organic material from the instruments using soft bristle brush.

c.Rinse thoroughly with plenty of water until the residue is completely removed.

d.Dry with a soft, clean and dry cloth or disposable paper.

e.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).

f.Send to the sterilization process

g.Never use saline solutions, especially

h.Hypochlorite sodium and saline, disinfectants, hydrogen peroxide or alcohol for cleaning or rinsing surgical instruments.

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

j.Do not accumulate the instruments in large amounts over each other to avoid deformation of smaller, delicate parts.

Recommendations

a. Wear appropriate paramentation (gloves, masks, glasses, caps, etc.)
b. Begin cleaning immediately after surgical use.
c. Never let the instrument dry containing organic material after surgical use.
d. Never let the instrument dry naturally after cleaning.

STERILIZATION

Product provided non-sterile and must be autoclaved prior to use.

a. Dry all instruments before the steam sterilization cycle.
b. Use packaging compatible with the sterilization process.
c. Sterilize by steam autoclaving in cycles of 121ºC to 1 ATM pressure for 30 minutes or at 134ºC to 2 ATM pressure for 20 minutes.
d. Always place the products in an autoclave on a flat surface and away from the walls of the device.
e. Never overlap objects or even other cases.

Recommendations

a. Sterilize on the day before or on the day of the procedure.
b. Chemical sterilization is not recommended as certain products may cause discoloration and damage to the case.
c. Do not use temperature above 60ºC for drying the products.
d. Never use dry heat stoves for sterilization of instruments and assemblies S.I.N.

DISMANTLE INSTRUCTIONS FOR THE 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 drive rod backward direction.
2. Remove the ratchet fitting head.
3. Rotate the torque wrench drum counterclockwise until it is fully loosened.
4. Remove the central axis of the torque wrench.
5. Remove the stem with torque
6. Start the washing procedure: immersing the pieces in aqueous solutions with a neutral detergent or enzyme pH and place them in ultrasound for 30 minutes. Then clean the parts using a brush with soft bristles, detergent and running water, rubbing carefully.

DISPOSAL OF MATERIAL

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

EXPIRATION DATE

The life of the kit is individualized therefore evaluate instruction of use according to each instrument.

The milling cutters can be used for up to 30 surgical instruments depending on the proper handling, cleaning and sterilization. It is necessary to check the sharpness of the instruments after each surgical procedure and if there is a lack of sharpening, the material should be discarded. Being:

•20 high-density bone perforations;

•30 perforations in low density bones.