SURGICAL KIT

Unitite Drills Replacement Set - KRFU

The Unitite Drills Replacement Set 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 training of the professional. 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 Unitite Drills Replacement Set is produced in stainless steel, at one end it has a fitting for contra-angle (active device) and at the other end an active tip with a cut and geometry compatible with the implant to be installed. The reamers are laser marked to determine the depth of the perforation according to the surgical plan.

INDICATIONS OF USE

The Unitite Drills Replacement Set is a composite of materials necessary for the installation of Unitite implants.

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

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

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

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

OPERATION PRINCIPLE

The purpose of the Unitite Drill Replacement Set is to drill the surgical socket with adequate dimensions for the installation of dental implants. The cutters have active surgical steel cutting tips that, by mechanical shear action, cut the bone.

HOW TO USE

1. Select the set of drills necessary to obtain the proper drilling of the site taking into account the desired length and width.
2. Ensure that the drills are properly sterilized when starting the procedures (see sterilization conditions contained in this instruction for use).
3. The drills must be fitted in the contra-angle, configure the motor at the appropriate speed, torque and irrigation for the type of implant that will be installed.
4. Carry out the drilling with continuous insertion and removal movements using the cutter with the planned length and diameter.
5. Proceed with the surgical procedures.

ATTENTION

The Unitite Replacement Drills Set 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 conditions suitable for the health and safety of the patient.

PRECAUTIONS

Before drilling, make sure that the cutter fits into the contra-angle and that the motor is adjusted with respect to rotation, torque and irrigation.
During drilling, the pressure must not be excessive, and intermittent movements must be made.
The drills cannot be sharpened and their use without cutting can generate undue bone heating, compromising the success of the procedure.
The use of the drills or the improper sequence of drills can compromise the performance of the implant resulting in system failures, such as loss or fracture of the Implant.
Before each procedure, check the conditions of the instruments, always respecting their useful life. It is necessary to replace the instruments in case of damage, erased markings, compromised sharpening, deformation and wear.

RECOMMENDATIONS

The product must only be used by qualified dental professionals who already have all the scientific information necessary for the correct use of the product.
Always clean and sterilize as recommended before the surgical procedure.
Care should be taken in cases of patients who show signs of allergy or hypersensitivity to stainless steel.

CONTRAINDICATIONS

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

ADVERSE EFFECTS

They 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 observe cracks, wear or oxidation/corrosion points. This may cause problems with the operation of the products, installation of implants and postoperatively. Some items show natural wear generated by use, such as drills, and should 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 products from S.I.N. – Implant System have sequential batches that allow traceability, thus promoting greater safety to the professional qualified for the procedure. Through this batch number it is possible to know the entire history of the product from the manufacturing process to the moment of distribution.

STORAGE

The Unitite Replacement Drills Set should be stored in a cool, dry place, at a maximum temperature of 35°C and protected from direct sunlight.

HANDLING CONDITIONS

Once sterilized, the instruments should only be handled in a sterile environment by professionals properly dressed and wearing appropriate clothing at the time of surgery for implant placement.

DISPOSAL OF MATERIAL

Disposal of materials must be carried out in accordance with hospital standards and local legislation applicable.

TRANSPORTATION

The Unitite Drills Replacement Set must be transported properly to avoid falling and stored at a maximum temperature of 35°C, protected from heat and humidity. Transport must be carried out in the original packaging.

ADDITIONAL INFORMATION

Multiple use product. Exclusively for dental use. Reprocessable. See cleaning and sterilization conditions contained in this instruction for use. In the event of an incident caused by the product, the professional must immediately inform the manufacturer.

CLEANING INSTRUCTIONS

1. Disassemble the part (if applicable), remove all internal organic material with running water and proceed to the next step only when performing these procedures.
2. Prepare the enzymatic detergent according to the manufacturer's instructions.
3. Immerse all parts of the product in the prepared detergent solution and leave for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove the parts from the detergent solution and rinse with running water for 1 minute, repeat the rinse for two more times, totaling 3 rinses of 1 minute each.
5. Visually inspect each part for residue from the cleaning process or organic residue from product use.
6. If the presence of residues in the product is confirmed, repeat the cleaning process until the residues are completely removed.
7. Dry with a soft, clean, dry cloth or disposable paper.
8. Proceed to the sterilization process.

RECOMMENDATIONS

a. Wear the proper attire (gloves, masks, glasses, hats, etc.).
b. Start cleaning immediately after surgical use.
c. Never allow the instrument to dry containing organic residues after surgical use.
d. Never let the instrument dry naturally after cleaning.
e. Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide or alcohol to clean or rinse surgical instruments and Kit trays.
f. Never use steel wool or sponges and abrasive products, so that the instruments are not damaged.
g. Do not stack instruments in large quantities on top of each other to avoid deformation of smaller and delicate parts.

STERILIZATION

Reusable product provided non-sterile and must be cleaned and sterilized before use.

1. Dry all instruments before the steam sterilization cycle.
2. Use packaging compatible with the steam sterilization process.
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or at 134°C at 2 ATM pressure for 20 minutes. Let dry for 30 minutes.
4. Always place the case in the autoclave on a flat surface away from the walls of the appliance.
5. Never overlap objects and not even other cases.reutilizável e fornecido não estéril e deve ser limpo e esterilizado antes do uso.

RECOMMENDATIONS

a. Sterilize the day before or the day of the procedure.
b. Chemical sterilization is not recommended as certain products can cause discoloration and damage to the case.
c. Do not use a temperature above 60°C for drying the products.
d. Never use dry heat ovens to sterilize S.I.N. – Implant System.

EXPIRATION DATE

The Unitite Replacement Burs Set can be used as below depending on proper handling, cleaning and sterilization.

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

	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	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA

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