






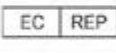



SYMBOLOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO 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
	LÍMITE SUPERIOR DE TEMPERATURA	UPPER LIMIT OF TEMPERATURE	LÍMITE SUPERIOR DE TEMPERATURA
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTES 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.

EC REP

DEVELOPED AND MANUFACTURED BY:

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PRODUCT:

KRFU – UNITITE Drilling Replacement Set
Anvisa Registration: 80108910079

CE

The **UNITITE Drilling Replacement 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 UNITITE Drilling Replacement Set is a kit composed by the surgical drilling line required for the installation of UNITITE Prime and UNITITE Slim implants.

INDICATIONS OF USE

The UNITITE Drilling Replacement Set is indicated to help the installation of the UNITITE implants family. Millings are indicated to perform the removal of material in reconstruction procedures (dental/buco-maxillo facial/orthodontic) with the objective of performing a stepped and controlled drilling to have a correct insertion of the implant.

Lance Pilot Drilling: It has the purpose of marking the place where the implant will be installed, in addition to promote the decorticalization of the bone in that area to facilitate the insertion of other drills.

Helical Drilling: Aimed to deepen the perforation in the bone tissue according to the planning carried out by the professional.

UNITITE Drilling: Aimed at progressive enlargement of the drilling and to promote a greater control of the work done, until the final dimension of the drilling allows the installation of the implant.

OPERATION PRINCIPLE

Drilling contained in the UNITITE Drilling Replacement Set base their working principle on the mechanical action of bone cutting, across its surface. As the material from which the drills are produced is harder and more resistant than these, by printing the rotational movement, the drills cut the tissue, promoting the removal of material, which varies according to the geometry of each commercial model presented.

HOW TO USE

1. Open the original package and remove the drill;
2. Before first use or after having been used in surgical procedures, wash the drill with enzymatic detergent and rub it vigorously with a nylon bristle brush. Check the detergent manufacturer's instructions for concentration and temperature conditions. Then rinse under running water;
3. Place the drill in the surgical kit and sterilize it in an autoclave, never exceeding the temperature of 121°C at 1 ATM pressure for 30 minutes or at 134°C at 2 ATM pressure for 20 minutes. Use a chemical or biological indicator to validate the sterilization process;
4. Once sterilized, the drill is ready to be used in surgical procedures.

CONTRAINDICATIONS

The UNITITE Drilling Replacement Set does not have contraindications if its recommendations are correctly followed and it is used by a qualified professional that will be responsible for the proper planning of the surgical procedure in which it will be used.

SIDE EFFECTS

The UNITITE Drilling Replacement Set does not have side effects if the choice of instrument and technique is proper to the procedure.

PRECAUTIONS AND RECOMENDATIONS

It is recommended to use up to 20 to 30 perforations, including:

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

It is recommended that immediately after use, the kit and its components are washed and sterilized.

Do not stick labels, tapes, write, or mark the surface of the product.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of dental drillings. All items may appear a natural wear due use and they should be replaced whenever the professional identifies loss of fitting capacity or accuracy of these products, as they may interfere with final work results.

TRACEABILITY

All S.I.N. – Sistema de Implante 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 to the distribution time.

STORAGE

The UNITITE Drilling Replacement Set must be stored in a cool and dry place, keep away from sunlight.

TRANSPORTATION

The UNITITE Drilling Replacement Set must be transported in room temperature, away from direct sunlight, avoiding places where large variations of temperature and humidity occur. The transportation must be carried out properly to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

The UNITITE Drilling Replacement Set, once sterilized, must be handled only in a sterile field by properly trained professionals and in appropriate scrubs at the time of the surgical procedure.

ADDITIONAL INFORMATION

Multiple use product. Reprocessing Allowed. Check Cleaning and Sterilization Conditions included in these Instructions of Use.

CLEANING INSTRUCTIONS

1. Pre-cleaning or De-embedding

- a. Remove the organic matter from the instruments without manual contact.
- b. Begin cleaning or de-embed quickly after surgical use.

Recommendations

- a. Wear appropriate scrubs (gloves, masks, goggles, caps, etc.).
- b. Use enzyme solutions at the concentration and time of exposure determined by the manufacturer of these chemical solutions.
- c. Perform a single rinse, directly in a stream of water, without the handling of the instruments.

2. Decontamination

- a. The cleaning of microorganisms in vegetative form
- b. This type of cleaning offers occupational hazards.

Recommendations

- a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- b. Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

3. Washing

- a. It is the removal of debris from surgical instruments through manual brushing or ultrasonic vibrations.

Recommendations

- a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- b. Use neutral soap at 1% or neutral detergent, both at pH 7.0.
- c. Always use brushes with natural or Nylon bristles for cleaning racks, serrations and fittings.
- d. Never use steel straws or sponges and abrasive products not to damage the instruments.
- e. Do not accumulate instruments in large quantities on top of one another to avoid deformation of minor and delicate parts.
- f. Try to handle a few pieces at a time.
- g. Ultrasonic cleaning, if used, should have the washing solution heated to at least 45°C and the instruments should be placed in the open position for 3 to 5 minutes of immersion at a frequency of 35 KHz.
- h. There may also be the need to brush the serrated parts and joints.

4. Rinse

- a. It is the removal of chemical residues, detergents and foams still present in the instruments.

Recommendations

- a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- b. Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

5. Drying

- a. It is the removal of residual water and moisture, after the rinsing procedure.

Recommendations

- a. Never let the instrument dry naturally.
- b. Always use soft, absorbent fabric (e.g. compresses) or moisture-free compressed air.
- c. Never use dry heaters to dry the S.I.N. instruments.

STERILIZATION

It is the procedure that aims at the total elimination of microorganisms (viruses, bacteria, microorganisms, and fungi), either in vegetative or sporulated form.

Recommendations

- a. Dry all instruments before the steam sterilization cycle.
- b. Use mechanical and chemical indicators (place the internal chemical indicator between instruments or materials to be sterilized) for each sterilization cycle.
- c. Allow instruments to dry and cool in the sterilizer before handling to prevent contamination and oxidation of materials.

- d. The autoclavable case can be sterilized at 121°C at 1 ATM pressure for 30 minutes or at 134°C at 2 ATM pressure for 20 minutes.
- e. Always place the case in an autoclave on a flat surface and away from the edges of the device.
- f. Never overlap objects or even other cases.
- g. Chemical sterilization is not recommended as some products may cause discoloration and damage to the case.

DISPOSAL OF MATERIAL

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

EXPIRATION DATE

Indicated on the label.