UNITITE SHORT DRILL KIT - KSDU

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON ESTERILE	NO ESTÉRIL
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
CE	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.

DEVELOPED AND MANUFACTURED BY:

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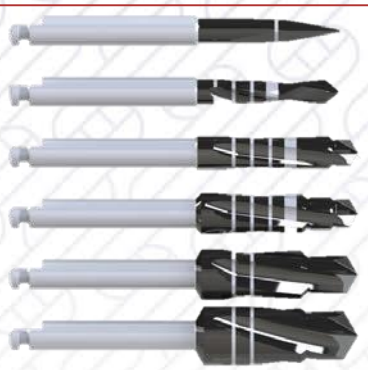
PRODUCT:

UNITITE SHORT DRILL KIT – KSDU
Anvisa Registration: 80108910074

CE

The Unitite Short Drill Kit is 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 in proper conditions for the health and safety of the patient.



PRODUCT DESCRIPTION

The Short Drill Unitite Kit is a kit consisting of the line of surgical drilling required for the installation of UNITITE Prime and UNIITE Slim implants.

INDICATIONS OF USE

The Short Drill Unitite Kit is intended to assist in the installation of the UNITITE implant family.
Millings are indicated to perform a stepped and controlled drilling for a correct insertion of the implant.

Lance Pilot Drill: 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 Drill: Aimed to deepen the perforation in the bone tissue according to the planning carried out by the professional.
Unitite Drill (Conical): It aims at progressive enlargement of the drilling and to promote a greater control of the performed work, until the final dimension of the drilling allows the installation of the implant.

OPERATION PRINCIPLE

Drilling contained in the UNITITE SHORT DRILL KIT base their working principle on the mechanical action of cutting the bone/mucosa through its surface.

As the material from which the drills are manufactured is harder and more resistant than these, by printing the rotational movement to the drills cut the tissue promoting the removal of material that varies according to the geometry of each commercial model in this presentation.

HOW TO USE

1. Open the original package and remove the drill;
2. Before the first use or after having been used in surgical procedures, perform the Cleaning and Sterilization instructions contained in this Use Instructions.
3. Once sterilized, the drills is ready for use in surgical procedures.

CONTRAINDICATIONS

The UNITITE SHORT DRILL KIT does not present contraindications if its recommendations are correctly followed and used by a specialized professional, who will be responsible for the adequate planning of the surgical procedure in which it will be used. None of the instruments are for permanent/implantable, only for transient use during surgery.

SIDE EFFECTS

The Unitite Short Drill Kit has no adverse effects provided that the choice of instrument and technique is appropriate to the procedure.

PRECAUTIONS AND RECOMMENDATIONS

The Unitite Short Drill Kit requires specialized surgical procedures, and must 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 inadequate procedures and conditions may impair the final outcome of the treatment and the patient leading to unsatisfactory results.

It is recommended to use up to 20 to 30 perforations, which are:

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

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of dental drilling. 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. products - Implant System 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 Short Drill Kit must be stored in a dry, fresh and ventilated place away from direct sunlight;

TRANSPORTATION

The Unitite Short Drill Kit 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, in order 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 in appropriate attire at the time of surgery to install dental implants.

ADDITIONAL INFORMATION

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

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.

a. Never use saline solutions, especially sodium Hypochlorite and physiological 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 a temperature of 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 physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

5. Drying

a. Is the removal of residual water and moisture, after the rinse procedure

Recommendations

a. Never let the instrument dry naturally.
b. Always use soft, absorbent fabric (e.g. Compressed material) 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, bacterias, 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 a temperature of 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. The chemical sterilization is not recommended as some products may cause discoloration and damage to the case.

DISPOSAL OF MATERIALS

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

EXPIRATION DATE

Indicated on the label.