S.I.N. ROTARY EXPANDER KIT

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR AS 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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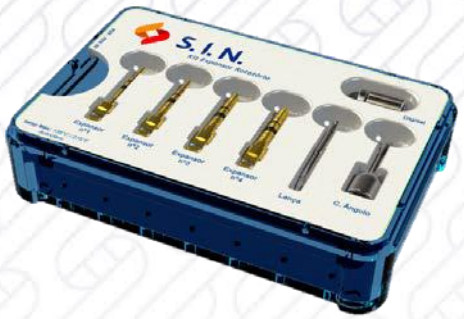
PRODUCT:

S.I.N Rotary Expander Kit - KER

Anvisa Registration: 80108910062

CE

The S.I.N. Rotary Expander 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 Rotary Expander Kit is a Kit consisting of rotary expanders, wrenches and a miller cutter shaft.

INDICATIONS OF USE

Rotary expanders are used as surgical instruments during the procedures of bone compactation or partial lifting of the maxillary sinus, not being implantable. They allow the installation of bone-integrated implants, with no or little use of drills to betteruse of the remaining bone tissue of the patient, often avoiding the need for bone grafting.

OPERATION PRINCIPLE

The operation principle applicable to Rotary Expanders is rotary and lever, that is, purely mechanical. The torque exerted on the square drive is transferred throughout the body of the instrument, to the proximal end that operates in the surgical site compacting the bone tissue.

DIRECTIONS

The dental surgeon must use the Rotary Expander in bone compactation procedures or partial for lifting of the maxillary sinus, following the aseptic surgical techniques, appropriate for each case. Described below, follows a suggested script to use Rotary Expanders in cases of bone compactation and partial lifting of the maxillary sinus. After the use of Rotary Expanders, separate them from other materials, wash and sterilize them following the instructions described in these operating instructions.

Bone Compaction:

1. First of all, the bone is subjected to a perforation in the implant site to be fitted with the milling cutter shaft, and then followed with the hellcoidal cutter to the planned depth. This process assumes an exact planning in the radiological image;
2. Before using the instruments, it is recommended to carefully observe the instrument height markings in order to not exceed the predetermined working depth;
3. Straight instruments allow easier access in the back area;
4. The larger diameter instruments are inserted manually with slightly rotating movements with the aid of a torque wrench or bi-digital wrench, in accordance with the length and diameter of the desired implant;
5. Careful insertion of the implant is recommended.

Partial lifting of the maxillary sinus floorboard:

1. First of all, the bone is subjected to a perforation in the implant site to be fitted with the milling cutter shaft, then the helicoidal cutter to the maxillary sinus floorboard boundary, with due care not to break such cortical with the cutter. This process assumes an exact planning in the radiological image;
2. Before using the instruments, it is recommended to carefully observe the height markers in order not to exceed the pre-determined working depth. Straight instruments allow easier access in the posterior area;

3. In a first step, the floorboard of the maxillary sinus is fractured, which requires exact radiological planning. It is recommended to carefully observe the height markings of the instrument, to not exceed the previously defined in the planning. The instrument is advanced with light twists clockwise, according to the desired implant length;
4. During lifting, a filler or an autologous bone and/or alloplastic material can be applied to the implant bed. The inserted material has the effect of a pad, thus, raising the Schneider membrane, according to the hydraulic principle;
5. Careful insertion of the implant is recommended.

CONTRAINDICATIONS

The S.I.N. Rotary Expander Kit has no contraindications provided its recommendations are properly followed and used by a specialized professional who will be responsible for the proper planning of the surgical procedure in which the SIN Rotary Expander Kit will be used.

SIDE EFFECTS

The S.I.N Rotary Expander Kit is used to assist in the installation of dental implants, thus adverse effects may occur only if the instrument choice is not appropriate.

PRECAUTIONS AND RECOMMENDATIONS

To use the S.I.N. Rotary Expander Kit it is recommended that the professional has a specialization course in Implantology or Oral and Maxillofacial Surgery. The professional must put the patient through a detailed anamnesis to diagnose cases mentioned below in contraindications. Excessive use of Rotary Expanders, bad positioning, added to the lever stress caused during use of the product may jeopardize the work tip of the expanders. The professional should be alert to the force exerted at the time of use of the product not to cause the patient and the product to be harmed. Before using the S.I.N. Rotary Expander Kit , the professional must sterilize it, according to standard sterilization protocol observing the drying cycle.

The S.I.N. Rotary Expander Kit should be cleaned after use with flowing water with mild detergent and a soft sponge. After rinsing, the instruments of the S.I.N. Rotary Expander should be dried with air jets to prevent rusting.
The professional must: prepare an environment with sterile gowning and surgical field, submit the patient to a good mouth asepsis, avoid contact with any non-sterile object when using the product to minimize the risk of contamination.
The professional must inform the patient: the risks related to the surgical procedure, the appropriate form of sanitation, the need for regular monitoring so that it avoids physical efforts after surgery.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of Rotary Expanders. All items may present 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. - 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 until the moment of distribution

STORAGE

The Rotary Expander Kit must be stored in a dry, fresh, and ventilated place away from direct sunlight;

TRANSPORTATION

The Rotary Expander 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 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.

COMPLEMENTARY 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 shortly 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 physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

3. Cleaning

a. It is the removal of dirt from surgical instruments by manual brushing or ultrasonic vibrations.

Recommendations

a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated for easy 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. For ultrasonic cleaning, a wash solution should be heated to a temperature of at least 45° C and 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. Rinsing

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. It 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. 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 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 walls of the unit.
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.