






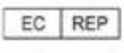


SYMBOLS	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO 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 COMUNIDADE EUROPEA
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTES DISPOSITIVOS 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:

Revolution Compact Surgical Kit - KRC

Anvisa Registration: 80108910060

CE

The Revolution Compact Surgical Kit - KRC is intended to 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 surgical kit Compact Revolution - KRC is a kit comprising the full range of milling Compact Revolution of implants.

INDICATIONS OF USE

The surgical kit Compact Revolution is indicated to perform drilling bone implant Compact Revolution family.

OPERATION PRINCIPLE

The instruments in the Revolution Compact Kit base their working principle on mechanical action. All instruments are indicated for use in the placement of Revolution Compact family implants and should be used following appropriate dental techniques.

HOW TO USE

1. Select the set of milling cutters required to obtain the proper drilling of the area taking into account the desired length and width.
2. Ensure that the milling cutters are properly sterilized before the procedure (see sterilization conditions in this use instruction manual).
3. At the appropriate time, insert the milling cutter into the counter angle or wrench and ensure that it is properly secured.
4. Perform the desired drilling.
5. Continue the surgical procedures.

Because it is an advanced surgical technique, installing implants using the Surgical Kit Compact Revolution, should be performed by professionals with deep technical knowledge acquired in the course of specialization in Implantology.

CONTRAINDICATIONS

The Revolution Compact Kit does not present contraindications since its recommendations are followed correctly and used by a specialized dental surgeon for implant surgery.

ADVERSE EFFECTS

The Revolution Compact Surgical Kit is used to aid in the installation of implants, so adverse effects will occur only if the choice of instruments is inappropriate.

PRECAUTIONS AND RECOMMENDATIONS

The Revolution Compact Surgical 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 inappropriate procedures and conditions may adversely affect the final treatment result and the patient leading to unsatisfactory results. For cutter, a maximum use of 20 to 30 drillings is recommended, being it:

- 20 drillings in high density bones
- 30 drillings in low density bones

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

It is recommended to immediately wash and sterilize the kit and its components after use.

WARNING

Do not use the instrument 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. Some items feature natural wear by use, such as cutters, and must be replaced whenever the professional identify loss of cutting capacity and precision of these products, as they may interfere with the outcome of the treatment.

TRACEABILITY

All S.I.N. Implant System products have sequential batches for traceability, which promotes greater safety for the professional qualified to the procedure. With this batch number, it is possible to access the entire history of the product from the manufacturing process to the distribution time.

STORAGE

The Revolution Compact Surgical Kit - KRC should be stored in a dry, fresh, ventilated place away from direct sunlight;

TRANSPORTATION

The Revolution Compact Surgical Kit - KRC should be transported at room temperature, away from direct sunlight, avoiding locations where large variations in temperature and humidity occur. The transportation must be carried out properly to avoid falling 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 gowning at the time of surgery to install dental implants. Risks, creases or indentations of the instruments should be avoided as such factors may increase the possibility of corrosion of the products.

ADDITIONAL INFORMATION

Multiple use product. Exclusive for dental use. Reprocessing Allowed. Refer to the cleaning and sterilization conditions in these Instructions.

CLEANING INSTRUCTIONS

1. Pre-cleaning or De-embedding

Remove the organic matter from the instruments without hand contact.

Begin cleaning or de-embed quickly after surgical use.

Recommendations

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

2. Decontamination

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

Recommendations

- 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.
- Never use saline solutions, especially sodium hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

3. Washing

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

Recommendations

- 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.
- Use neutral soap at 1% or neutral detergent, both at pH 7.0.
- Always use brushes with natural or Nylon bristles for cleaning racks, serrations and fittings.

- d. Never use steel wool 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.

Try to handle a few pieces at a time.

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.

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. 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. Set 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 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.