

SYMBOLOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	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
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.

## DEVELOPED AND MANUFACTURED BY:

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## PRODUCT:

KZ – Zygomatic Set

Anvisa Registration: 80108910037



The Kit KZ - Zygomatic Set is intended 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 KZ – Zygomatic Set is a Kit consisting of fasteners, cutters, depth rods, and lip protector.

## INDICATIONS OF USE

The KZ – Zygomatic Set is composed of surgical instruments used to drill the alveolus and for the installation of the Zygomatic Implant.

**Fasteners:** They help in the fixation or removal of components and implants.

**Cutters:** Recommended to perform the removal of material in the restoration procedures;

**Lip Protector:** Protects the patient's lip during the drilling of the alveolus.

**Rod:** They are recommended to assist and guide a correct drilling.

## OPERATION PRINCIPLE

The instruments contained in the Kit base their working principle on mechanical action. All instruments assist in the surgery to install the Zygomatic Implant;

## MODE OF USE

Surgery techniques vary according to the choice of the surgeon, and the surgeon has the final choice of method, type and size of the products to be employed, as well as the criteria for evaluating the results of the surgery.

1. To carry out sterilization of the Instrumental Kit for placement of zygomatic implants according to the instructions recommended below.
2. To handle the instruments of the Instrumental Kit for implant placement only in appropriate environments with due care (only be handled with sterile gloves). Only trained professionals should handle the Instrumental Kit.
3. Aseptically remove the kit box from the from the sterilization package.
4. Open the box and check if all the instruments are present before starting the surgical procedure.
5. Perform the Zygomatic implant technique according to previous training of the surgical implant technique.
6. After the surgery is finished, immediately wash all the instruments and sterilize them, according to the instructions for use.

## CONTRAINDICATIONS

The KZ - Zygomatic Set 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 the Kit will be used.

## ADVERSE EFFECTS

The KZ Kit – Zygomatic Set has no adverse effects.

## PRECAUTIONS AND RECOMMENDATIONS

Each patient should be carefully examined and assessed in order to determine the radiographic, psychological, and physical state, as well as dental, bone or adjacent soft tissue deficits

That may influence the final outcome of the intervention. The patient should be instructed to maintain a perfect oral hygiene.

**Surgical Procedure:** Every effort should be made to minimize host tissue damage, with special focus on thermal or surgical trauma and on the elimination of contaminants and other sources of infection. The surgical procedure requires a high level of accuracy and care due to the limits for acceptable tissue handling being much narrower than in the case of general oral surgery. Any divergence from the principle of the least possible injury during the installation of the implants increases the risk of non-bone integration on part of the component. All drilling procedures should be performed at low speed (around 800 to 1200 rpm). The procedures should be performed with delicate and well-sharpened instruments under constant and abundant irrigation for adequate cooling. All instruments used in the intervention must be kept in good conditions. Due to the reduced dimensions of instruments, extreme care should be taken to prevent the patient from swallowing or aspirating them.

## WARNING

There are surgical instruments appropriate for each stage of surgery. The usual wear and tear, excessive force exertion, and the use of instruments for project-excluded purposes may impair procedure evolution and implant damage. The combination of SIN products with those of other manufacturers may present variations in material, design or quality. The use of separate instruments may entail the risk of improper fixation and other technical complications. The instruments are metallic components that are subject to important mechanical demands during continuous use for a variable and indefinite term, requiring inspection and revision for its conditions of use.

In case of performance deviation, loss of precision, instability or loss of cutting capability, it should be immediately replaced.

For milling cutters, it is recommended to use up to 20 to 30 perforations, which are:

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

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

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

## 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 KZ Kit – Zygomatic Set must be stored in a cool and dry place and away from sunlight.

## TRANSPORTATION

The KZ Kit – Zygomatic 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

Once sterilized, instruments should be handled only in a sterile environment by properly trained professionals and wearing appropriate gowning at the time of surgery to install dental implants. Risks, creases or indentations of the surgical instruments should be avoided as such factors may increase the possibility of corrosion of the products.

## COMPLEMENTARY INFORMATION

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



## CLEANING INSTRUCTIONS

### 1. Pre-cleaning or Desincrustation

- a. Remove the organic matter from the instruments without manual contact.
- b. Begin cleaning or desincrustation 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 such chemical solutions
- c. Perform a single rinse, directly in a stream of water, without the handling of the instruments

### 2. Decontamination

The cleaning of microorganisms in vegetative form. 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 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. 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

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 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.