






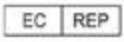


SYMBOLOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO 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
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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RESPONSIBLE TECHNICIAN:

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PRODUCT:

TI Instruments
Anvisa Registration: 80108910022

CE

TI Instruments are 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

TI Instruments are indicated to aid in the placement of implants and other surgical procedures following the appropriate dental techniques.

INDICATIONS OF USE

All instruments are recommended to assist in the placement of implants and other surgical procedures, as follows:

Fixer: Aids in the fixation or removal of components and implants.

Rounder, Cylinders and Washer head: They are recommended to assist and guide a correct drilling.

Expanders and Milling Screw: Used to ground the thread.

Lip Protector: Protects the patient's lip during milling.

Waste: Used for easy handling of components and implants in the surgical procedure.

Hammer: Used in maxillary sinus elevation surgeries.

Vacuum: Used in the suction of irrigation serum and secretions generated in the surgery.

Stabilizers: Assist in the setting of surgical guides.

OPERATION PRINCIPLE

All dental instruments are based on mechanical principles of power transmission, for the activation of secondary elements (such as keys).

HOW TO USE

1. Open the original packaging and remove the Instruments;
2. Before first use or after having using them in surgical procedures, perform the cleaning and sterilization procedures contained in these Instructions of Use.
3. After sterilization, the instruments are ready for use.

CONTRAINDICATIONS

The TI Instruments do not present contraindications if their use recommendations are correctly followed and if they are used by specialized professionals.

SIDE EFFECTS

Not Applicable. Adverse effects will occur only if the choice of instruments is inadequate.

PRECAUTIONS AND RECOMMENDATIONS

The product should only be used by qualified dentistry professionals who already have all the scientific information necessary for the correct use of the product.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause instrument performance problems.

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

TI Instruments should be stored in a dry, fresh and ventilated place, away from direct sunlight;

TRANSPORTATION

TI Instruments should be transported at room temperature, away from direct sunlight, avoiding locations where greater variations in 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 in appropriate suits at the time of the surgical procedure.

COMPLEMENTARY INFORMATION

Multiple use product. Reprocessing Allowed. Refer to the cleaning and sterilization conditions contained in these 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 handling 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. 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.

- a. Always use brushes with natural or Nylon bristles for cleaning racks, serrations and fittings.
- b. Never use steel straws or sponges and abrasive products not to damage the instruments.
- c. 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.

The 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. 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 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, once 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.