

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 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:

S.I.N. Sistema de Implante Nacional S/A

CNPJ: 04.298.106/0001-74

Rua Soldado Ocimar Guimarães da Silva, 2445 Vila Rio Branco Zip Code: 03348-060 - São Paulo - SP - Brasil Fone/Fax: +55 (11) 2169-3000

SERVICE TO PROFESSIONALS

0800 770 8290

+55 (11) 2169-3000

www.sinimplante.com.br

email: sin@sinimplante.com.br

EC REP

OVER-REV-UNIPESOAL LDA.

Rua General Ferreira Martins, nº10 - 8D 1495-137 Algés - Portugal

TECHNICIAN RESPONSIBLE:

Alessio Di Risio

CREA-SP: 5061207169

PRODUCT:

Tryon Surgical Kit - KCHE 03

Anvisa Registration: 80108910081

CE

The Tryon Surgical Kit is for specialized procedures, which must be performed by qualified professionals. The use of the product and surgical technique is subject to the professional's training. The use of the product must be performed in a sterile environment and in proper conditions for the health and safety of the patient.



PRODUCT DESCRIPTION

The Tryon Surgical Kit is a Kit composed by the complete line of instruments such as Cutters, Wrenches, Male Threads and other instruments required for the installation of Tryon, Conical Tryon and Revolution Micro Mini implants, also offering the Surgical Torque Wrench.

INDICATIONS OF USE

The Tryon Surgical Set is indicated to help the installation of the Tryon, Conical Tryon, and Revolution Micro Mini implant families.

OPERATION PRINCIPLE

The instruments contained in the TRYON Surgical Kit base their working principle on mechanical action. All instruments are indicated for use in the placement of Tryon, Conical Tryon, and Revolution Micro Mini implants, and should be used following appropriate dental techniques.

DIRECTIONS

The form of use is inherent to the training of the professional responsible for using the material. It can only be used and/or applied by dental surgeon specialized in implant surgery.

CONTRAINDICATIONS

The Tryon Surgical 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 the Kit will be used.

SIDE EFFECTS

The Tryon Surgical Kit is used to assist in the installation of dental implants, thus adverse effects may occur only if the instrument choice is inappropriate.

PRECAUTIONS AND RECOMMENDATIONS

The Tryon 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 impair the final outcome of the treatment and the patient leading to unsatisfactory results.

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.

WARNING

Do not use the instruments 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 may present natural wear due use and they should be replaced whenever the professional identifies loss of cutting capacity or accuracy of these products, as they may interfere with final treatment 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 Tryon Surgical Kit must be stored in a dry, fresh, and ventilated place away from direct sunlight;

TRANSPORTATION

The Tryon Surgical 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 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 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 such chemical solutions
- c. Perform a single rinse, directly in a waterjet, 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, 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

- 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. Instruments.

CLEANING INSTRUCTIONS FOR THE TORQUE WRENCH

1. Rotate the torque wrench drum counterclockwise until it is fully loosened.
2. After releasing the drum, remove the body and the head of the torque wrench.
3. Remove the spring and washers from the torque wrench
4. Start the washing procedure by:
 - Immersing the parts in a detergent aqueous solution with neutral or enzymatic pH and place them on ultrasound for 30 minutes.
 - Then clean the parts using a brush with soft bristles, detergent and running water, rubbing carefully.
 - Rinse thoroughly, and the last rinse should be in deionized or demineralized water.
 - Dry with compressed air.
 - After complete drying, the Torque wrench is assembled following the same disassembly procedure but in reverse order.

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.