


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 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 CEP: 03348-060 - São Paulo - SP - Brazil

Phone/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-UNIPESOAAL LDA.

Rua General Ferreira Martins, no. 10 – 8D 1495-137
Algés - Portugal

RESPONSIBLE TECHNICIAN:

Alessio Di Risio

CREA-SP: 5061207169

PRODUCT:

Tryon Surgical Set - KCHE 02

Anvisa Registration: 80108910070

CE

The Tryon Surgical Kit – KCHE 02 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 Tryon Surgical Set consist of Fixers, Cutters, Direction Cylinders, Depth Rod and Hook are necessary instruments for the installation of Tryon and Revolution Micro Mini implants, also offering the surgical fastener torque.

INDICATIONS OF USE

The Tryon Surgical Set is indicated to help in the installation of the Tryon and Revolution Micro Mini Implants, containing,:

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

Strawberries (Countersink, Pilot, Spear and Helical): Indicated for perforation of the bone tissue for implant installation.

Cutter Thread / Male Thread : Indicated for making the thread in the bone tissue before implant placement.

Direction cylinders: Indicated to assist and correct drilling.

Depth Rod: It allows to measure depth quickly and easily in the initial milling stage.

Connector Hook: Used to attach over the implant fitting and install the implant with the contra angle.

OPERATION PRINCIPLE

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

HOW TO USE

The form of use is inherent to the training of the professional who will use the material. It can only be used and/or applied by dentists specialized in surgery/implant dentistry.

CONTRAINDICATIONS

The Tryon Surgical Set does not present contraindications since its recommendations are followed correctly and used by a specialized dental surgeon for implant surgery. None of the instruments are for permanent/implantable, only for transient use during surgery.

ADVERSE EFFECTS

The Tryon Surgical Set 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 Tryon Surgical Set requires specialized surgical procedures, only to 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 inadequate 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 drillings high-density bones;
- 30 drillings 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 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 present wear-and-tear, such as cutters, and should be replaced whenever the professional identifies loss of cutting ability or accuracy of these products as they may interfere with the final treatment result.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches for 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

Tryon Surgical Set must be stored in a cool and dry place, keep away from sunlight.

TRANSPORTATION

Tryon Surgical 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 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 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 gowning (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 water jet, 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. Washing

- 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 parts at a time.
- g. For ultrasonic cleaning, a wash solution should be heated to a temperature of 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.
- h. There may also be the need to brush the sawn 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. Instruments.

CLEANING INSTRUCTIONS FOR THE TORQUE WRENCH

Cleaning must be carried out immediately after use of the torque wrench. For cleaning, the torque wrench must be dismantled, so it is not necessary to use tools.

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. 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, wiping carefully. Rinse well, and the last rinse should be in deionized or demineralized water. Dry with compressed air.
 - After complete drying, mount the Torque wrench following the same disassembly procedures 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.