

The Tryon Conical Millings Replacement Set is intended for expert 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 Set of Tryon Conical Milling Replacement is a kit composed by the Surgical Milling Lines required for the installation of Tryon Conical implants.

INDICATIONS OF USE

The Set Rep. Of Tryon Conical Milling Set is indicated to help the installation of the Tryon Conical implants' line. It is composed by three conical millings.

The millings are indicated to perform the removal of material in reconstruction procedures (dental/buco-maxillo facial/orthodontic) with the objective of performing a stepped and controlled drilling to have a correct insertion of the implant.

Conical Milling: It aims to deepen the perforation in the bone tissue according to the planning carried out by the professional.

OPERATION PRINCIPLE

Milling contained in the Set The Tryon Conical Milling Replacement Set are based in the working principle on the mechanical action of bone cutting, across its surface. As the material from which the millings are produced is harder and more resistant than these, by printing the rotational movement, the millings cut the tissue, promoting the removal of material, which varies according to the geometry of each commercial model presented.

HOW TO USE

1. Open the original package and remove the milling;
2. Prior to first use or after having been used in surgical procedures, perform the cleaning and sterilization procedures contained in these Use Instructions;
3. Once sterilized, the milling cutter is ready for use in surgical procedures.



ATTENTION

The Set of Tryon Conical Milling Replacement is intended for specialized procedures, which should be performed by qualified professionals in dentistry. The use of the product must be performed in a surgical environment and under appropriate conditions for the health and safety of the patient.

PRECAUTIONS

The Set Rep. Of Tryon Conical Millings 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 inadequate procedures and conditions may impair the final outcome of the treatment and the patient leading to unsatisfactory results.

RECOMMENDATIONS

It is recommended to use between 20 to 30 perforations, including:

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

It is recommended that immediately after use, the kit and its components are washed and sterilized.

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

CONTRAINDICATIONS

The Set The Tryon Conical Milling Replacement Set does not have contraindications if its recommendations are correctly followed and it is used by a qualified professional that will be responsible for the proper planning of the surgical procedure in which it will be used.

SIDE EFFECTS

The Set The Tryon Conical Milling Replacement Set does not have side effects if the choice of instrument and technique is proper to the procedure.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of dental millings. 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. - Implant System products have sequential batches that allow for traceability, thus providing greater security to the professional who is qualified for the procedure. Through this lot number it is possible to know the entire history of the product from the manufacturing process to the moment of distribution.

STORAGE

The Set Tryon Conical Milling Replacement Set must be stored in a cool and dry place, keep away from sunlight.

HANDLING

The Set of Tryon Conical Milling Replacement Set, once sterilized, must be handled only in a sterile field by properly trained professionals and in appropriate scrubs at the time of the surgical procedure.

DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

TRANSPORTATION

The Set Tryon Conical Milling Replacement 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.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive of Odontological use. Possible of reprocessing. See cleaning and sterilization conditions contained in this use instruction. In case of any incident caused by the product, the professional must inform the manufacturer immediately. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplante.com.br or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Remove manually all surgical instruments from the kit. Remove the kit box parts (lid, tray and bottom).

2. Prepare the enzymatic detergent, according to manufacturer's recommendation.
3. Immerse the trays into the prepared detergent solution and keep in contact for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove trays from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
5. Visual inspection of each part for cleaning process residue or organic waste from product use.
6. If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
7. Dry with a soft, clean, dry cloth or disposable paper.

RECOMMENDATIONS

- a. Use the proper PPEs (gloves, masks, goggles, caps, etc.).
- b. Start the cleaning right after the surgical use.
- c. Never let the instruments dry with organic waste after the surgical use.
- d. Never let the instrument dry naturally after cleaning.
- e. Never use saline solutions, include sodium hypochlorite, disinfectant, hydrogen peroxide or alcohol to cleaning or rinsing the surgical instruments and kits.
- f. Never use steel wool and abrasive products, so that the instruments are not damaged.
- g. Do not stack the instruments in lots to avoid the deformation of smaller and delicate pieces.

STERILIZATION

Reusable product and provided non-sterile. It must be clean and sterilized in autoclave before use.

1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed in a steam sterilizable wrap.
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave over a plane surface and away of device walls.
5. Never stack objects or other cases.

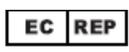
RECOMMENDATIONS

- a. Sterilize the products in the same day or one day earlier the procedure.
- b. The chemical sterilization is not recommended, once some products may cause the discoloration and damages to the case.
- c. Do not use temperature higher than 60°C to drying process.
- d. Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N. - Implant System.

LIFE TIME

The KRFTC Kit - Tryon Tapered Milling Cutter Replacement Set can be used as follows depending on proper handling, cleaning and sterilization.

Tapered Cutters: 20 Perforations in high density bone (type I and II) and 30 perforations in low density bone (type III and IV).

	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
	LIMITE SUPERIOR DE TEMPERATURA	UPPER LIMIT OF TEMPERATURE	LÍMITE SUPERIOR DE TEMPERATURA
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.
	FABRICANTE	MANUFACTURE	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCLABLE PACKAGING	EMBALAJE RECICLABLE

DEVELOPED AND MANUFACTURED BY:

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

CNPJ: 04.298.106/0001-74

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EC	REP
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PRODUCT: KRFTC - Set Rep. Of Tryon Conical Millings

ANVISA REGISTRATION: 80108910082