Tryon

Tryon® is the classic S.I.N. implant. This line has external hexagon and cone morse connections with double acid-etching surface treatment that ensures high primary stability, efficiency and safety for your surgeries.

PRODUCT DESCRIPTION

Tryon implants are produced in commercially pure Titanium (Grade 4). The macrogeometry of the implant is cylindrical (Tryon Cylindrical model: SAT, ST and CY) or conical (Tryon Conical model: SC and CO), and external hexagon and cone morse prosthetic coupling. The implant surface is roughened by a double acid etching process. It comes with the cover screw as an accessory.

Implant Diameters (mm)	Length (mm)
3.25, 3.5, 3.75, 4.0, 5.0	7.0, 8.5, 10, 11.5, 13, 15.

Implant Chemical Composition according ASTM F67:

Chemical Element	Composition % (mass/mass)
Nitrogen	≤ 0.05
Carbon	≤ 0.08
Hydrogen	≤ 0.015
Iron	≤ 0.50
Oxygen	≤ 0.40
Titanium	Balance

The cover screw is according ASTM F136:

Chemical Element	Composition % (mass/mass)
Nitrogen	≤ 0.05
Carbon	≤ 0.08
Hydrogen	≤ 0.012
Iron	≤ 0.25
Oxygen	≤ 0.13
Aluminum	5.5 - 6.5
Vanadium	3.5 - 4.5
Titanium	Balance

INDICATIONS OF USE

The Tryon are indicated for human adults and elderly with good general health, surgical procedures in maxillary or mandibular bones generating a support platform for the installation of prosthetic components that will receive an artificial tooth, restoring the patient's masticatory function. They can be used in conventional procedures (1 and 2 surgical stages) and immediate loading (activation in up to 48 hours) when there is acceptable primary stability (above 45N.cm) and proper occlusal load. They can be used in single or multiple restorations. **Tryon Cylindrical (SAT, ST and CY):** Implant models indicated for all bone types. **Tryon Conical (SC and CO):** Implant models indicated for type III and IV bones.

PURPOSE AND OPERATION PRINCIPLE

The purpose is to replace missing, condemned teeth or conventional prostheses, with the aim of restoring aesthetics and masticatory function, stopping bone resorption and reducing overload on remaining teeth.

HOW TO USE THE TRYON EXTERNAL HEXAGON AND CONE MORSE IMPLANTS

The Tryon line has models that meet the surgical installation in any bone density, in maxilla or mandible, provided that the maximum insertion torque (80N.cm) is respected. In case the installation reaches a torque that exceeds the limit, it is recommended to use a specific males drill for each model before the end of the installation. The males drill can be used in the surgical alveolus with ratchet or counter-angle depending on the fitting of the purchased product. For the implants with morse taper connection a 1.5 mm intraosseous installation must be performed, whereas for the implants with external hexagon connection the installation must be performed at bone level.

- Remove the blister from the outer cartridge.
- Keep the traceability labels that came with the product.
- In sterile surgical field and after breaking the sterile sealing of the blister, grasp the primary package (tube) with the non-dominant hand and open the lid.
- The implant will be exposed inside the tube to capture the driver.
- For motor installation, use the contra-angle driver.
- Grab the implant by holding the driver still and rotating the internal support slightly, looking for the perfect fit between the connection and the Implant. Press the driver to the implant to get better fixation.
- Transport the implant to the bony site.
- In the surgical motor, use a maximum torque of 35 N.cm and rotation between 20-40 RPM.
- Preferably, complete the Implant installation with the Surgical Torque driver or a ratchet driver.
- The recommended maximum installation torque is 80 N.cm.
- The choice between installing the implant cap, healing or prosthetic component is at the professional's discretion.
- Select the intermediaries between the Implant and the prosthesis, observing its indications and limitations, according to the applicable literature.

⚠ ATTENTION

Tryon implants are intended for specialized procedures, which must be performed by qualified professionals in implantology. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTION

Observe the conditions of intra-oral tissues, bone quality and bone quantity of the Implant receptor site, through radiographic and/or tomographic exams. Failure to perform the pre-surgical assessment can lead to the impossibility of finding pre-existing diseases. Consider the general health conditions of the patient. The patient must undergo a thorough clinical and radiological analysis before the surgery to assess the physical and psychological conditions of the patient. Patients that present local or systemic factors that may interfere with the healing processes of bone or soft tissues or in the integration process should receive special care. Handle the material only in sterile field. All materials used in the procedure must be sterile. Sterilization is only ensured if the secondary packaging (blister) is not damaged. Do not use the product if the package is damaged. Only open the package at the time of surgery and use the product immediately. Implants not used after opening the carton should be discarded Expired products should not be used. In rehabilitations of a surgical stage (immediate loading), the primary stability should reach at least 45 N.cm. The maximum angulation allowed for S.I.N. is up to 30 degrees. An insertion torque higher than the recommended maximum can damage the product, causing the loss of its primary function. Observe the conditions of use of surgical instruments. Drill and other instruments with low cutting power can generate heating during use, which hinders the osseointegrated process. Replace instruments in case of damage, erasure of marks, impaired sharpening, deformation, and wear. The surgical motor used in the procedure should be adjusted according to the specification of the implant to be used (torque and RPM). Check your motor and angling conditions before surgery. If necessary, perform preventive/corrective maintenance with the manufacturer. Deregulated equipment may directly interfere with the product performance during the surgical and prosthetic procedure, only use components and instruments specified by S.I.N.; they have specific dimensions and tolerances for each implant system to ensure the product longevity. Other brand components or adapted to implant models may reduce the life time of the system and cause irreversible damage. The professional should ensure that the patient does not aspirate the product. The professional is responsible for using S.I.N. in accordance with the instructions for use, as well as determining if it suits the individual situation of each patient. The patient should be informed about all possible surgical complications, contraindications, warnings, precautions, and side effects. All documentation accompanying the product should also be made available to the customer. 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.

RECOMMENDATION

S.I.N recommends prior planning of the installation surgery for Tryon implants. Inadequate planning and/or lack of occlusal adjustment may compromise the performance of the implant/prosthesis combination resulting in system failure, such as implant loss or fracture, loosening or fracture of the prosthetic screws. S.I.N does not recommend the installation of the implant in patients with inadequate oral hygiene, uncooperative and unmotivated patients, with drug or alcohol abuse, psychoses, chemical dependence, prolonged functional disorders that resist any drug treatment, xerostomia, bruxism, other parafunctional habits, tobacco abuse. Diseases that can compromise the immune system, diseases that require the use of steroids

regularly, endocrine disorders, drug allergy, diabetes mellitus, anticoagulation/ bleeding diathesis medications, should be evaluated with the primary medical for a combination of the treatment plan.

CONTRAINDICATION

S.I.N. does not recommend the installation of implants in patients with: acute inflammatory or infectious processes of living tissues, inadequate bone volume or quality (as assessed by the clinician), root remains in the surgical site, serious medical issues, including bone metabolism disorders, blood coagulation disorders, poor healing capacity, incomplete maxillary growth, allergy or hypersensitivity to titanium, patients with a history of head and neck irradiation, bone condition anatomically unfavorable for implant stability, acute periodontitis, treatable pathological maxillary diseases and alterations of the oral mucosa. S.I.N. does not recommend the installation of dental implants in children, and pregnant or lactating women.

SIDE EFFECTS

Because it is a surgical procedure, the installation of implants can cause side effects such as irritation at the implantation site, mild bleeding, mild inflammation, localized pain, tenderness, edema and ecchymosis. In case of failure in planning or executing the surgical procedure, adverse effects such as chronic pain, paresthesia, paralysis, infection, hemorrhage, oroantral oronasal fistula, affected adjacent teeth, bone necrosis, fractures of the implant or prosthesis, bone loss around the implant or loss of the implant (not osseointegration).

WARNING

Implants should receive components with compatible geometry and installation indication. S.I.N. suggests an application table of implants and components according to the region to be applied, but it is up to the dentist, trained in the specialty, the choice and arbitration with regards the diameter and length of the implant installation in relation to the region and anatomy. S.I.N. Implants are designed to withstand the maximum torque of 80N.cm. Torques above this value can cause irreversible damage, as well as surgical complications. This product is for single use and cannot be reused nor reesterelized. The reuse or re sterilization of this product may cause loss of the implant (non Osseointegration), contagious infectious disease, deformation and wear of the product. The torque for fixation of the intermediates on the implant is 20N.cm. The torque for fixation of components above intermediates is 10 N.cm. Do not install the protective screw (implant cap) with ratchet driver or torque driver in order to not damage the implant; the tightening must be performed manually through digital driver. During prosthesis maintenance, the recommended torque value for each component must be respected. Higher values can damage/fracture the implant, reducing its useful life.

TRACEABILITY

All S.I.N. 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. The implants are available with three (3) traceability labels.

STORAGE

The S.I.N. medical device should be stored in a cool dry place at a temperature of 15°C to 35°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

S.I.N implants are sent to the professionals properly packaged, sealed and sterilized. Therefore, its packaging (blister) should be opened in a sterile surgical field, and the implant should be handled only with the specific instruments available in the Tryon Surgical Kit.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

Tryon implant must be transported adequately to avoid falling and stored under a maximum temperature of 35°C, protected from heat and moisture. Carriage must be carried out in it original packaging.

COMPLEMENTARY INFORMATION

Magnetic Resonance Imaging (MRI): Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. devices are MR Conditional.

CAUTION: Patient imaging can only be obtained by delimiting at least 30cm from the implant or ensuring that the implant is located outside the radiofrequency coil.

A patient with this device can be safely scanned on an MRI system under the following conditions:

Device Name	S.I.N. Dental Implant System
Static Magnetic Field Strength (B0)	≤ 3.0 T
Maximum Spatial Field Gradient	50 T/m (5,000 gauss/cm).
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head coil and body coil permitted. Extremity T/R coils permitted.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2.4 W/kg (15 minutes of scanning, Normal Operating Mode)
Maximum Head SAR	2.0 W/kg (15 minutes of scanning, Normal Operating Mode)

Scan Duration	15 minutes
Temperature Rise	Maximum temperature rise of 0.45 °C/(W/kg), after 15 minutes of continuous scanning in a static magnetic field of 3 T with either head type or body type coils
Artifact	When imaged using a gradient-echo sequence and a 3 T MR system, image artifact can extend up to approximately 12 mm with a body coil type, and up to approximately 32 mm with a head coil type

Product Exclusively for Odontological use. Reprocessing not allowed. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed version of this instruction for use or a copy of the summary of safety and clinical performance (SSCP), without any cost, please request by e-mail to sin@sinimplantsystem.com or call to 0800 770 8290 will receive until 7 days calendar.

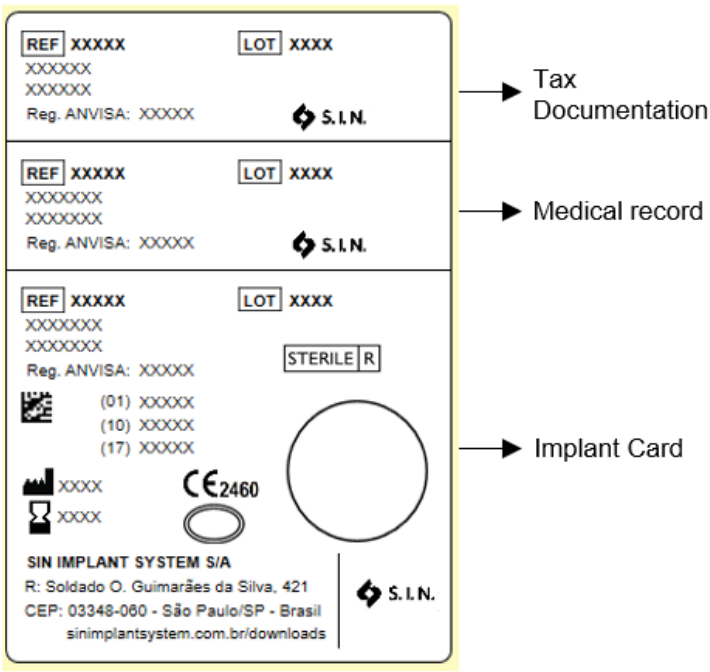
TRACEABILITY LABELS

The Tryon implant are available from S.I.N. with 3 (three) labels containing product information. The labels must be used as follows:

Tax label: The dental surgeon must stick a label on the implant's tax documentation.

Medical record label: The dental surgeon must paste a label in the patient's medical record in order to maintain traceability of the products used.

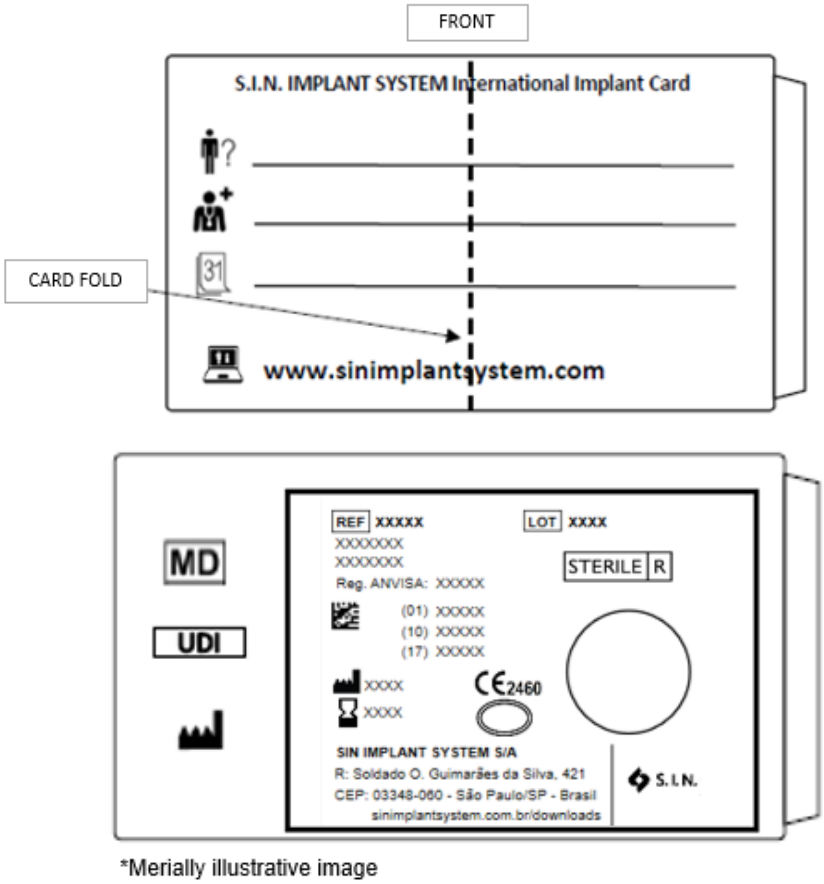
Implant card label: The dental surgeon must attach a label to the implant card to inform which products have been used.



*Merially illustrative image

IMPLANT CARD

The Tryon implant are provided by S.I.N. with an implant card. This card must be given to the patient, who must be instructed on how to keep and preserve this information.



*Merially illustrative image

STERILE R FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and for single use (sterilization method: gamma radiation), individually packaged with triple protection: tertiary package (cardboard), blister package (pet film and surgical grade paper) and primary package (transparent pipe).

EXPIRATION DATE

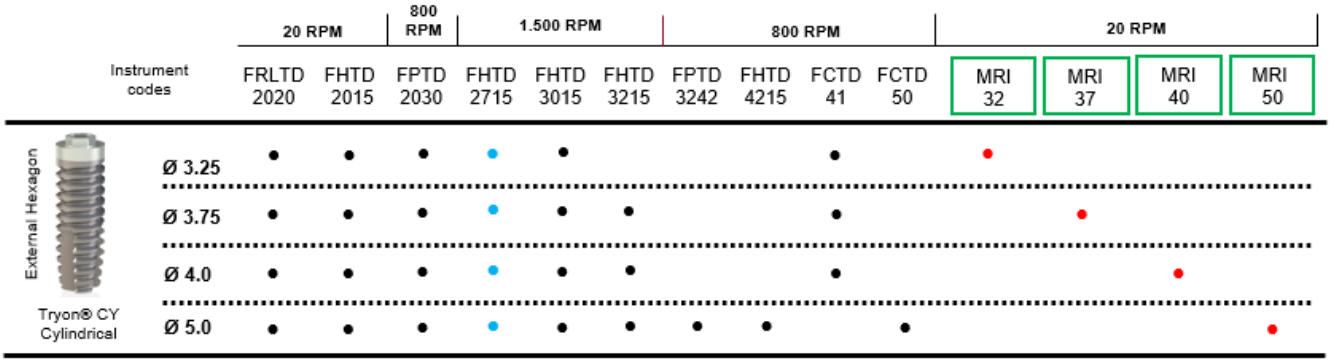
The information regarding the expiration date can be found on the labeling of the product. After installation on the patient, the product must be monitored by the professional.

INDICATION OF IMPLANT APPLICATION PER REGION

Arch	Position		Tooth	Cone Morse		External Hexagon		
				Implant diameter	Component Diameter	Implant diameter	Implant platform	Component Diameter
MAXILLARY	11	21	CENTRAL INCISOR	Ø3.75 / Ø4.0	Ø3.3	Ø3.75 / Ø4.0	Ø4.1	Ø3.6 / Ø4.1
	12	22	LATERAL INCISOR	Ø3.5	Ø3.3	Ø3.25	Ø4.1	Ø3.6 / Ø4.1
	13	23	CANINE	Ø3.75 / Ø4.0	Ø3.3	Ø3.75 / Ø4.0	Ø4.1	Ø3.6 / Ø4.1
	14	24	1st PREMOLAR	Ø3.75 / Ø4.0	Ø3.3	Ø3.75 / Ø4.0	Ø4.1	Ø3.6 / Ø4.1
	15	25	2nd PREMOLAR	Ø4.0 / Ø5.0	Ø3.3 / Ø 4.5	Ø4.0 / Ø5.0	Ø4.1 / Ø5.0	Ø4.1 / Ø5.0
	16	26	1st MOLAR	Ø4.0 / Ø5.0	Ø3.3 / Ø 4.5	Ø4.0 / Ø5.0	Ø4.1 / Ø5.0	Ø4.1 / Ø5.0
	17	27	2nd MOLAR	Ø5.0	Ø4.5	Ø5.0	Ø5.0	Ø4.1 / Ø5.0
	18	28	3rd MOLAR	Ø5.0	Ø4.5	Ø5.0	Ø5.0	Ø4.1 / Ø5.0
MANDIBLE	41	31	CENTRAL INCISOR	Ø3.5	Ø3.3	Ø3.25	Ø4.1	Ø3.6
	42	32	LATERAL INCISOR	Ø3.5	Ø3.3	Ø3.25	Ø4.1	Ø3.6
	43	33	CANINE	Ø3.75 / Ø4.0	Ø3.3	Ø3.75 / Ø4.0	Ø4.1	Ø3.6 /Ø4.1
	44	34	1st PREMOLAR	Ø3.75 / Ø4.0	Ø3.3	Ø3.75 / Ø4.0	Ø4.1	Ø3.6 /Ø4.1
	45	35	2nd PREMOLAR	Ø4.0 / Ø5.0	Ø3.3 / Ø 4.5	Ø4.0 / Ø5.0	Ø4.1 / Ø5.0	Ø4.1 / Ø5.0
	46	36	1st MOLAR	Ø4.0 / Ø5.0	Ø3.3 / Ø 4.5	Ø4.0 / Ø5.0	Ø4.1 / Ø5.0	Ø4.1 / Ø5.0
	47	37	2nd MOLAR	Ø5.0	Ø4.5	Ø5.0	Ø5.0	Ø4.1 / Ø5.0
	48	38	3rd MOLAR	Ø5.0	Ø4.5	Ø5.0	Ø5.0	Ø4.1 / Ø5.0

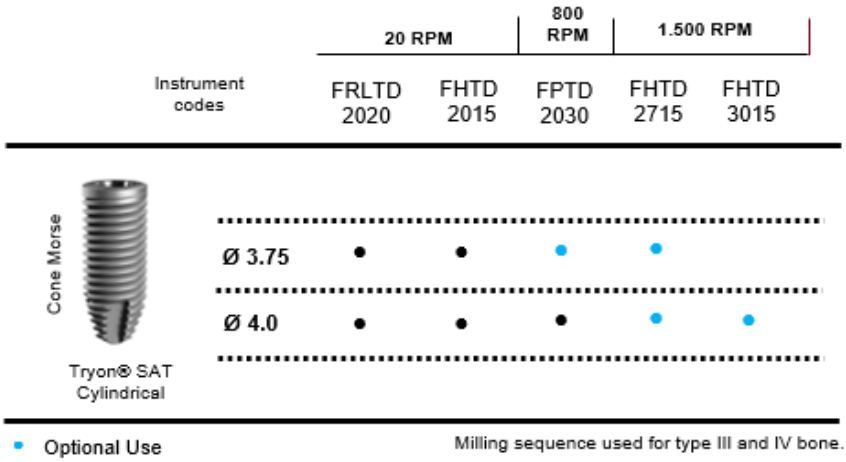
DRILLING SEQUENCE OF TRYON CYLINDRICAL IMPLANTS

Tryon® CY, Tryon® SAT e Tryon® ST



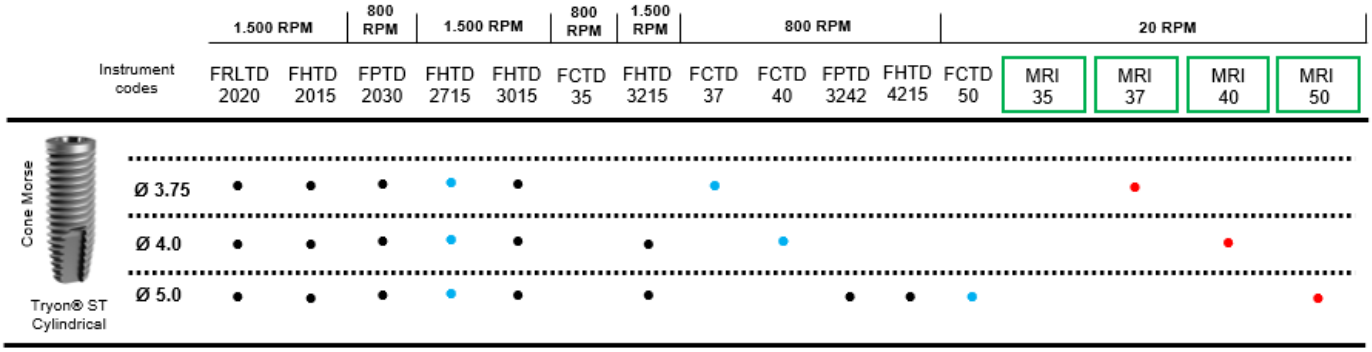
- The use of the male drill is optional, however the maximum torque must always be respected
- Optional Use
- Male drill: Tightening should not exceed 60N.cm.

Milling sequence used for type I and II bone.



- Optional Use

Milling sequence used for type III and IV bone.

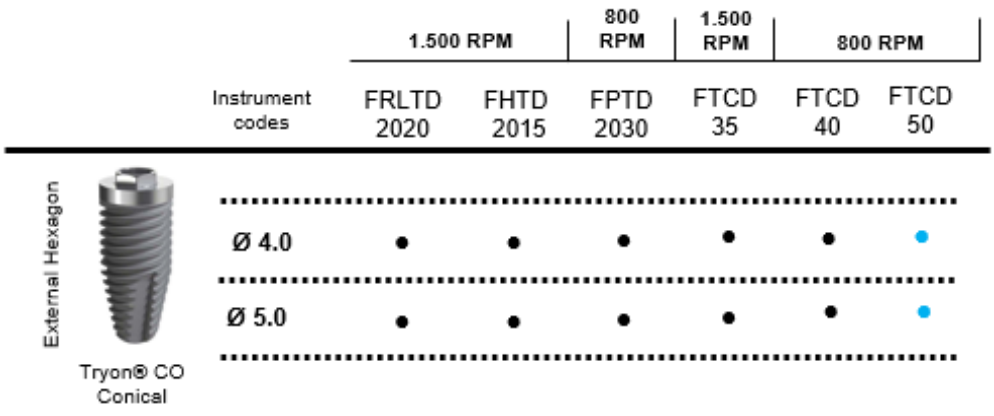


- The use of the male drill is optional, however the maximum torque must always be respected
- Optional Use
- Male drill: Tightening should not exceed 60N.cm.

Milling sequence used for type I and II bone.

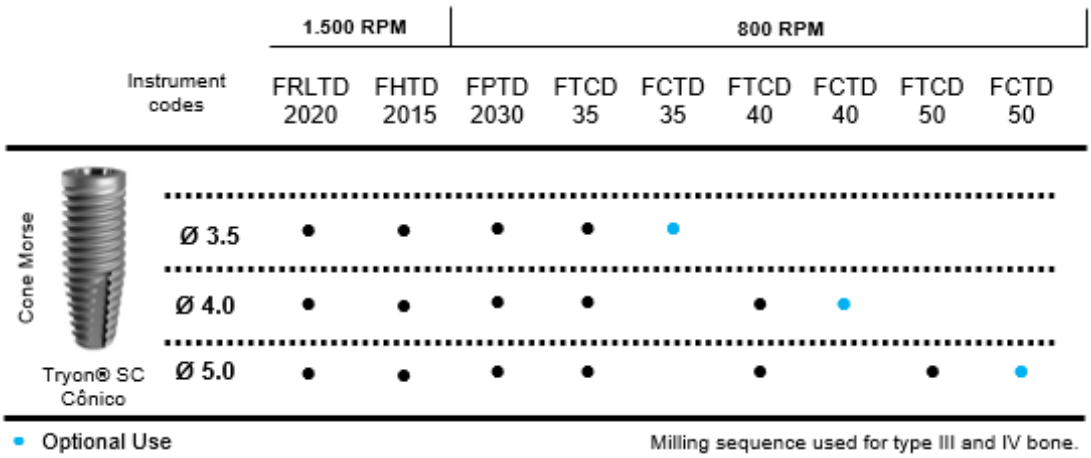
DRILLING SEQUENCE OF TRYON CONICAL IMPLANTS

Tryon® CO e Tryon® SC



- Optional Use

Milling sequence used for type III and IV bone.



- Optional Use

Milling sequence used for type III and IV bone.

STERILE R	PRODUTO ESTERILIZADO POR RADIAÇÃO GAMA	PRODUCT STERILIZED THROUGH GAMMA RAYS	PRODUCTO ESTERILIZADO POR RADIACIÓN GAMA
	NÃO REUTILIZAR	DO NOT REUSE	NO LO REUTILICE
	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
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO REESTERILIZAR
	ATENÇÃO	CAUTION	PRECAUCIÓN
EU REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LÍMITE 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	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDEZ
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
MD	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
UDI	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	SISTEMA DE BARREIRA DOUPLO ESTÉRIL	DOUBLE STERILE BARRIER SYSTEM	SISTEMA DE DOBLE BARRERA ESTÉRIL
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DESTRIBUTOR	DISTRIBUIDOR

	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE
	MR CONDICIONAL	MR CONDITIONAL	MR CONDICIONAL
	DATA DA IMPLANTAÇÃO	DATE OF IMPLANTATION	FECHA DE APLICACIÓN
	NOME E ENDEREÇO DA INSTITUIÇÃO	NAME AND ADDRESS OF THE IMPLANTING HEALTHCARE INSTITUTION	NOMBRE Y DIRECCIÓN DE LA INSTITUCIÓN
	NOME DO PACIENTE OU IDENTIFICAÇÃO DO PACIENTE	PATIENT NAME OR PATIENT ID	NOMBRE DEL PACIENTE O IDENTIFICACIÓN DEL PACIENTE
	SITE DE INFORMAÇÕES PARA OS PACIENTES	INFORMATION WEBSITE FOR PATIENTS	PÁGINA WEB DE INFORMACIÓN AL PACIENTE

MANUFACTURER
S.I.N. Implant System LTDA
CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 421 - Vila Rio Branco
CEP: 03348-060 - São Paulo - SP - Brasil

EU REP
OBELIS S.A.
Bd. Général Wahis 53
1030 Brussels, Belgium

CE 2460

SERVICE TO PROFESSIONALS
0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com
e-mail: sin@sinimplantsystem.com

RESPONSIBLE TECHNICIAN
Alessio Di Risio
CREA-SP: 5061207169

PRODUCT
SIN Dental Implants with Surface Treatment and Implants

ANVISA REGISTRATION
80108910009 and 80108910012