Tryon

TRYON® is the classic implant of S.I.N. The implant that has external hexagon and morse tapper, double acid etched and ensures high primary stability, effectiveness and safety for your surgeries.

Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

INDICATIONS OF USE

S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

PRODUCT DESCRIPTION

Tryon implants are manufactured from unalloyed titanium conforming to ASTM F67, Grade 4, and are provided with an acid etched surface treatment. All Tryon MT implants have an 11.5° Morse taper connection.
Provided STERILE. Sterilized by irradiation.

Implant Line	Diameter (mm)	Plataform Diameter (mm)	Lenght (mm)
HE	3.25, 3.5, 3.75, 4.0, 5.0	4.1, 5.0	7.0, 8.5, 10, 11.5, 13, 15.
MT	3.5, 3.75, 4.0, 5.0.	3.5, 3.75, 4.0, 5.0.	7.0, 8.5, 10, 11.5, 13, 15.

Tryon implants are for conventional 1-stage and 2-stage surgical technique and immediate loading.

CONTRAINDICATIONS

S.I.N. Dental Implant System is contraindicated in the following conditions:

- The mandibular or maxillary bone quantity and quality is insufficient to provide initial stability to the implant.
- When the site or systemic conditions show inadequate or poor oral hygiene.
- Acute or chronic periodontal infection.
- Chemical dependence.
- Occlusal parafunction.
- Radiation history to the implant site.
- Inappropriate patient for prolonged or complicated oral surgery.
- Inability to build a functional prosthesis.
- Rehabilitation with dental implants is also contraindicated for children, pregnant women and during breastfeeding

WARNINGS

The surgical technique of dental implant installation is highly specialized and the surgical procedure complex, it is recommended that the professionals be technically qualified so that the application of the S.I.N. implants is safe and efficient.

Product is for professional use only.

Product is sterilized by gamma radiation. Sterility is ensured except in cases where the package has been violated or damaged. Do not use if the package is damaged package or after the expiration date.

Single use only. Do not resterilize.

The reuse or re-sterilization of this product can cause damage to health.

PRECAUTION

Before implant installation, to obtain a predictable long-term outcome, the professional must submit the patient to a detailed and careful medical history, examination, radiographs, laboratory tests, and study models for appropriate planning.

ADVERSE EFFECTS

Loss of the implant and prosthesis is possible due to a number of reasons, including implant contamination, inappropriate surgical technique, poor bone quality, inappropriate oral hygiene, and parafunctional habits (tooth grinding).

SURGICAL COMPLICATIONS

The implant installation surgical procedure may bring risks during and after the surgery, such as: pain, edema, hemorrhage, dehiscence, paresthesia, and infection.

SHIPMENT AND HANDLING

The S.I.N. implants are sent to professionals duly packaged, sealed and sterilized. Therefore, the package must be opened using sterile technique, and must be handled only with sterilized titanium instruments.

ATTENTION

In order to obtain technical support or additional information material about the product, contact: SIN - Sistema de Implante Nacional S.A. Contact details are provided at the end of these instructions.

MRI SAFETY INFORMATION

Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. Dental Implant System devices are MR Conditional.
A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	S.I.N. Dental Implant System
Static Magnetic Field Strength (B_0)	≤ 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

INSTRUCTIONS FOR USE

Note: During all drilling to shape the implant site, avoid deflecting the drill sideways, and use continuous, copious irrigation.

S.I.N. implants were designed for a maximum torque of 80 Ncm. Higher torques may cause irreversible damages to the implants as well as surgical complications.

The torque for intermediary fixation (cemented abutment, conic abutment or mini-abutment) on the implant is 20 Ncm. The torque for component fixation on the intermediaries is 10 Ncm.

Optionally, use the countersink drill according to the implant placement level (800 RPM).
For the surgical sequence for each implant diameter, refer to the guide in the catalog.

2. Remove the adhesive part of the package and the inner tray containing the dental implant.
   Place the inner tray over a surgical tray or organizer.
   Remove the Tyvek label, exposing the implant.
3. Attach the wrench (CTUM 20) to the contra-angle.Attach the wrench CTIT 20 to the internal hex of the TryOn implant.
4. Optionally, use the CTIT 24 to contra-angle and the CCIT 20 and CCIT 24 to ratchet wrench to the installation of the TryOn implant.
5. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
6. If necessary, complete the installation with the ratchet wrench (TMECC attached to the CCIT 20 or CCIT 24.)
7. For delayed loading procedures, after placing the implant, use the 0.9 mm hexagonal drive (CDH 0920 or CDH 1220) to place the cover screw. After installation of the cover screw, suture the gingiva.
8. For a single-stage surgical procedure or immediate loading, install the selected intermediary abutment and prosthetic components.

Tryon MT Conical Implant (Ø 4.0)

1. At the surgical site penetrate the cortical bone with the initial drill, Ø 2.0 mm (1200 RPM).
   Prepare the surgical site with the FH 2015 helical drill (1500 RPM).
   Use the pilot drill FPTD 2030 to enlarge the surgical site from Ø 2.0 mm to Ø 3.0 mm (800 RPM).
   Use the FTCD 35 and FTCD 40 conical drills to the complete the surgical site preparation (800 RPM).
   Optionally, use the countersink drill FCTD 40 according to the implant placement level (800 RPM).
   For the surgical sequence for each implant diameter, refer to the guide in the catalog.
2. Reserve the traceability labels that come with the product.
   In a sterile surgical field and after breaking the sterility blister seal, hold the primary packaging (tube) with your non-dominant hand and open the lid.
   The implant will be exposed inside the tube to capture with the driver handpiece.

Do not install the protection screw (cover screw) with the ratchet wrench or torque meter since this may damage the implant; tighten it manually with a digital driver.

1. At the surgical site penetrate the cortical bone with the initial drill, Ø 2.0 mm (1500 RPM).
   Prepare the surgical site with the Ø 2.0 mm helical drill (1500 RPM).
   Use the pilot drill to enlarge the surgical site from Ø 2.0 mm to Ø 3.0 mm.
   Use the Ø 3.0 mm helical drill to the complete the surgical site preparation.
   Optionally, use the countersink drill according to the implant placement level (800 RPM).
   For the surgical sequence for each implant diameter, refer to the guide in the catalog.
2. Remove the adhesive part of the package and the inner tray containing the dental implant.
   Place the inner tray over a surgical tray or organizer.
   Remove the Tyvek label, exposing the implant.
3. Attach the wrench (CTIT 20) to the contra-angle. Attach the wrench CTIT 20 to the internal hex of the TryOn implant.
   Optionally, use the CTIT 24 to contra-angle and the CCIT 20 and CCIT 24 to ratchet wrench to the installation of the TryOn implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If necessary, complete the installation with the ratchet wrench (TMECC or TMECC 02 attached to the CCIT 20 or CCIT 24.
6. For delayed loading procedures, after placing the implant, use the 0.9 mm hexagonal drive (CDH 0920 or CDH 0924) to place the cover screw. After installation of the cover screw, suture the gingiva.
7. For a single-stage surgical procedure or immediate loading, install the selected intermediary abutment and prosthetic components.

Tryon MT Conical Implant (Ø 3.5)

1. At the surgical site penetrate the cortical bone with the initial drill, Ø 2.0 mm (1200 RPM).
   Prepare the surgical site with the Ø 2.0 mm helical drill (1200 RPM).
   Use the pilot drill to enlarge the surgical site from Ø 2.0 mm to Ø 3.0 mm.
   Use the Ø 2.95 mm conical drill to the complete the surgical site preparation (800RPM).

3. Attach the wrench (CTUM 20) to the contra-angle. Attach the wrench CTUM 20 to the internal hex of the Tryon MT implant.
4. Optionally, use the CTUM 24 to contra-angle and the CCM 20 and CCM 24 to ratchet wrench to the installation of the Tryon MT implant.
5. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
6. If necessary, complete the installation with the ratchet wrench (TMECC attached to the CCM 20 or CCM 24.)
7. For delayed loading procedures, after placing the implant, use the 1.2 mm hexagonal driver (CDH 1220 or CDH 1224) to place the cover screw. After installation of the cover screw, suture the gingiva.

Tryon MT Conical Implant (Ø 5.0)

1. At the surgical site penetrate the cortical bone with the initial drill, FRL 2020 (1500 RPM).
   Prepare the surgical site with the FH 2015 helical drill (1500 RPM).
   Use the pilot drill FPTD 2030 to enlarge the surgical site from Ø 2.0 mm to Ø 3.0 mm (800 RPM).
   Use the FTCD 35, FTCD 40 and FTCD 50 conical drills to the complete the surgical site preparation (800 RPM).
   Optionally, use the countersink drill FCTD 50 according to the implant placement level (800 RPM).
   For the surgical sequence for each implant diameter, refer to the guide in the catalog.
2. Reserve the traceability labels that come with the product.
   In a sterile surgical field and after breaking the sterility blister seal, hold the primary packaging (tube) with your non-dominant hand and open the lid.
   The implant will be exposed inside the tube to capture with the driver handpiece.
3. Attach the wrench (CTUM 20) to the contra-angle. Attach the wrench CTUM 20 to the internal hex of the Tryon MT implant.
4. Optionally, use the CTUM 24 to contra-angle and the CCM 20 and CCM 24 to ratchet wrench to the installation of the Tryon MT implant.
5. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
6. If necessary, complete the installation with the ratchet wrench (TMECC attached to the CCM 20 or CCM 24.)
7. For delayed loading procedures, after placing the implant, use the 1.2 mm hexagonal driver (CDH 1220 or CDH 1224) to place the cover screw. After installation of the cover screw, suture the gingiva.

Tryon MT Cylindrical Implant (Ø 3.5)

1. At the surgical site penetrate the cortical bone with the initial drill, Ø 2.0 mm (1200 RPM).
   Prepare the surgical site with the Ø 2.0 mm helical drill (1200 RPM).
   Use the pilot drill to enlarge the surgical site from Ø 2.0 mm to Ø 3.0 mm.
   Use the Ø 2.95 mm cylindrical drill to the complete the surgical site preparation (800RPM).
   Optionally, use the countersink drill according to the implant placement level (800 RPM).
   For the surgical sequence for each implant diameter, refer to the guide in the catalog.
2. Remove the adhesive part of the package and the inner tray containing the dental implant.
   Place the inner tray over a surgical tray or organizer.
   Remove the Tyvek label, exposing the implant.
3. Attach the wrench (CTUM 20) to the contra-angle. Attach the wrench CTIT 20 to the internal hex of the Tryon implant.
4. Optionally, use the CTIT 24 to contra-angle and the CCIT 20 and CCIT 24 to ratchet wrench to the installation of the Tryon implant.
5. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
6. If necessary, complete the installation with the ratchet wrench (TMECC attached to the CCIT 20 or CCIT 24.)
7. For delayed loading procedures, after placing the implant, use the 0.9 mm hexagonal drive (CDH 0920 or CDH 1220) to place the cover screw. After installation of the cover screw, suture the gingiva.

Symbols Glossary

ANSI/AAMI/ ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol6	Title of Symbol (References Number)	Meaning of Symbol
	Caution (5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Keep away from sunlight (5.3.2)	Indicates a medical device that needs protection from light sources.
	Upper limit of temperature (5.3.6)	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	Keep dry (5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Do not use if package Damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not re-use (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Date of manufacture (5.1.3)	Indicates the date when the medical device was manufactured
	Manufacturer (5.1.1)	Indicates the medical device manufacturer.
	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	MR Conditional (n/a)	Conditions under which a medical device can safely enter the MR environment

DEVELOPED AND MANUFACTURED BY:

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

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 - Brazil

SERVICE TO PROFESSIONALS

0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com email: sin@sinimplante.com.br

RESPONSIBLE TECHNICIAN:

Alessio Di Risio
CREA-SP: 5061207169

PRODUCT:

Tryon dental Implants

510 (k) FDA-US:

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