SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
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
CE	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
EC REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
PROIBIDO REPROCESSAR	PROIBIDO REPROCESSAR	PROHIBITED REPROCESSING	PROHIBIDO REPROCESAR
	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.

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, 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
e-mail: sin@sinimplante.com.br

OVER-REV-UNIPESSOAL LDA.

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

RESPONSIBLE TECHNICIAN:

Alessio Di Risio
CREA-SP: 5061207169

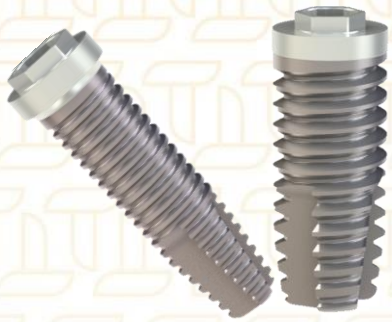
PRODUCT:

Implants / SIN Dental Implants with Superficial Treatment

Anvisa Registration: 80108910012 and 80108910009

CE 2460

S.I.N. osseointegrated implants are intended for expert procedures, which must be performed by qualified professionals in Implant Dentistry. 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

TTryon Implants are produced in commercially pure Titanium (Grade 4). The macrogeometry of the implant is (cylindrical and conical macrogeometry) and the prosthetic coupling is the external hexagon type. The surface of the implant is rough obtained by double acid-etched process.

INDICATIONS OF USE

S.I.N. implants are indicated for surgical procedures in maxillary or mandibular bones generating a support platform for the installation of prosthetic components such as artificial teeth, 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 45 N.cm) and proper occlusal load. They can be used in single or multiple restorations.

APPLICATIONS

Tryon Implants are indicated for surgical installation in all bone densities, maxilla or mandible, as long as the maximum insertion torque (80 N.cm) is not surpassed. If the installation reaches a torque that exceeds the limit, it is recommended to use a specific Bone Tap for each model before the installation is finished.

CONTRAINDICATIONS

S.I.N. does not indicate the installation of implants in patients who have: acute inflammatory or infectious processes of living tissues, inadequate bone volume or quality, local root residues, serious medical problems such as: disorders of bone metabolism, disorders of blood coagulation, low healing capacity, incomplete jaw growth, allergy or hypersensitivity to titanium, patients with history of head and neck irradiation, bone conditions anatomically unfavorable to the implant stability, acute periodontitis, treatable pathological maxillary diseases, and oral mucosa alterations.

RECOMMENDATIONS

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, low levels in the immune system, diseases that require the use of steroids regularly, endocrine disorders, drug allergy, diabetes mellitus, anticoagulation/bleeding diathesis medications, bruxism, other parafunctional habits, tobacco abuse, installation in children, or pregnant or lactating women.

PRECAUTIONS

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.
- A 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. Millings 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.
- 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 Prosthetic Screws.
- 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.

IMPLANT INSTALLATION

- 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 wrench.
- For motor installation, use the contra-angle wrench.
- Grab the Implant by holding the wrench still and rotating the internal support slightly, looking for the perfect fit between the connection and the Implant. Press the wrench 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 Wrench.
- 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.

TRACEABILITY

All S.I.N. products - The Implant System 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 to the distribution time.

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).

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

SIDE EFFECTS

Because it is a surgical procedure, the implant installation can cause a slight discomfort and localized edema. More persistent symptoms may arise such as: chronic pain related to the dental implant, permanent paraesthesia, dysesthesia, loss of maxillary/mandibular bone border, localized or systemic infection, oro-antral or oro-nasal fistula, adjacent teeth adversely affected, irreversible damage to adjacent teeth, implant, maxillary, bone or prosthesis fractures, aesthetic problems, nerve damage, exfoliation, hyperplasia, loss of implant and/or prosthesis.

TRANSPORTATION

Tryon implants must be transported in an appropriate manner to avoid falling and storage under a maximum temperature of 35 °C, away from heat and humidity. Transportation must be carried out in its original packaging.

STORAGE

Tryon implants should be stored in a cool, dry place at a maximum temperature of 35°C and protected from direct sunlight in the original closed package and from damage.

DISPOSAL OF MATERIAL

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

EXPIRATION DATE

Indicated on the label.

ADDITIONAL INFORMATION

Magnetic Resonance Imaging (MRI): The safety and compatibility of S.I.N. dental implants with the MRI environment were not evaluated. The heating, displacement or distortion suffered by S.I.N. dental implants in the MRI environment were not tested. The safety of S.I.N. dental implants in the MRI environment is unknown. Performing an MRI on a patient with this device may harm the patient.

HANDLING

The alveolus should be made according to the necessary care for the reduction of surgical trauma, including millings in a good cutting state with rotation from 800 to 1500 RPM and under abundant irrigation. Select the drill sequence according to the type and diameter of the intended implant (see table 2). For the infra-osseous positioning of the cervical portion of the implant, it is recommended to add 1 or 2 mm to the implant length during surgical instrumentation.

WARNING

Implants should receive components with compatible geometry, or specific components for the switching platform technique and installation indication.

S.I.N. - Sistema de Implante 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 80 N.cm. Torques above this value can cause irreversible damage, as well as surgical complications. The Product is for single use and cannot be resterilized.

The torque for fixing intermediates (conical abutment or mini abutment) on the implant is 20 N.cm and the cemented abutment is 32 N.cm. The torque for fixation of components above intermediates is 10 N.cm. Do not install the cover screw (implant cap) with ratchet wrench or torque wrench in order not to damage the implant; the tightening must be performed manually through digital wrench. During prosthesis maintenance, the recommended torque value for each component must be respected. Higher values can damage/fracture the implant, reducing its useful life.

TABLE 1: INDICATION OF IMPLANT APPLICATION PER REGION

ARCH	POSITION		TOOTH	PLATFORM	COMPONENT
UPPER	11.	21	CENTRAL INCISOR	Ø4,1	FIT/HE
	12.	22	LATERAL INCISOR	Ø4,1/3,5*	FIT
	13.	23	CANINE	Ø4,1	FIT/HE
	14.	24	1st PREMOLAR	Ø4,1	FIT/HE
	15.	25	2nd PREMOLAR	Ø4,1/5,0	HE
	16.	26	1st MOLAR	Ø5,0/Ø4,1	HE
	17.	27	2nd MOLAR	Ø5,0	HE
	18.	28	3rd MOLAR	Ø5,0	HE
LOWER	41.	31	CENTRAL INCISOR	3,5**	FIT/**
	42.	32	LATERAL INCISOR	3,5**	FIT/**
	43.	33	CANINE	Ø4,1	FIT/HE
	44.	34	1st PREMOLAR	Ø4,1	FIT/ HE
	45.	35	2nd PREMOLAR	Ø4,1/5,0	HE
	46.	36	1st MOLAR	Ø4,1/5,0	HE
	47.	37	2nd MOLAR	Ø5,0	HE
	48.	38	3rd MOLAR	Ø5,0	HE

** Indicated for cases where the mesio-distal prosthetic space is higher than 6mm;*
*** It is recommended to use implants with 3.5 mm diameter from the Strong SW Morse (SWCM 35XX) family and their corresponding components, or Unitite Slim 2.9 (UCMS 29XX N) for better aesthetic contour.*
FIT: Components with prosthetic closure Ø3.6 mm and anatomical transmucosal profile.
HE: Components with prosthetic closure Ø4.1mm / Ø5.0mm and divergent profile.

TABLE 2: MILLING SEQUENCE OF CYLINDRICAL TRYON IMPLANTS

			1500 rpm		800 rpm	1500 rpm			800 rpm			20 rpm			
															
	PLAT. (mm)	DIÂM. (mm)	FRL 2020	FH 2015	FP 2030	FH 2715	FH 3015	FH 3215	FPC 4250	FC 100	FH 4215	MRI 32	MRI 37	MRI 40	MRI 50
 Tryon	4,1	3,25	•	•	•	•	•			•		•			
	4,1	3,75	•	•	•		•	•		•			•		
	4,1	4,0	•	•	•		•	•		•				•	
	5,0	5,0	•	•	•		•	•	•		•				•

- *Indicated for bones type I or II, use of the screw tap.*

TABLE 3: MILLING SEQUENCE OF CONICAL TRYON IMPLANTS

			1500 rpm		800 rpm	1500 rpm	800 rpm		
									
	PLAT. (mm)	DIÂM. (mm)	FRL 2020	FH 2015	FP 2030	FH 2715	FTCI	FTC 40	FTH 50
 Tryon	3,6	3,5	•	•	•	•	•		
	4,1	4,0	•	•	•	•	•	•	
	5,0	5,0	•	•	•	•	•	•	•

- *Indicated for bones type III or IV.*