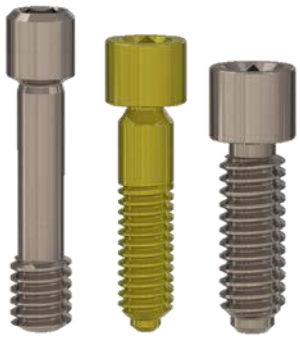
COMPONENT

S.I.N. Fixation Screw

The S.I.N. Fixation Screw 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 DESCRITION

The S.I.N. Fixation Screw it has a cylindrical shape with hexagonal or square connection for fitting the keys, it has pyramidal threads with a diameter corresponding to the internal thread of the implant or prosthetic intermediate to be fixed. They are manufactured in titanium V and made available to the professional together with the prosthetic or unitary component for replacement.

The chemical composition of the Dental Components is according to 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 S.I.N. Fixation Screw is indicated to fix the prosthesis on the implant or on the prosthetic intermediate.

PURPOSE AND OPERATION PRINCIPLE

It has the purpose of fixing the prosthesis to the implant, and thus transmitting the chewing force to the bone plate, in which they are surgically implanted. The principle of operation is the combined effect of rotation and pressure. The torque force exerted on the distal (wider) end, with the help of the driver, is transferred throughout the component body, fixing the assembly on which the screw is inserted.

HOW TO USE THE COMPONENT

Fixation Screws Conical Abutments: After planning and choosing the conical abutment as the prosthetic intermediate to be used, it must be fitted over the implant connection and transfixed by the accompanying screw with a torque of 20 N.cm using the Mini Abutment or Conical driver and the prosthetic torque ratchet.

Mini Abutments Fixation Screws: After planning and choosing the Mini Abutment as prosthetic intermediary to be used, it must be fitted over the implant connection and transfixed by the accompanying screw with a torque of 20N.cm, using the Mini Abutment or Conical driver and the prosthetic torque ratchet.

Mini Angled Abutment Fixation Screws: After planning and choosing the Angled Mini Abutment as the prosthetic intermediate to be used, it must be fitted over the implant connection (external hexagon or cone morse) and transfixed by the screw that accompanies it using a 0.9mm Hex Driver (with a torque of 10Ncm) or using a 1.2mm Hex Driver (with a torque of 20N.cm) and the prosthetic torque ratchet.

Cemented Abutment Fixation Screws: After planning and choosing the Cemented Abutment as the prosthetic component to be used, it must be fitted on the implant connection (external hexagon, internal hexagon or cone morse) or prosthetic intermediate and transfixed by the screw that accompanies it with a torque of 10N.cm when on intermediate, 20N.cm when on external hexagon and cone morse or 32N.cm when on external hexagon for abutments and torque of 20N.cm for provisional cylinders, for which it is necessary to use the hex driver 1.2 or 0.9mm or the square driver 1.3mm and the prosthetic torque ratchet.

Cylinder Fixation Screw for Mini Abutment, Conical Abutment and Micro Mini Abutment: After planning and choosing the Cylinder as the prosthetic component to be used, it must be fitted over the intermediary already installed and transfixed by the screw that accompanies it with a torque of 10N.cm, for which it is necessary to use the 1.2mm hexagonal driver and a prosthetic torque ratchet.

⚠ ATTENTION

The S.I.N. Fixation Screw are intended for expert procedures, which must be performed by qualified professionals in implant dentistry. The product must be used in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTIONS

Consider the general state of health of the patient, which must be subjected to a thorough clinical analysis. Failure to carry out the pre-surgical evaluation may result in the impossibility of finding pre-existing diseases. Patients who have local or systemic factors that may interfere with the soft tissue healing processes should receive special attention. Sterilization is only guaranteed if the primary packaging (blister) is undamaged. Do not use the product if the packaging is broken. Open the package only at the time of surgery and use the product immediately. Only handle the material in a sterile field. All material used in the procedure must be sterile. Components not used after opening the package must be discarded. Expired products should not be used. During the surgical and prosthetic procedure, use only implants, components and instruments specified by S.I.N., they have specific dimensions and tolerances for each implant system, ensuring the longevity of the product. Components from other brands

or adapted to implant models can reduce the life of the system causing irreversible damage. If a correct diameter is not used, soft tissue irritation may occur. Drills are recommended for material removal in restorative procedures (dental/oral and maxillofacial/orthodontic). The dentist must be aware of the force exerted when applying the product so as not to damage it. The Abutment platform that fits the implant must not be altered in any way. The professional must ensure that the patient does not aspirate the product. It is the professional's responsibility to use S.I.N. in accordance with the instructions for use, as well as determining whether it suits the individual situation of each patient. The patient should be informed about all possible surgical complications, contraindications, warnings, precautions and adverse reactions. All documentation accompanying the product must also be made available to the customer. The professional must inform the patient about the correct way of cleaning, the need for regular monitoring, avoiding physical and mechanical tensions and not subjecting the product to inadequate efforts.

RECOMMENDATIONS

For the placement of abutments, it is recommended that the professional has a specialization course in the area and prepares a prosthetic execution plan. Improper planning and/or lack of occlusal adjustment can compromise the performance of the Implant/Prosthesis set resulting in system failures such as loss or fracture of the Implant, loosening or fracture of the prosthetic screws. The implant diameter and angulation, as well as the gingival height, must be taken into account when choosing the S.I.N. to be used. The S.I.N. does not recommend implant placement 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 immune system, diseases that require the use of steroids regularly, endocrine diseases, drug allergy, diabetes mellitus, anticoagulant drugs/hemorrhagic diathesis, bruxism, other parafunctional habits, tobacco abuse, installation in children and pregnant women and during the breastfeeding period.

CONTRAINDICATIONS

The use of the screw is contraindicated in cases of chronic periodontal inflammation, patients not prepared to undergo oral rehabilitation, inadequate parafunctional habits, for example bruxism, untreatable occlusion/articulation problems, active intraoral infection and in case of immediate loading, stability inadequate implant primary.

SIDE EFFECTS

Installation recommendations must be followed for the proper functioning of the product, if not, the final result may be compromised, generating, loss or fracture of the part. The product can cause transient side effects due to compression of peri-implant tissues, such as slight bleeding, swelling, pain, discomfort or even infection in case of aseptic barrier breach.

WARNING

As it is the surgical technique for the installation of highly specialized and complex dental prosthesis components, it is highly recommended that professionals carry out specialized training so that the application of prosthetic components is safe and effective. If the technique

used is not adequate and the patient is not indicated for this type of surgery, the component may not be successful and will be lost. Compatible only with S.I.N.

TRACEABILITY

All S.I.N. products have sequential lots 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. The components are available with three (3) way 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

The S.I.N. Fixation Screw is a sterile product that should be handled only in a sterile field by properly trained professionals and in appropriate scrubs at the time of the surgical procedure.

DISPOSAL OS MATERIAL

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

TRANSPORTATION

The S.I.N. Fixation Screw 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

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.
Static Magnetic Field Strength	≤ 3.0 T

Maximum Spatial Field Gradient	50 T/m (5.00 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.

Exclusive Product for Dental 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 safety and clinical performance summary (SSCP), at no cost, please request it by email to sin@sinimplantsystem.com or call 0800 770 8290 and you will receive it within 7 calendar days.

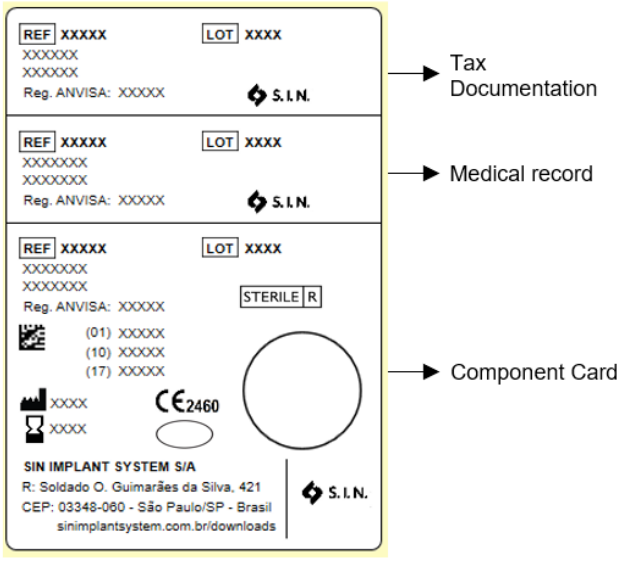
TRACEABILITY LABELS

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

Tax Documentation 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.

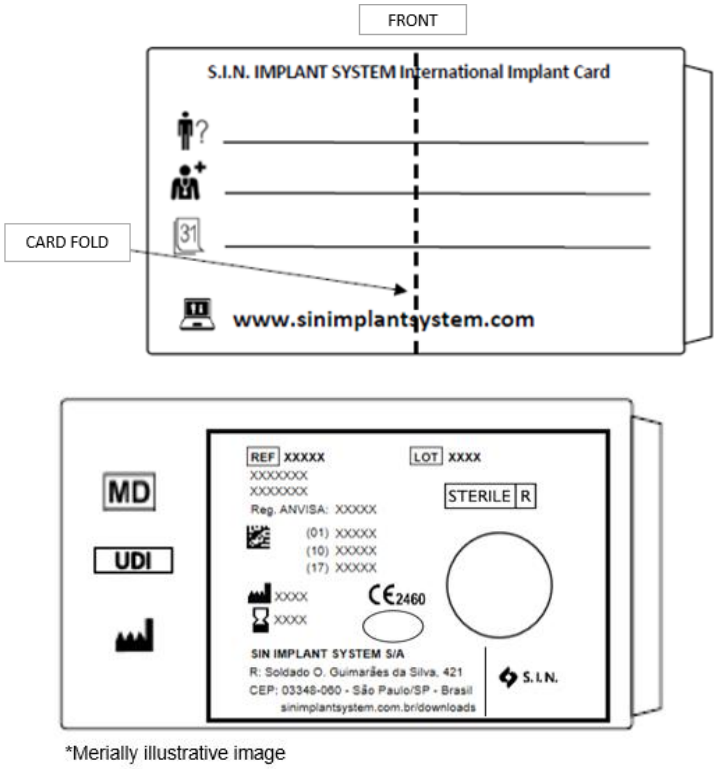
Component Card Label: The dental surgeon should attach a label to the component card to inform which products were used.



*Merially illustrative image

COMPONENT CARD

The S.I.N. Fixation Screw are provided with an component 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 single-use (sterilization method: gamma radiation) packaged in a unit that offers double protection: secondary packaging (cardboard) and primary blister packaging (PET film and surgical grade paper).

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.

	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
	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
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	SISTEMA DE BARREIRA ESTÉRIL	SINGLE STERILE BARRIER SYSTEM	SISTEMA DE BARRERA ESTÉRIL SIMPLES
	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
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Rua Soldado Ocimar Guimarães da Silva, 421 - Vila Rio Branco
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PRODUCT
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