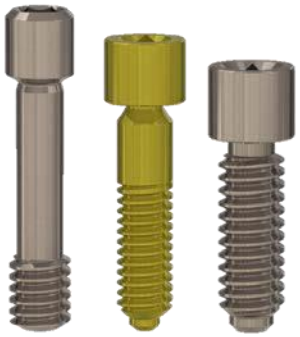
COMPONENT

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 DESCRIPTION

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.

INDICATIONS FOR USE

S.I.N. Fixation Screw are components with the function of fixing prosthesis on implant or prosthesis on prosthetic intermediates.

OPERATION PRINCIPLE

The operating principle applicable to S.I.N. Fixation Screws is pressure, through the combined effect of rotation and pressure, i.e. purely mechanical. The torque force exerted at the distal (wider) end, with the help of the wrench, is transferred throughout the body of the component by Fixation the assembly onto which the screw is inserted.

HOW TO USE

Fixation Screws Conical Abutments: After completing the prosthesis in which the components indicated for it have been selected, fit the prosthesis over the implant hexagon, transfix the screw and torque to 20Ncm, for this, it is necessary to use the connection wrench torque 2.0 and the prosthetic torque wrench.

Mini Abutments Fixation Screws: After completion of the prosthesis in which the components indicated for it have been selected, fit the prosthesis on the implant hexagon, transfix the screw and torque to 20Ncm, for this, it is necessary to use the connection wrench torque 2.0 and the prosthetic torque wrench.

Mini Angled Abutment Fixation Screws: After the completion of the prosthesis in which the components indicated for it have been selected, fit the prosthesis over the implant hexagon, transfix the screw and give a torque of 15 or 20Ncm, for this, it is necessary to use the 0.9mm or 1.2mm torque connection wrench and the prosthetic torque wrench.

Cemented Abutment Fixation Screws: After completion of the prosthesis in which the components indicated for it have been selected, fit the prosthesis over the implant hexagon, transfix the screw and torque 10, 20 or 32Ncm for abutments and torque of 20Ncm for temporary cylinders, for this it is necessary to use the torque wrench 1.2, 4, 1.3 or 9mm and the prosthetic torque wrench.

Cylinder Fixation Screw for Mini Abutment, Conical Abutment and Micro Mini Abutment: After completion of the prosthesis in which the components indicated for it have been selected, fit the prosthesis over the component, transfix the screw and give a torque of 10Ncm, to it is necessary to use the torque 1.2 connection wrench and the prosthetic torque wrench.

ATTENTION

The S.I.N. Fixation Screw implants 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. - Implant System 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.

STORAGE

S.IN Fixation Screw they must be stored in a dry and cool place, at a maximum temperature of 35°C and protected from direct sunlight, in their original, unopened packaging, and must not be damaged.

HANDLING

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 OF 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 INFORMATION

Single-use product. Reprocessing prohibited. Product for dental use only. In the event of any incident caused by the product, the professional must immediately inform the manufacturer and the competent authority of the Member State in which the user and/or patient is located. 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.

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.

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
	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
	VALIDADE	USE-BY DATE	VALIDEZ
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA
MD	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
UDI	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	SISTEMA DE BARREIRA ESTÉRIL	SINGLE STERILE BARRIER SYSTEM	SISTEMA DE BARRERA ESTÉRIL SIMPLE
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
LOT	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE

DEVELOPED AND MANUFACTURED BY:
S.I.N. Sistema de Implante Nacional S/A
Corporate Taxpayer's Registry (CNPJ): 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 2445 - Vila Rio Branco CEP: 03348-060 - São Paulo - SP - Brazil

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PRODUCT: S.I.N. Fixation Screw

ANVISA REGISTRATION: 80108910068