COMPONENT

S.I.N. Sterile Components

S.I.N. Sterile Components are 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

Mini Abutment and Micro Mini Abutment: It consists of a cylindrical abutment made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to professionals in sterile form. They may or may not accompany screw.

Angled Mini Abutment: Consists of a cylindrical, hexagonal abutment with a variation of angulation of 17°, 30° and 45° (45° - exclusively for long implants), made of V-grade titanium with connection, following the seating platforms according to each implant model, it has an internal perforation to access the prosthesis fixing screw, it may or may not be anodized (yellow or pink), depending on the professional's needs. They are available to the professional in sterile form. It comes with a grade V titanium screw. It enables the correction of misaligned implants.

Conical Abutment/Multifuncional: It consists of a conical abutment made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to professionals in sterile form. They may or may not accompany screw.

Cemented Abutment: It consists of a cylindrical abutment made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to professionals in sterile form. They may or may not accompany screw.

Angled Cemented Abutment: It consists of a cylindrical abutment with an angulation variation of 17° or 30°, made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to professionals in sterile form. Supplied with grade V titanium screw.

Interface: It consists of a cylindrical abutment made of titanium grade V with connection according to the implant platform or Abutment to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to the professional in STERILE form. Supplied with grade V titanium screw.

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

S.I.N. Epikut 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 S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

PURPOSE AND OPERATION PRINCIPLE

Mini Abutment and Micro Mini Abutment: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Mini Abutment is used for the manufacture of screwed, multiple, partial and total dental prostheses. In the case of the Micro Mini Abutment, it can also be used to make single prostheses. They enable passive rehabilitation in cases with divergent implants up to 25 ° for Mini Abutments and 20 ° for Micro Mini Abutments. The recommended torque for installing the Mini Abutment is 20N.cm.

Angled Mini Abutment: Its purpose is to form a set with the implant and thus transmit the mastication forces to the bone plate. They are based on the mechanical principles of load transmission system assembly. The Angulated Mini Abutment is used to manufacture screwed, multiple, partial and total dental prosthesis. It enables the correction of angulated implants, with an angulation variation of 17º, 30º and 45º (45° - exclusively for long implants). The recommended torque for installing the Mini Abutment is 20 N.cm.

Conical Abutment/Multifunctional: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Conical Abutment is used for making dental prostheses screwed, multiple or unitary (rotational or anti-rotational). The recommended torque for the installation of Conical Abutment is 20N.cm. and for the Multifunctional Abutment is 32 N.cm.

Cemented Abutment and Universal Abutment: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Cemented Abutment is used for making dental prostheses cemented, unitary, multiple e partial. Prosthetic Platform CM: The recommended torque for the installation of Cemented Abutment for cone morse (CM) implant is 20N.cm, except for Universal Cemented Abutment model of the Unitite Slim line that the recommended torque is 15N.cm and Universal Abutment model through bolt morse cone that the recommended torque is 10N.cm. Prosthetic Platform HE: The recommended torque for the

installation of Cemented Abutment for external hexagon implant (HE) is 32N.cm except for the Universal Abutment model the recommended torque is 20N.cm. HI Prosthetic Platform: The recommended torque for the installation of Cemented Abutment for internal hexagon (HI) implant is 20N.cm.

Angled Cemented Abutment and Angle Universal Abutment: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Angled Cemented Abutment is used for making dental prostheses cemented, unitary, multiple and partial. It allows the correction of angled implants, with an angulation variation of 17º and 30º. Prosthetic Platform CM: The recommended torque for the installation of Angled Cemented Abutment for cone morse (CM) implant is 20N.cm and add: except for Universal Angled Abutment model, the recommended torque is 10N.cm. Prosthetic Platform HE: The recommended torque for the installation of Angled Cemented Abutment for external hexagon (HE) implant is 32N.cm. HI Prosthetic Platform: The recommended torque for the installation of Angled Cemented Abutment for internal hexagon (HI) implant is 20N.cm.

Interface: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The interface is used for making dental prostheses cemented oy screwed, multiple, unitary, partial and total by the CAD-CAM system. Prosthetic Platform CM: The recommended torque for the installation of the titanium interface for cone morse (CM) implant is 20N.cm. Prosthetic Platform HE: The recommended torque for the installation of titanium interface for external hexagon (HE) implant is 32N.cm. HI Prosthetic Platform: The recommended torque for the installation of the titanium interface for internal hexagon (HI) implant is 20N.cm. Mini Abutment and Micro Mini Abutment: The recommended torque for the installation of the titanium interface for implant Mini Abutment and Micro Mini Abutment is 10N.cm. Abutment Conical/Multifunctional: The recommended torque for the installation of the titanium interface for Conical Abutment/Multifunctional implant is 10N.cm.

HOW TO USE THE COMPONENT

CEMENTATED PROTHESES: Cemented Abutment, Universal Abutment, Angled Cemented Abutment or Interface:

a. Selection of the component to be used in relation height x diameter x multiple or single;
b. Installation and torque of the component;
c. Registering the three-dimensional position of the implant through molding technique with open or closed tray transfer or, scanning by digital transfer for CAD-CAM system;
d. Finalization of the prosthesis on the analog installed in the plaster or milling in the CAD-CAM system, using the component of your choice;
e. Fixation of the prosthesis through the cement of your choice.

PROSTHETIC SCREWS: Mini Abutments, Angled Mini Abutments, Conical Abutments or Interface:

a. Selection of the component to be used in relation to height x diameter x multiple or unit;
b. Installation and component torque;
c. Registration of the three-dimensional implant position by open or closed tray transfer impression technique or digital transfer scanning to CAD-CAM system;
d. Finalization of the prosthesis on the analogue installed in the gypsum or drilling in the CAD-CAM system, using component of your choice;
e. Fixation of the prosthesis through a screw and suitable torque.

ATTENTION

The S.I.N. Sterile Components 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 health of the patient, the same must undergo a thorough clinical analysis. Failure to perform the pre-surgical evaluation can lead to the impossibility of finding pre-existing diseases. Patients with local or systemic factors that may interfere with the soft tissue healing process should receive special attention. Sterilization of S.I.N. Sterile Components is only guaranteed if the primary packaging (blister) is not damaged. Do not use the product if the packaging has been tampered with. Only open the package at the time of surgery and use the product immediately. Handle the material only in a sterile field. All material used in the procedure must be sterile. Components not used after opening the carton should be discarded. Products with expired validity should not be used. During the surgical and prosthetic procedure only use implants, components and instruments specified by S.I.N., they have specific dimensions and tolerances for each implant system guaranteeing longevity of the product. Other brand components or adapted to the implant models can reduce the life of the system causing irreversible damage. The platform of S.I.N. Sterile Components that adapts to the implant must not be altered in any way. The professional must ensure the patient does not aspirate the product. It is the responsibility of the professional to use S.I.N. in accordance with the instructions for use, as well as to determine if it is appropriate to the individual situation of each patient. If a correct diameter is not used, soft tissue irritation may occur. The patient should be informed about all possible surgical complications, contraindications, warnings, precautions and adverse reactions. All documentation accompanying the product should also be made available to the customer. The professional must inform the patient about the correct form of cleaning, the need for regular monitoring, avoiding physical and mechanical tensions and not subjecting the product to inappropriate efforts.

RECOMMENDATIONS

For the placement of S.I.N. Sterile Components, it is recommended that the professional have a specialization course in the area and prepare a prosthetic execution plan. 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. The diameter and the angulation of the implant, as well as the gingival height, must be taken into account when choosing the model of S.I.N. Sterile Components to be used. The S.I.N. does not recommend implant installation in patients with inadequate oral hygiene, uncooperative and unmotivated patients, drug or alcohol abuse, psychoses, chemical dependence, prolonged functional disorders that resist any drug treatment, xerostomia, low immune system, diseases which require the use of steroids regularly, endocrinological diseases, drug allergy, diabetes mellitus, anticoagulants/bleeding diathesis, bruxism, other parafunctional habits, tobacco abuse, installation in children and pregnant women and during breastfeeding.

CONTRAINDICATIONS

The use of S.I.N. Sterile Components is contraindicated in cases of chronic periodontal inflammation, a patient not prepared to undergo oral rehabilitation, inappropriate parafunctional

habits, for example bruxism, untreatable occlusion/joint problems, active intraoral infection and in the case of immediate loading, primary implant stability inadequate.

SIDE EFFECTS

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

WARNING

The implants must receive components with compatible geometry or specific components for the technique switching platform and installation indication compatible only with S.I.N. system. The products are for single use and cannot be re-sterilized and/or reused. The reuse or re sterilization of this product may cause contagious infectious disease, deformation and wear of the product.

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 25°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

The S.I.N. Sterile Components are sterile products 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. Sterile Components must be transported adequately to avoid falling and stored under a maximum temperature of 25°C, protected from heat and moisture. Carriage must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Magnetic Resonance Imaging (MRI): Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. Implant System 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. Implant System
Static Magnetic Field Strength (B0)	≤ 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.

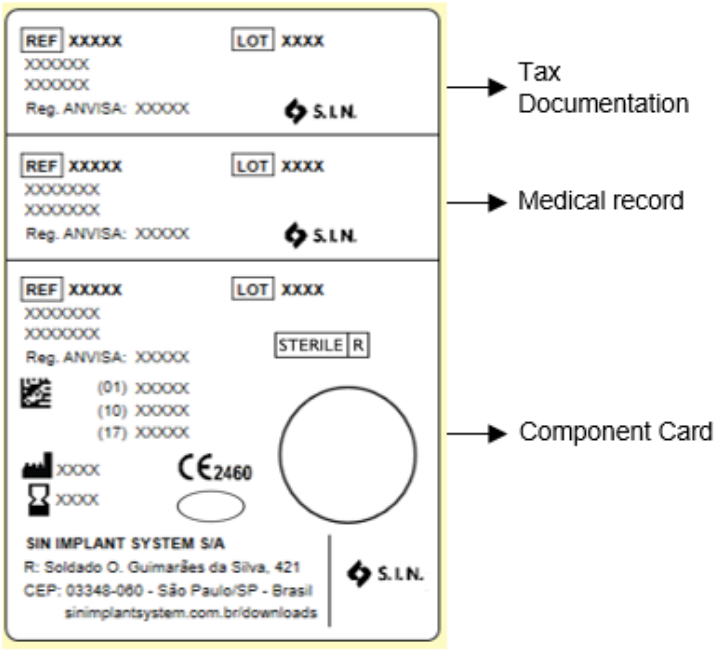
TRACEABILITY LABELS

The Abutments are available from S.I.N. 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.

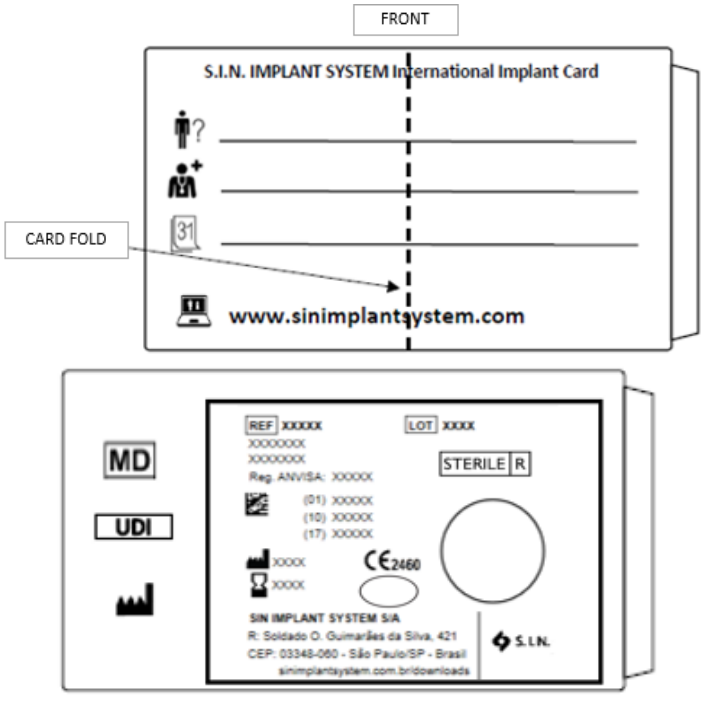
Label of Component Card: The dental surgeon should attach a label to the component card to inform which products were used.



*Merially illustrative image

COMPONENT CARD

The S.I.N. Sterile Components are provided by S.I.N. 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

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
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 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
DESCRIPTION ON THE LABEL	CONTÉM: 1 UNIDADE	CONTENT: 1 UNIT	CONTENU: 1 UNITÉ
DESCRIPTION ON THE LABEL	PRODUTO NÃO ESTÉRIL	NON STERILE PRODUCT	PRODUIT NON STÉRILE
DESCRIPTION ON THE LABEL	MAT. TITANIUM	MAT. TITANIUM	MAT. TITANIO

MANUFACTURER
S.I.N. Implant System LTDA
CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
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CEP: 03348-060 - São Paulo - SP - Brazil

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PRODUCT
S.I.N. Sterile Components

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