

The Temporary Abutment is intended to be used in humans for the making of provisional prostheses, assisting in the treatment of rehabilitation of masticatory function.



PRODUCT DESCRIPTION

The Temporary Abutment is a prosthetic component, consists of a cylindrical abutment made of titanium grade V with internal perforation to access the prosthesis fixation screw. They are made available to the professional in NON-STERILE form. Supplied with titanium grade V 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

It has the finality of, together with the implant, transmitting the strength of mastication to the bone board, in which they are surgically implanted. The Temporary Abutment are based on the mechanical principles of assembling the load transmission system.

HOW TO USE THE COMPONENT

Temporary Abutment and screws must be sterilized before use according to the guidelines contained in this instruction for use.

- Directly in the mouth or on a model with an analog, attach the Temporary Abutment and adjust the height of the component according to the available interocclusal space;
- Build or cement the temporary restoration taking care to maintain the screw access hole;
- Perform necessary adjustments such as polishing, occlusal adjustments;
- Connect the temporary restoration together with the Temporary Abutment or prosthetic intermediaries to the implant platform;
- Temporarily close the screw access with Teflon and restorative material.

*The recommended torque for installing the Temporary Abutment is 20 N.cm when installed directly over the implant connection, be it external hexagon, internal hexagon or morse taper, and 10 N.cm when installed over prosthetic intermediaries.



ATTENTION

The Temporary Abutment 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, he must undergo a thorough clinical analysis. Failure to perform 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. The Temporary Abutment must be sterilized before use, prepare the environment with a sterile surgical drape, subject the patient to a good oral asepsis, prevent the product from touching non-sterile objects at the time of application, in order to minimize contamination risks. Only handle the material in a sterile field. All material used in the procedure must be sterile. 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 of other brands or adapted for implant models can reduce the life of the system causing irreversible damage. If a correct diameter is not used, irritation of the soft tissue may occur. The platform of the Temporary Abutment that adapts to the implant must not be altered in any way. The professional should ensure that the product is not aspirated by the patient. 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 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 Temporary Abutment, it is recommended that the professional has a specialization course in the area and prepare a prosthetic execution plan. Inadequate planning and/or lack of occlusal adjustment can compromise the performance of the implant/prosthesis set resulting in system failures, such as implant loss or fracture, 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 Temporary Abutment to be used. The S.I.N. does not recommend installing the implant in patients with inadequate oral hygiene, uncooperative and unmotivated patient, with abuse of drugs or alcohol, psychosis, chemical dependency, prolonged functional disorders that resist any drug treatment, xerostomia, low immune system, diseases that require the use of steroids regularly, endocrinological diseases, drug allergies, diabetes mellitus, anticoagulant medications/hemorrhagic diathesis, bruxism, other parafunctional habits, tobacco abuse, installation in children and pregnant women and during the breastfeeding period.

CONTRAINDICATIONS

The use of Temporary Abutment 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. It is also contraindicated to use the Temporary Abutment as a definitive prosthesis.

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 peri-implant tissues such as slight bleeding, edema, pain, discomfort or even infection in case of breaking aseptic barrier.

WARNING

As these are temporary prostheses usually made of acrylic resin, the time of use of the Temporary Abutment should be at most 06 months after installation in the mouth. Compatible only with S.I.N. system.

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

Once sterilized, the Temporary Abutment should only be handled in a sterile environment by professionals with proper attire and in appropriate clothing at the time of the surgical procedure.

DISPOSAL DE MATERIAL

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

TRANSPORTATION

Temporary Abutment 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 INFORMATION

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.

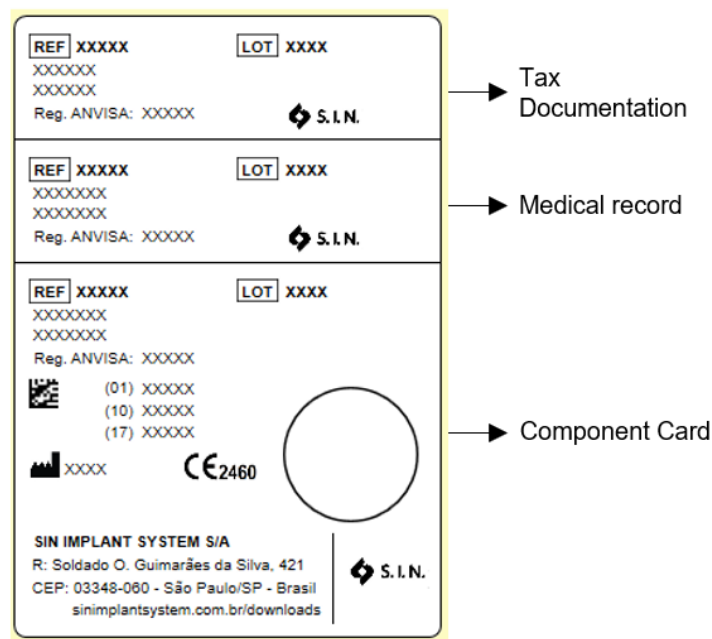
TRACEABILITY LABELS

The Temporary Abutment 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.

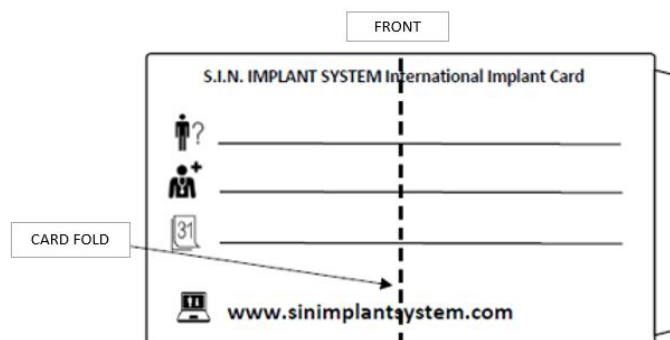
Label of Component Card: The dental surgeon should attach a label to the component card to inform which products were used.

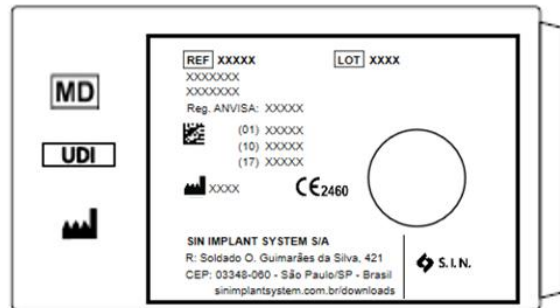


*Merially illustrative image

COMPONENT CARD

The Temporary Abutment 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






















STERILIZATION






Product provided non-sterile. It must be sterilized in autoclave before use.

1. The product must be enclosed in a steam sterilizable wrap;
2. Steam sterilize in cycles to 121°C at 1 ATM pressure for 30 minutes or to 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes;
3. Always accommodate the product in autoclave over a plane surface and away of device walls;
4. Never stack objects or other products;

RECOMMENDATIONS

- a. Sterilize the products in the same day or one day earlier the procedure;
- b. The chemical sterilization is not recommended once some products may cause damages to the product;
- c. Do not use temperature higher than 60°C to drying process;
- d. Do not use dry heat stoves for sterilization of the prosthetic components from S.I.N. Implant System;

| | | | |
|---|--|--|---|
|  | NÃO ESTÉRIL | NON-ESTERILE | NO ESTÉRIL |
|  | 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 RSTERILIZE | NO LO REESTERILIZAR |
|  | ATENÇÃO | CAUTION | PRECAUCIÓN |
|  | REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA | AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY | REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA |
|  | LÍMITE 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 |
|  | 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 |
|  | 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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PRODUCT

Temporary Abutment

MDL LICENSE CANADA

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