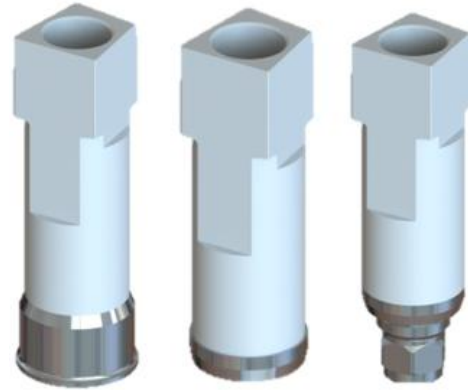


S.I.N. CAD-CAM TI Transfer are intended for expert procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.



PRODUCT DESCRIPTION

The S.I.N. CAD-CAM TI Transfer consists of a Abutment that follows the implant seating platforms. Made of grade V titanium and PEEK, accompanied by a fixation screw. They are available in NON-STERILE form.

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. CAD-CAM TI Transfer is indicated to copy and transfer the position of the implant to a virtual work model where the prosthesis will be made.

PURPOSE AND OPERATION PRINCIPLE

It has the finality of transfer the position of the implant installed in the oral cavity using a dental mold to reproduce functional models. Its working principle is based on the transfer of the implant or installed Abutment in the oral cavity through an intraoral scan or an extraoral model.

HOW TO USE THE COMPONENT

Stage 01: Definition of the implant or Abutment feature;

Stage 02: Definition of the CAD-CAM transfer to be used;

Stage 03: Screwing of the transfer over the implant or Abutment;

Stage 04: Scanning of the intraoral transferor or in the model;

Stage 05: Finalization of the prosthesis on the Analogue installed in the model or directly in the mouth;

Stage 06: Fixation of the prosthesis through screw.



ATTENTION

The S.I.N. CAD-CAM TI Transfer 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

For placing the S.I.N. CAD-CAM TI Transfer it is recommended that the professional has a specialization course in the area and that he elaborates a prosthetic execution plan. The professional must sterilize the instruments, prepare the patient to minimize the risk of contamination and prevent the product from having contact with any non-sterile object. The S.I.N. CAD-CAM TI Transfer that adapts to the implant or prosthetic intermediate should not be altered in any way. The professional must be aware of the force exerted when applying the product so as not to damage it.

RECOMMENDATIONS

For the placement of S.I.N. CAD-CAM TI Transfer, it is recommended that the professional have a specialization course in the area and prepare a prosthetic execution plan. 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

As long as the material is used properly, there is no contraindication to use. Transitional product used only to copy and transfer the implant position.

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

Compatible only with S.I.N. The product is 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.

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

Once sterilized, the S.I.N. CAD-CAM TI Transfer 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

S.I.N. CAD-CAM TI Transfer must be transported adequately to avoid falling and stored under a maximum temperature of 35°C, protected from heat and moisture. Carriage must be carried out in its original packaging.

COMPLEMENTARY INFORMATION

Single use product. Product Exclusively for odontological 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, without any cost, please request by e-mail to sin@sinimplantsystem.com or call to 0800 770 8290 will receive until 7 days calendar.



















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.

	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 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
	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

**MANUFACTURER****S.I.N. Implant System LTDA.**

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74

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RESPONSIBLE TECHNICIAN

Alessio Di Risio

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PRODUCT

S.I.N. CAD-CAM TI Transfer