COMPONENT

S.I.N. CAD-CAM Transfer



S.I.N. CAD-CAM 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.



PROUDCT DESCRITION

The S.I.N. CAD-CAM Transfer it consists of a conical or square abutment following the seating platforms according to each implant model (3.4mm, 4.1mm, 4.3, 4.5mm, 5.0mm and Cone Morse). Made of titanium grade 5 and PEEK, they come with a fixing screw and are available in NON-STERILE

Information applicable to JBHE 34; JBHE 36 JBHE 41; JBHE 45; JBHE 50 models:

- · Product with pass screw (with screw);
- · Manual screwing torque on the implant;
- · Compatible with external hexagon implants.

Information applicable to JBHI 38; JBHI 45; JBHI 50 models:

- Product with pass screw (with screw);
- Manual screwing torque on the implant;
- Compatible with internal hexagon implants.

Information applicable to JBSWCM model:

- · Product with pass screw (with screw);
- Manual screwing torque on the implant;
- · Compatible with cone morse implants.

Information applicable to JBUCM model:

- Product with pass screw (with screw);
- Manual screwing torque on the implant;
- Compatible with Unitite cone morse implants.
- Information applicable to JBMA model:
- · Product with pass screw (with screw);
- · Manual screwing torque on the component;
- · Compatible with mini-abutment components.

Information applicable to JBMMA model:

Product with pass screw (with screw);

- Manual screwing torque on the component;
- · Compatible with micro mini-abutment components.

Information to models: JBAC 00; JBAC 06:

- · Product with pass screw (with screw);
- · Manual screwing torque on the component;
- · Compatible with conic abutment components.

INDICATIONS OF USE

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

OPERATION PRINCIPLE

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

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 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 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 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 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 perimplant 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 resterilized 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. – Implant System 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. CAD-CAM Transfer should be stored in a cool dry place at a maximum temperature of 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 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 OF MATERIAL

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



TRANSPORTATION

The S.I.N. CAD-CAM Transfer ponents 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 INFORMATIONS

Single use product. Reprocessing prohibited. Product for exclusive dental use. In the event of an incident caused by the product, the professional must immediately inform the manufacturer. 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.

STERILIZATION

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

- 1. The product must be enclosed in a steam sterilizable wrap.
- 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

- Sterilize the products in the same day or one day earlier the procedure.
- 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.



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NON	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
(2)	NÃO REUTILIZAR	DO NOT REUSE	NO LO REUTILICE
[]i	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
CE	MARCAÇÃO CE	CE MARK	MARCA CE
Ť	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
STERRIZE	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO REESTERILIZAR
\triangle	ATENÇÃO	CAUTION	PRECAUCIÓN
EC REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
35°C	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.	(USA) RESTRICTS THIS DEVICE TO SALE BY OR ON	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
M	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
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
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
BRA	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
LOT	LOTE	BATCH CODE	LOTE
Δ	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE



DEVELOPED AND MANUFACTURED BY: S.I.N. Sistema de Implante Nacional S/A

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74 Rua Soldado Ocimar Guimarães da Silva, 2445 - Vila Rio Branco CEP: 03348-060 - São Paulo - SP - Brazil

SERVICE TO PROFESSIONALS

0800 770 8290 +55 (11) 2169-3000

<u>www.sinimplantsystem.com</u> **email**: <u>sin@sinimplante.com.br</u> EC REP

OBELIS S.A.

Bd. Général Wahis 53 1030 Brussels, Belgium ϵ

RESPONSIBLE TECHNICIAN:

Alessio Di Risio

CREA-SP (register): 5061207169

PRODUCT: S.I.N. CAD-CAM Transfer

ANVISA REGISTRATION 80108910076