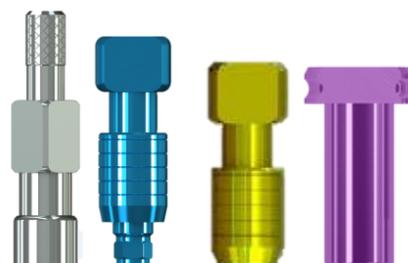


S.I.N. Transfer are intended for expert procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health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



PROUDCT DESCRIPTION

The S.I.N. Transfer it consists of a conical or square abutment following the seating platforms according to each implant model (3.4mm, 3.5mm, 3.6mm, 3.8mm, 4.1mm, 4.4mm, 4.5mm, 4.8mm, 5.0mm, 5.5mm, 6.0mm and Cone Morse) supplied with a fixing screw. Made of titanium grade 5 are available in NON-STERILE.

Information applicable to: TMAI 3605; TMAI 4105; TMAI 5005; TMAI 5006; TMAI 4105EA; TMAI 4105EB; TMAI 4105EC; TMAI 505; TMFDIS; TMFI 3438; TMFI 3605; TMFI 38; TMFI 4105; TMFI 45; TMFI 5005; TMFI 55; TMFI 5506; TMFIS 55; TMIM 06; TMAHE 36; TMFHE 36.

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

Information applicable to: TIHI 38; TMAI 45; TMAI 4505; TMAI 55; TMAIS 45; TMAIS 55; TMFI 4505; TMFIS 38; TMFIS 45; TIHIS 38; TMAI 5506.

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

Information applicable to: TMAIE.

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

Information applicable to: TMFIM 35C; TMFIM 40C; TMFIM 45C; TMFIM 50C; TMAIM 35C; TMAIM 45C; TMAIM 40C; TMAIM 50C.

- Product with pass screw (with screw);
- Manual screwing torque on the implant;

- Compatible with cone morse implants.

Information applicable to: TMAMU; TMFMU; TMFMUS.

- Product with pass screw (with screw), with exception of TMFMUS;
- Manual screwing torque on the implant;
- Compatible with cone morse Unitite implants.

Information applicable to: TMAM 4800; TMFM 4800

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

Information applicable to: TMM 33; TMM 3306; TMMF 33; TMMF 3306.

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

Information applicable to: TMAS

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

Information applicable to: TMAA 4800; TMAA 4806; TMFA 4800; TMFA 4806.

- Product with pass screw (with screw);
- Manual screwing torque on the component;
- Compatible with conical abutment componentes.

Information applicable to: TMAAM 00; TMAAM 06; TMFAM 00; TMFAM 06.

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

INDICATIONS OF USE

The S.I.N. 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: Select the open or closed S.I.N. Transfer according to the installed Abutment;

Stage 02: Fit the Transfer and screw it to ensure adaptation;

Stage 03: For the impression procedure, select the appropriate tray and manipulate the impression material. For the open tray transfer, the tray must have a hole for the screw exit;

Stage 04: After the impression material setting time, for open tray transfer, first unscrew the transfer agent and then remove the whole assembly, check if the transfer agent has been transferred from the mouth to the mold successfully. For the closed tray transfer, first remove the assembly and then unscrew the transfer, then fit it into the impression;

Stage 05: Make the necessary individualizations and preparations for the making of the model using the selected Analogue;

Stage 06: After building the model, the transferor can be discarded.



ATTENTION

The S.I.N. 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. 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. 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. 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 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. – 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. 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. 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. 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 INFORMATIONS

Single use product. Reprocessing prohibited. Product for exclusive dental use. In case of an incident caused by the product, the professional must immediately inform the manufacturer and the competent authority of the Member State in which user and/or patients is established. 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.

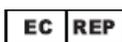
STERILIZATION

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

1. The product must be enclosed in a steam sterilizable wrap.
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 LALUZ SOLAR
	NÃO UTILIZAR SE AEMBALAGEM ESTIVERVIOLADA	DO NOT USE IF PACKAGEIS DAMAGED	NO LO UTILICE SI ELENVOLTORIO ESTÁ DAÑADO
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO REESTERILIZAR
	ATENÇÃO	CAUTION	PRECAUCIÓN
	REPRESENTANTEAUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTEAUTORIZADO EN LA COMUNIDAD EUROPEA
	LIMITE SUPERIORDE TEMPERATURA	UPPER OFTEMPERATURE LIMIT	LÍMITE SUPERIORDE TEMPERATURA
Rx only	ATENÇÃO: LEI FEDERAL (EUA) LIMITA A VENDA DESTE DISPOSITIVO POR ORDEM DE UM PROFISSIONAL DE SAÚDE LICENCIADO	CAUTION: FEDERAL LAW(USA) RESTRICTS THISDEVICE TO SALE BY OR ONTHE ORDER OF A LICENSEDHEALTHCARE PRACTITIONER.	PRECAUCIÓN: LAS LEYESFEDERALES (USA) RESTRINGENLA VENTA DE ESTEDISPOSITIVO POR O EN ELORDEN DE UN PROFESIONALDE LA SALUD LICENCIADO.
	FABRICANTE	MANUFACTURE	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	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

www.sinimplantsystem.com

email: sin@sinimplante.com.br

EC	REP
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OBELIS S.A.

Bd. Général Wahis 53
1030 Brussels, Belgium



RESPONSIBLE TECHNICIAN:

Alessio Di Risio
CREA-SP (register): 5061207169

PRODUCT: S.I.N. Transfer

ANVISA REGISTRATION: 80108910050