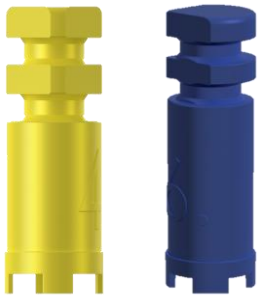
COMPONENT

Universal Transfer

Universal 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 Universal Transfer is an Abutment that has a connection to fit the prosthetic intermediate fixed in the implant. They are made of polyacetal.

INDICATIONS OF USE

Universal Transfers are indicated to copy and transfer the implant position to a working model where the prosthesis will be made.

PURPOSE AND OPERATION PRINCIPLE

Its principle of operation is by transferring the position of the implant that is in the mouth to a (negative) mold that will then be transformed into a (positive) working model.

HOW TO USE THE COMPONENT

Stage 01: Select the Universal Transfer Device according to the Universal Abutment installed;
Stage 02: Fit the Universal Transferring Device until you hear the "click" to ensure the adaptation to the Universal Abutment;
Stage 03: Definition of the type of impression material to be used;
Stage 04: After the setting time of the impression material, remove the tray and check if the Universal Transfer was successfully transferred from the mouth to the impression;
Stage 05: Make the necessary individualizations and preparations for the model fabrication using the selected Universal Abutment Analog;
Stage 06: After the model construction, the transfer can be discarded.

⚠ ATTENTION

The Universal 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

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. Transferents 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 transfer platform that adapts to the component must 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. 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 Universal Transfer, it is recommended that the professionals 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

S.I.N. does not indicate the installation of components in patients who have: acute inflammatory or infectious processes of living tissues, serious medical problems such as disorders of bone metabolism, disorders of blood coagulation, poor healing capacity, incomplete maxillary growth, inadequate parafunctional habits, ex. bruxism, allergy or hypersensitivity to titanium, acute periodontitis and oral mucosa alterations.

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.

TRACEBILITY

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 Universal 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

Universal 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

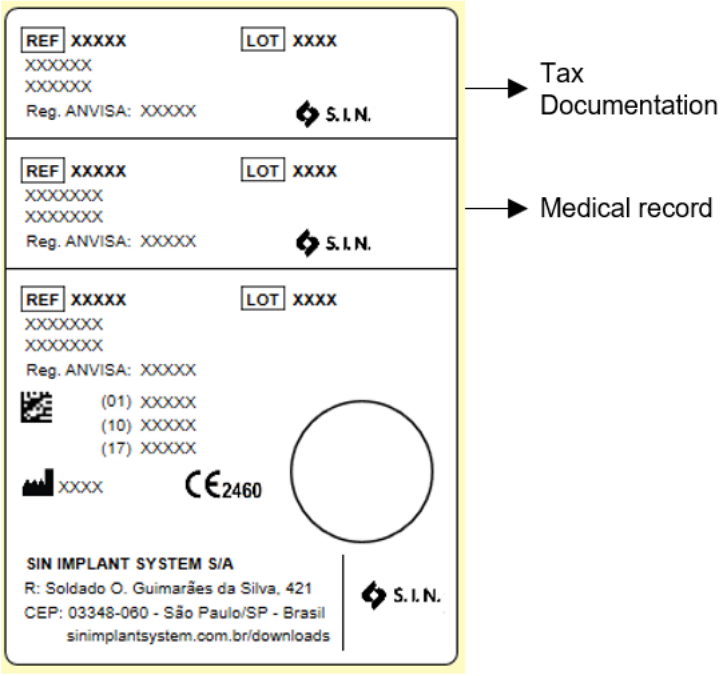
Single use product. Product Exclusively for odontological use. Reprocessing not allowed. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed 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.

TRACEABILITY LABELS

The Universal Transfer are available from S.I.N. with 3 (three) labels containing product information. The labels must be used as follows:

Tax 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.



*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.

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.

	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
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
	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

MANUFACTURER
S.I.N. Implant System LTDA.
CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
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PRODUCT
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