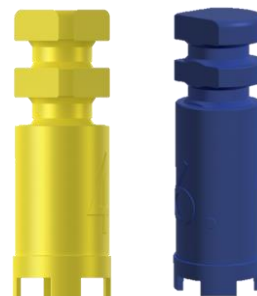


Universal Transfer are intended for expert procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health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



PROUDCT DESCRIPTION

The Universal Transfer is an abutment that has a connection for fitting with the prosthetic intermediate fixed on the implant. They are manufactured in polymetal and are available to the professional in a non-sterile format.

INDICATIONS OF USE

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

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

- Stage 01:** Definition of the implant feature;
- Stage 02:** Definition of the abutment to be used;
- Stage 03:** Definition of accessory type to be used;
- Stage 04:** Transfer from the implant to a model through the transfer;
- Stage 05:** Finalization of the prosthesis on the analogue installed in the model;
- Stage 06:** Cemented prosthesis fixation.



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

For placing the Universal 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 Universal 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 Universal 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 Universal 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 Universal Transfers should be handled only in a sterile environment by properly trained professionals wearing appropriate uniforms 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 Universal 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.

ESTERILIZAÇÃO

Produto fornecido não estéril e deve ser esterilizado antes do uso.


1. Utilizar embalagem compatível com o processo de esterilização a vapor;
2. Esterilizar a vapor em ciclos de 121°C a 1 ATM de pressão durante 30 minutos ou a 134°C a 2 ATM de pressão durante 20 minutos. Deixar secar por 30 minutos;
3. Sempre acomode o produto na autoclave sobre uma superfície plana e afastada das paredes do aparelho;
4. Nunca sobreponha objetos e nem mesmo outros produtos.

RECOMENDAÇÕES

- a. Esterilizar na véspera ou no dia do procedimento;

- b. A esterilização química não é recomendada, uma vez que certos produtos podem provocar danos ao produto;
- c. Não utilize temperatura superior a 60°C para secar os produtos;
- d. Nunca utilize estufas de calor seco para esterilização dos componentes 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
	LIMITE SUPERIOR DE TEMPERATURA	UPPER LIMIT OF TEMPERATURE	LÍMITE SUPERIOR DE TEMPERATURA
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTES 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	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
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EC	REP
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RESPONSIBLE TECHNICIAN:

Alessio Di Risio
CREA-SP (register): 5061207169

PRODUCT: Universal Transfer

ANVISA REGISTRATION 80108910051