COMPONENT

Temporary Abutments

The Temporary Abutment is intended to be used in humans for the making of provisional prostheses, assisting in the treatment of rehabilitation of masticatory function.

PRODUCT DESCRIPTION

The Temporary Abutment is a pronthetic component, consists of a cylindrical abutment made of titanium grade V with internal perforation to access the prosthesis fixation screw. They are made available to the professional in NON-STERILE form. Supplied with titanium grade V screw.

INDICATIONS OF USE

The Temporary Abutment is indicated for the preparation of the provisional prosthesis over implants or prosthetic intermediary, being fixed by screw. This product allows a temporary prosthetic solution, the maximum period indicated for use is 06 months. It can have two fitting options: Rotational (without hexagon) - indicated for Multiple prosthesis and Antirrotational (with hexagon) - indicated for unitary prosthesis.

OPERATION PRINCIPLE

It has the finality of, together with the implant, transmitting the strength of mastication to the bone board, in which they are surgically implanted. The Temporary Abutments are based on the mechanical principles of assembling the load transmission system.

HOW TO USE

Temporary Abutment and screws must be sterilized before use according to the guidelines contained in this instruction for use.

1. Directly in the mouth or in a model with an analogue, connect the temporary abutment and adjust the height of the component according to the available interocclusal space;
2. Build or cement the temporary restoration with care to keep the hole for access to the screw;
3. Make the necessary adjustments such as polishing, occlusal adjustments;
4. Connect* the temporary restoration assembly with the temporary abutment or prosthetic intermediate on the implant platform;
5. Temporarily close the screw access with Teflon and restorative material.

*The recommended torque for the installation of temporary abutments is 20 N.cm for implants external hexagon, internal hexagon and cone morse and 10N.cm for prosthetic intermediate.

ATTENTION

The Temporary Abutments implants 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

Consider the general state of health of the patient, he must undergo a thorough clinical analysis. Failure to perform the pre-surgical evaluation may result in the impossibility of finding pre-existing diseases. Patients who have local or systemic factors that may interfere with the soft tissue healing processes should receive special attention. The Temporary Abutment must be sterilized before use, prepare the environment with a sterile surgical drape, subject the patient to a good oral asepsis, prevent the product from touching non-sterile objects at the time of application, in order to minimize contamination risks.

Only handle the material in a sterile field. All material used in the procedure must be sterile. During the surgical and prosthetic procedure, use only implants, components and instruments specified by S.I.N., they have specific dimensions and tolerances for each implant system ensuring the longevity of the product. Components of other brands or adapted for implant models can reduce the life of the system causing irreversible damage. If a correct diameter is not used, irritation of the soft tissue may occur. The platform of the Temporary Abutment that adapts to the implant must not be altered in any way. The professional should ensure that the product is not aspirated by the patient. It is the professional's responsibility to use S.I.N. in accordance with the instructions for use, as well as determining whether it suits the individual situation of each patient. The patient should be informed about all possible surgical complications, contraindications, warnings, precautions and adverse reactions. All documentation accompanying the product must 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 Temporary Abutment, it is recommended that the professional has a specialization course in the area and prepare a prosthetic execution plan. Inadequate planning and/or lack of occlusal adjustment can compromise the performance of the implant/prosthesis set resulting in system failures, such as implant loss or fracture, loosening or fracture of the prosthetic screws. The implant diameter and angulation, as well as the gingival height, must be taken into account when choosing the Temporary Abutment to be used. The S.I.N. does not recommend installing the implant in patients with inadequate oral hygiene, uncooperative and unmotivated patient, with abuse of drugs or alcohol, psychosis, chemical dependency, prolonged functional disorders that resist any drug treatment, xerostomia, low immune system, diseases that require the use of steroids regularly, endocrinological diseases, drug allergies, diabetes mellitus, anticoagulant medications/hemorrhagic diathesis, bruxism, other parafunctional habits, tobacco abuse, installation in children and pregnant women and during the breastfeeding period.

CONTRAINDICATIONS

The use of Temporary Abutments is contraindicated in cases of chronic periodontal inflammation, a patient not prepared to undergo oral rehabilitation, inappropriate parafunctional habits, for example bruxism, untreatable occlusion/joint problems, active intraoral infection and in the case of immediate loading, primary implant stability inadequate.
It is also contraindicated to use the Temporary Abutment as a definitive prosthesis.

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

As these are temporary prostheses usually made of acrylic resin, the time of use of the temporary abutments should be at most 06 months after installation in the mouth. Compatible only with S.I.N. system.

TRACEABILITY

All S.I.N. - Sistema de Implante 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 Temporary Abutment 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 Temporary Abutments 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

Temporary Abutment 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

Magnetic Resonance Imaging (MRI): The safety and compatibility of S.I.N. products with the MRI environment have not been evaluated. No heating, displacement or distortion experienced by S.I.N. dental implants and components in the MRI environment have been tested. The safety of these products in the MRI environment is unknown. MRI scanning a patient with this device may result in harm to the patient. Single use product. Reprocessing prohibited. Product for exclusive dental use. Consult conditions of sterilization in this instruction of use. In the event of an incident caused by the product, the professional must immediately inform the manufacturer. Se hai bisogno di una versione stampata di queste istruzioni per l'uso, gratuitamente, ti preghiamo di richiederla via e-mail a sin@sinimplante.com.br o chiamare lo 0800 770 8290 e la riceverai entro 7 giorni di calendario.

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;
2. Always accommodate the product in autoclave over a plane surface and away of device walls;
3. 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
	REPRESENTANTEAUTOR IZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTEAUTORIZADO EN LA COMUNIDAD EUROPEA
	LIMITE SUPERIORDE TEMPERATURA	UPPER LIMIT OFTEMPERATURE	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
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PRODUCT: Temporary Abutments

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