COMPONENT

Metallic Abutment

The Metallic Abutment are intended for specialized 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

Chromium Cobalt Abutment: Consist of a cylindrical abutment, based on chromium-cobalt and polyacetal body, its plastic structure allows the laboratory to delimit the desired shape of the future prosthesis to be waxed, it has an internal perforation to access the prosthesis fixation screw. They come with the titanium grade V screw and are made available to the professional in a non-sterile format.

Chrome Cobalt Interface: Consist of a cylindrical abutment, based on chromium-cobalt and polyacetal body, its plastic structure allows the laboratory to delimit the desired shape of the future prosthesis to be waxed, it has an internal perforation to access the prosthesis fixation screw. They come with the titanium grade V screw and are made available to the professional in a non-sterile format.

INDICATIONS OF USE

The Metallic Abutment is indicated for making single or multiple prostheses, used as a working mold for casting. They can be used directly on implants of external hexagon, internal hexagon and cone morse or on prosthetic intermediate. There may be two fitting options: Rotational (without hexagon) – indicated for multiple prostheses and Anti-rotational (with hexagon) – indicated for single prostheses.

OPERATION PRINCIPLE

Chromium Cobalt Abutment: It has the finality of, together with the implant, transmitting the strength of mastication to the bone board. Based on the mechanical principles of assembling the load transmission system. The Chromium Cobalt Abutment is indicated for casting, in the fixation of the unitary or multiple prosthesis in the implant. The recommended torque for fixing the Chromium Cobalt Abutment directly on implants with internal hexagon or cone morse connection is 20Ncm. On implants of external hexagon is 32Ncm. On prosthetic intermediate the torque is 10Ncm.

Chrome Cobalt Interface: It has the finality of, together with the implant, transmitting the strength of mastication to the bone board. Based on the mechanical principles of assembling the load transmission system. The Chrome Cobalt Interface is indicated for CAD-CAM system for casting, in the fixation of the unitary or multiple prosthesis in the implant. The recommended torque for fixing the Chrome Cobalt Interface directly on implants with internal hexagon or cone morse connection is 20Ncm. On implants of external hexagon is 32Ncm. On prosthetic intermediate the torque is 10Ncm.

HOW TO USE

1. Chromium Cobalt Abutment:

a. After accessing the dental implant platform connection, a position transfer impression must be performed;
b. The metallic components must be sent to the laboratory together with the model obtained for the manufacture of metallic infrastructure through the process of casting in lost wax.
c. After making the prosthetic crown over the Metallic Abutments, the set must be sterilized before being installed on the dental implant in the oral cavity according to the guidelines contained in this instruction for use.

2. Chrome Cobalt Interface:

a. Separate the metal base and plastic cylinder.
b. Position the plastic cylinder on the metal base.
c. Fit the plastic cylinder over the metal base until it snaps into place.
d. Option of direct fit of the projects machined in wax inside the CAD-CAM process on the Chrome Cobalt Interface for casting of all set.

ATTENTION

The Metallic 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 Metallic 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 Metallic 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 Metallic 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 gingival height, must be taken into account when choosing the Metallic 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 Metallic Abutment 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.

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

The implants must receive components with compatible geometry, or specific components for the technique switching platform and installation indication. Compatible only with S.I.N.. The product is for single use and cannot be re-sterilized and/or reused.

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 Metallic 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 Metallic 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

Metallic 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. 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.

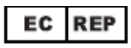
STERILIZATION

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.

	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
	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 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	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: Metallic Abutment

ANVISA REGISTRATION: 80108910033