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.

The chemical composition of the Dental Components is according to ASTM F1537:

Element	Composition % (mass/mass)
Carbon	≤ 0.14
Chromium	26.0 - 30.0
Molybdenum	5.0 - 7.0
Nickel	≤ 1.0
Iron	≤ 0.75
Silicon	≤ 1.0
Manganese	≤ 1.0
Nitrogen	≤ 0.25
Cobalt	Balance

The cover screw is according to ASTM F136:

Chemical Element	Composition % (mass/mass)
Nitrogen	≤ 0.05
Carbon	≤ 0.08
Hydrogen	≤ 0.012
Iron	≤ 0.25

Oxygen	≤ 0.13
Aluminum	5.5 - 6.5
Vanadium	3.5 - 4.5
Titanium	Balance

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.

PURPOSE AND OPERATION PRINCIPLE

Chromium Cobalt Abutment and Chrome Cobalt Interface: Its purpose is, together with the implant, to transmit the force of mastication to the bone plate. They are based on the mechanical principles of load transmission system assembly.

HOW TO USE THE COMPONENT

The recommended torque for fixing the Chromium Cobalt Abutment and Chrome Cobalt Interface directly on implants with internal hexagon or cone morse connection is 20 Ncm. For external hexagon implants it is 32 Ncm. In the prosthetic intermediate the torque is 10 Ncm.

CHROMIUM COBALT ABUTMENT

a. After accessing the dental implant platform connection, a position transfer impression must be performed;
b. The Metallic Abutment 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 Abutment, 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.

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 Abutment 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.

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. The components are available with three (3) way traceability labels.

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 Metallic Abutment 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

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): Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. devices are MR Conditional.

CAUTION: Patient imaging can only be obtained by delimiting at least 30cm from the implant or ensuring that the implant is located outside the radiofrequency coil.

A patient with this device can be safely scanned on an MRI system under the following conditions:

Device Name	S.I.N. Implant System
Static Magnetic Field Strength (B0)	≤ 3.0 T
Maximum Spatial Field Gradient	50 T/m (5.00 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head coil and body coil permitted. Extremity T/R coils permitted.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2.4 W/kg (15 minutes of scanning, Normal Operating Mode)
Maximum Head SAR	2.0 W/kg (15 minutes of scanning, Normal Operating Mode)
Scan Duration	15 minutes.
Temperature Rise	Maximum temperature rise of 0.45 °C/(W/kg), after 15 minutes of continuous scanning in a static magnetic field of 3 T with either head type or body type coils
Artifact	When imaged using a gradient-echo sequence and a 3 T MR system, image artifact can extend up to approximately 12 mm with a body coil type, and up to approximately 32 mm with a head coil type

Exclusive Product for Dental 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 or a copy of the safety and clinical performance summary (SSCP), at no cost, please request it by email to sin@sinimplantsystem.com or call 0800 770 8290 and you will receive it within 7 calendar days.

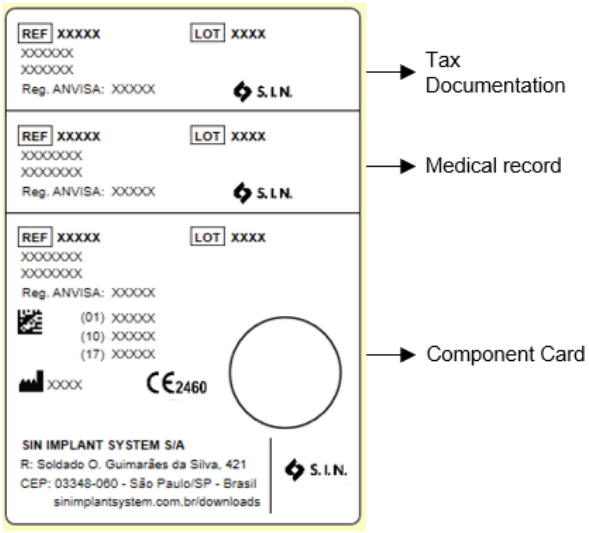
TRACEABILITY LABELS

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

Tax Documentation 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.

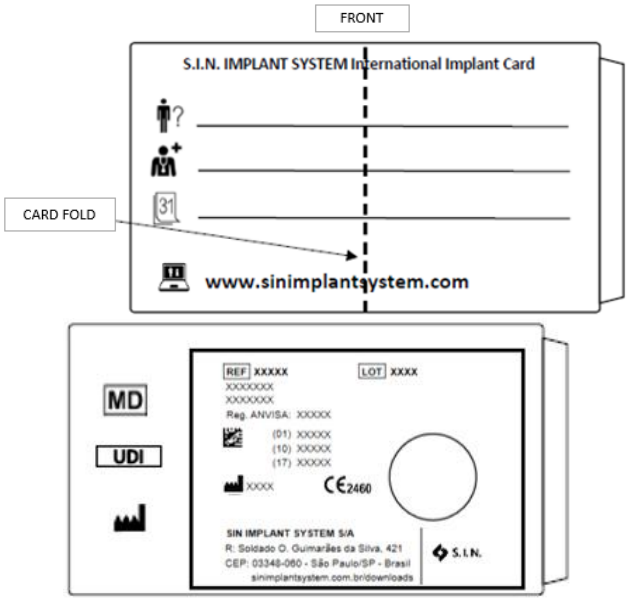
Label of Component Card: The dental surgeon should attach a label to the component card to inform which products were used.



*Merially illustrative image

COMPONENT CARD

The Metallic Abutment are provided by S.I.N. with an component card. This card must be given to the patient, who must be instructed on how to keep and preserve this information.



*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.

	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
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
LOT	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE

	MR CONDICIONAL	MR CONDITIONAL	MR CONDICIONAL
	DATA DA IMPLANTAÇÃO	DATE OF IMPLANTATION	FECHA DE APLICACIÓN
	NOME E ENDEREÇO DA INSTITUIÇÃO	NAME AND ADDRESS OF THE IMPLANTING HEALTHCARE INSTITUTION	NOMBRE Y DIRECCIÓN DE LA INSTITUCIÓN
	NOME DO PACIENTE OU IDENTIFICAÇÃO DO PACIENTE	PATIENT NAME OR PATIENT ID	NOMBRE DEL PACIENTE O IDENTIFICACIÓN DEL PACIENTE
	SITE DE INFORMAÇÕES PARA OS PACIENTES	INFORMATION WEBSITE FOR PATIENTS	PÁGINA WEB DE INFORMACIÓN AL PACIENTE

MANUFACTURER
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PRODUCT
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