COMPONENT

Prosthesis Components Overdenture

The Prosthesis Components Overdenture 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

Prosthesis Components Overdenture and their accessories are used over S.I.N. implants. The Prosthesis Components Overdenture is an intermediate between the implant and the total movable prosthesis (denture), it has variations of diameter, internal hexagon, external, cone morse, in relation to the existing implant diameters and the height of transmucosal (gingival mucosa). Its purpose is to fix the mobile prosthesis in the implanto-supported technique (fixed to the implant and supported on the mucosa).

The chemical composition of the Dental Components 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

Attachment O'Ring/Abutment O'Ring: It consists of a cylindrical pillar, following the settlement platform according to each implant model. They are available to professionals in STERILE form by Gamma Radiation. They are recommended for the manufacture of overdenture prosthesis, to be fixed to the implant and to receive or support a total prosthesis fixed thereon by means of buttoning (male and female). This attachment provides more options for cases where large amounts of bone are not available.

ACCESSORIES:

Attachment/Washer Capsule: It consists of a metal ring. Manufactured in grade 5 titanium, according to ASTM F136-08. Indicated to attach the total prosthesis over the Attachment O'Ring.

The O'Ring Attachment/O'Ring: It consists of a rubber ring made of polymer. It has the function of locking the total prosthesis over the attachment or O'Ring.

Positioner: It has cylindrical shape, available in angles of 0º (White), 7º (yellow) and 14º (blue) being manufactured in Poliacetal. Indicated as a spacer at the moment of acrylization of the total prosthesis on top of the Attachment O'Ring, providing greater softness to the prosthesis during mastication.

Plastic clip 90º: It is a device used for overdenture type prosthesis. It functions as a female part that clamps the overdenture bar. Made of Polyacetal. Recommended for attaching the total denture (overdenture type) to the bar that is screwed onto the implants.

Overdenture Wire: It is a bar with 45mm in length where the plastic clip will be positioned. Made of Polyacetal. Indicated for making bar for overdenture and for placement of clips. It has the function of connecting two implants with the help of the uclas forming a kind of bridge (bar) where the clips will be later fit.

Note: The accessories above are sold separately and in the NON-STERILE form, however, the completion of the work is only properly carried out if the professional uses the Prosthesis Components Overdenture together with their accessories, considering that each item has its contribution in each stage of the work, such as already described above. The accessories are designed to be used exclusively with S.I.N. Sterile Prosthesis Components and are not interchangeable with other systems from other manufacturers.

PURPOSE AND OPERATION PRINCIPLE

The principle of operation of Prosthesis Components Overdenture is based on the mechanical principles of load-carrying system assembly. Since it is the purpose of Prosthesis Components Overdenture with the implant, the transmission of the mastication force goes to the bone support, on which they are implanted surgically.

HOW TO USE THE COMPONENT

1. Open the package and remove the Abutment O'Ring component;
2. Screw the Abutment O'Ring component over the implant to the recommended maximum torque level (20Ncm). Use 20 or 24 CCAO keys;
3. Insert the positioner into the Abutment O'Ring body (note the required angulation using the 0, 7 or 14 positioners);
4. Adapt the capsule on the Abutment O'Ring by leaning on the positioner;
5. Use placeholder to wear at the exact location of the part of the total prosthesis;
6. Perform wear on the prosthesis by creating a housing for positioning the capsules;
7. Use acetate or rubber dam to isolate O'Ring in the act of capture with acrylic resin;
8. Insert self-cured acrylic resin over the capsules and in the housings created in the prosthesis;
9. Position the prosthesis over the capsules and close the mouth with the teeth of the prosthesis in occlusion;
10. Wait for the resin holding time in approximately 10 minutes;
11. Remove the prosthesis and see if the capsules are well adapted;
12. Remove excess acrylic resin and check for interference.

Note: The O'Rings in the capsule have natural wear depending on the cycle of use of the prosthesis. Therefore, always check the patient's prosthesis adaptation and if the presented retention is low, replace the O'Ring with a new one.

O'Rings replacement process:

1. Slowly screw the O'Ring wrench into the O'Ring until the key is fully engaged;
2. Pull the O'Ring remover wrench together with the O'Ring;
3. Place the new O'Ring over the acrylated capsule on the prosthesis using the O'Ring Assembly wrench;
4. Press the O'Ring over the capsule until the final settlement;
5. Remove O'Ring Assembly wrench;
6. Adapt the prosthesis back to O'Rings Abutments.

⚠ ATTENTION

The Prosthesis Components Overdenture 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 health of the patient, the same must undergo a thorough clinical analysis. Failure to perform the pre-surgical evaluation can lead to the impossibility of finding pre-existing diseases. Patients with local or systemic factors that may interfere with the soft tissue healing process should receive special attention. Sterilization of the Prosthesis Components Overdenture is only guaranteed if the primary packaging (blister) is not damaged. 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. Components 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 platform of the Prosthesis Components Overdenture that adapts to the implant must not be altered in any way. 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 Prosthesis Components Overdenture, 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 Prosthesis Components Overdenture 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 Prosthesis Components Overdenture 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

For being the surgical technique of installation of highly specialized dental prosthetic components, and surgical procedures used are complex, it is recommended to all professionals to perform specialized training, so that the application of Prosthesis Components Overdenture is safe and effective. If the technique used is not appropriate and the patient is not suitable for this type of surgery, the prosthesis component may not succeed and there shall be loss of it. 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. 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 Prosthesis Components Overdenture 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

Prosthesis Components Overdenture 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 not allowed. Exclusive Product for Dental use. 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.

STERILE R FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and single-use (sterilization method: gamma radiation) packaged in a unit that offers double protection: secondary packaging (cardboard) and primary blister packaging (PET film and surgical grade paper).

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.

	PRODUTO ESTERILIZADO POR RADIAÇÃO GAMA	PRODUCT STERILIZED THROUGH GAMMA RAYS	PRODUCTO ESTERILIZADO POR RADIACIÓN GAMA
	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
	SISTEMA DE BARREIRA ESTÉRIL	SINGLE STERILE BARRIER SYSTEM	SISTEMA DE BARRERA ESTÉRIL SIMPLES
	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

MANUFACTURER
S.I.N. Implant System LTDA.
CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 421 - Vila Rio Branco
CEP: 03348-060 - São Paulo - SP - Brasil

EU REP

OBELIS S.A.
Bd. Général Wahis 53
1030 Brussels, Belgium

CE 2460

SERVICE TO PROFESSIONALS
0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com
e-mail: sin@sinimplantsystem.com

RESPONSIBLE TECHNICIAN
Alessio Di Risio
CREA-SP: 5061207169

PRODUCT
Prosthesis Components Overdenture