COMPONENTS OVERDENTURE PROSTHESIS

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
STERILE R	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
CE	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 RESTERILIZAR
	ATENÇÃO	CAUTION	PRECAUCIÓN
EC REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
PROIBIDO REPROCESSAR	PROIBIDO REPROCESSAR	PROHIBITED REPROCESS	PROHIBIDO REPROCESAR
	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.

DEVELOPED AND MANUFACTURED BY:

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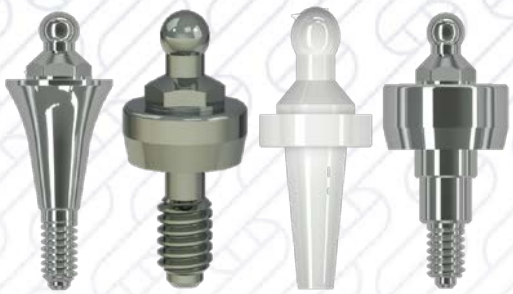
PRODUCT:

Overdenture Prosthesis Components

Anvisa Registration: 80108910030

CE 2460

Overdenture Prosthesis Components 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.



PRODUCT DESCRIPTION

Overdenture Prosthesis Components and their accessories are used over S.I.N. implants

The Overdenture Prosthesis Component 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).

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 Overdenture Dental Components 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 SIN Sterile Prosthesis Components and are not interchangeable with other systems from other manufacturers.

OPERATION PRINCIPLE

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

DIRECTIONS

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 Abutmen 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.

CONTRAINDICATIONS

The use of these components is contraindicated in the following cases:

- Chronic periodontal inflammation;
- Patient not prepared to undergo oral rehabilitation;
- Inappropriate parafunctional habits, for example, bruxism;
- • Intractable occlusion/joint problems;
- • Active intraoral infection;
- In cases of immediate loading, improper primary stability of the implant.

SIDE EFFECTS

If the technique is not adequate and the patient is not subjected to the indicated tests, the final result of application of the components may not succeed, generating product loss or fracture. The application of the product may cause effects in the area where it was applied, such as pain, tenderness of short duration, tissue reaction or infection.

PRECAUTIONS AND RECOMMENDATIONS

For the placement of Overdenture Prosthesis Components, it is recommended that the professional has a specialization course in the area and to prepare a prosthetic execution plan. The practitioner should sterilize all instruments prior to use, prepare the patient to minimize risk contamination risks and prevent the product from being in contact with any non-sterile objects.

The professional should inform the patient the forms of hygiene to be made after application of the product.

For the placement of the Overdenture Prosthesis Components, the professional should submit the patient to a thorough visual inspection to diagnose cases cited in the contraindications. The diameter and angulation of the implant, as well as the gingival height should be taken into consideration. If a correct diameter is not used, it may occur irritation of the soft tissue.

The settlement platform of the components that adapt to the implant shall not be changed at all.

Components and accessories have been designed to be used only once. The dentist should sterilize all surgical instruments prior to use, prepare the environment with a sterile surgical field, submit the patient to a good oral asepsis, check the packaging of the product for its identification and integrity, be aware of the expiration date of the product, never use it with an expired validity and prevent the product from touching any non-sterile object at the time of application, in order to minimize contamination risks.

The professional should be aware of the force exerted when applying the product so as not to damage it.

The professional should inform the patient the proper way of cleaning, the need for regular monitoring, avoiding physical and mechanical stresses and do not subject the product to improper efforts.

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 prosthetic components 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.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches 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 until the moment of distribution

STORAGE

Overdenture Prosthesis Components must be stored in a cool and dry place, keep away from sunlight.

TRANSPORTATION

S.I.N. Components must be transported in room temperature, away from direct sunlight, avoiding places with great temperature and humidity instability. The transportation must be carried out properly to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

SIN Components are sterile products that should be handled only in a sterile field by properly trained professionals and in appropriate scrubs at the time of the surgical procedure.

COMPLEMENTARY INFORMATION

Single use product. Prohibited Reprocessing. Sterile product. Sterilization process by Gamma Radiation.

Exclusive dental use product.

DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

EXPIRATION DATE

Indicated on the label.