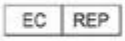
S.I.N. STERILE COMPONENTS

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	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
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
	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:

S.I.N. Sistema de Implante Nacional S/A

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PRODUCT:

S.I.N. Sterile Components
Anvisa Registration: 80108910028

CE 2460

S.I.N. Sterile 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

Mini-Abutment: It consists of a cylindrical, hexagonal, straight pillar, following the settlement platform according to each implant model. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for manufacture of screwed, multiple, partial, and complete prosthesis. It enables passive rehabilitation in cases with divergent implants up to 25.0. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

Aesthetic Mini-Abutment: It consists of a cylindrical, hexagonal, straight pillar, following the settlement platform according to each implant model. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for manufacture of screwed prosthesis, multiple, single or total, it enables passive rehabilitation in cases with divergent implants up to 25º. Used in cases when the peri-implant tissue (thin) around the implant appears to be translucent. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

Angled Mini-Abutment: It consists of a cylindrical, hexagonal pillar, with angulation variation of 17° and 30°, following the settlement platform according to each implant model. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for manufacture of screwed prosthesis, multiple, single or total. It enables the correction of misaligned implants. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

Aesthetic Angled Mini-Abutment: It consists of a cylindrical pillar, with angulation variation of 17° and 30°, following the settlement platform according to each implant model. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for manufacture of screwed prosthesis, multiple, single or total. It enables the correction of misaligned implants. Used in cases when the peri-implant tissue (thin) around the implant appears to be translucent. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

Conic Abutment: It consists of a conic, hexagonal, straight pillar, following the settlement platform according to each implant model. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for manufacture of screwed prosthesis, multiple unit (rotational or anti-rotational). Used in implants that are well positioned and within an acceptable slope, it is also responsible for the distribution of forces, acting as a buffer between the tooth (crown) and the implant. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

Aesthetic Conic Abutment: It consists of a conic, hexagonal, straight pillar, following the settlement platform according to each implant model. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for manufacture of screwed prosthesis, multiple, single or total, it enables passive rehabilitation in cases with divergent implants up to 25º. Used in cases when the peri-implant tissue (thin) around the implant appears to be translucent. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

Cemented Abutment: It consists of a cylindrical pillar, straight, following the settlement platform according to each implant model. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for manufacture of cemented prosthesis, multiple or single, partial or total, it allows to hold the fixed prosthesis on the implant. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

Angled Cemented Abutment: It consists of a cylindrical pillar, with angulation variation of 17° and 30°, following the settlement platform according to each implant model. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for manufacture of cemented prosthesis, multiple or single, partial or total. It enables the correction of misaligned implants. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

Titanium Interfaces: It consists of a cylindrical pillar, straight, following the settlement platform according to each implant model. External hexagon, internal hexagon and Cone Morse are available for prosthetic platforms, as they can be used on conical abutments, mini abutments and micro mini abutments. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for production of cemented or screwed prosthesis, multiple or single, partial or total through the CAD-CAM system, which allows holding the fixed prosthesis on the implant. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

TiForms: It consists of a cylindrical pillar, straight, customizable, following the settlement platform according to each implant model. Compatible with prosthetic platforms of external hexagon, internal hexagon and Cone Morse type. They are available to professionals in **STERILE** form by Gamma Radiation. Intended for production of cemented or screwed prosthesis, multiple or single, partial or total through the CAD-CAM system, which allows holding the fixed prosthesis on the implant. This product may or may not present anodizing (yellow or pink), depending on the needs of the professional.

INDICATIONS OF USE

S.I.N. Sterile Components are indicated in the final reparation of multiple or single element, whether or not there is aesthetic need, being fixed by screw, glass ionomer or other cements indicated for the procedures.

OPERATION PRINCIPLE

S.I.N. Sterile Components are used on S.I.N. implants based on the mechanical principles of load-carrying system assembly. Since it is the purpose of prosthetic components associated with the implant, the transmission of the mastication force goes to the bone support, on which they are implanted surgically.

HOW TO USE

Cemented Prostheses:
Stage 1: Definition of the component feature;
Stage 2: Definition of the component to be used;
Stage 3: Definition of accessory type to be used;
Stage 4: Transfer from the implant to a model through the transfer;
Stage 5: Finalization of the prosthesis on the Analogue installed in the model;
Stage 6: Fixation of the prosthesis through cement;

Screwed prostheses:
Stage 1: Definition of the implant feature;
Stage 2: Definition of the component to be used.
Stage 3: Definition of the accessory type to be used.
Stage 4: Transfer from the implant to a model through the transfer;
Stage 5: Finalization of the prosthesis on the Analogue installed in the model;
Stage 6: Fixation of the prosthesis through screw;

CONTRAINDICATIONS

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

- Chronic periodontal inflammation;
- Unprepared patient to undergo oral rehabilitation;

- Inappropriate parafunctional habits, e.g. bruxism;
- Intractable occlusion/joint problems;
- Active intraoral infection;
- In cases of immediate loading, inadequate 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.
Surgical Complications: The surgical procedure of implant installation may bring risks in the trans-operative and postoperative, such as pain, edemia, bleeding, hematoma, dehiscence, paresthesia, infection, etc.

PRECAUTIONS AND RECOMENDATIONS

For the placement of prosthesis components, it is recommended that the professional has a specialization course in the area and to prepare a prosthetic execution plan. Professionals should sterilize all instruments before use, prepare the patient to minimize the risk of contamination and prevent the product comes into contact with any non-sterile object The professional should inform the patient the forms of hygiene to be made after application of the product.
For the placement of these 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, irritation of the soft tissue may occur. The settlement platform of the components that adapt to the implant shall not be changed at all. Components which are sent sterilized have been designed to be used only once. The professional shall sterilize all surgical instruments before use, prepare the environment with scrub and sterile surgical field, refer the patient to a good oral asepsis, check the packaging of the product and its identification and integrity, be careful to the expiration date of the product, never use the product with expired validity and at the time of application, prevent the product to come into contact with any non-sterile object to minimize the risk of contamination.

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. - Sistema de Implante 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 to the distribution time.

STORAGE

S.I.N. Sterile Components must be stored in a cool and dry place, keep away from sunlight.

TRANSPORTATION

S.I.N. Sterile Components must be transported in room temperature, away from direct sunlight, avoiding places where large variations of temperature and humidity occur. The transportation must be carried out properly to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

S.I.N. Sterile 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.

ADDITIONAL INFORMATION

Single use product. Prohibited Reprocessing.
Sterile Product. Process of Sterilization 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.