COMPONENT

S.I.N. Component

S.I.N. Component 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.

PROUDCT DESCRITION

Healing Cap: It consists of a cylindrical pillar, its lower end adapts to the implant connection and has a thread for fixation. They are manufactured in titanium grade V and sold in sterile form.

Protector: It consists of a cylindrical pillar, its lower end adapts to the abutment (prosthetic intermediary) and has a thread for fixation. They are manufactured in titanium grade V and sold in sterile form.

Implante Cover: It consists of a cylindrical titanium grade V abutment available for external hexagon, internal hexagon and cone morse and has a thread for fixing the implant.

INDICATIONS OF USE

The S.I.N. Components are indicated for guide the proper healing of periimplant gingival tissue, shaping the prosthesis space in the patient's gums. It is also indicated to protect the interior of the implant until the installation of the prosthesis, against any contaminating particle that can enter its hole. Indicated to be used up to 30 days.

OPERATION PRINCIPLE

Healing Cap: It has the finality of forming the emergency profile for correct seating of the prosthesis, in addition to protecting the interior of the implant from intraoral contamination. They are based on the principle of stabilization and epithelialization of gingival tissue.

Protector: It has the finality of forming the emergency profile for correct seating of the prosthesis, in addition to protecting the interior of the component from intraoral contamination. They are based on the principle of stabilization and epithelialization of gingival tissue.

Implante Cover: Its finality is to protect the interior of the implant from intraoral contamination.

HOW TO USE

After implant installation or after reopening procedure.

1. Evaluate the fibromucosal tissue: thickness, type and height available.
2. X-ray to know the correct location of the implant with appropriate radiographic technique (parallelism or bisector - periapical X-Ray).
3. Check the diameter of the implant.
4. Check the angulation of the installed implant.
5. Calculate the height of the healing caps, through a probe millimeter according to the height of the fibromucosa in its crest to the platform of the implant, and the Healing Cap should be approximately 2mm higher than this measurement.
6. Note that the Diameter of components has variations according to implanted tooth (greater or lesser), implant location, gap between teeth, implant diameter, border thickness or space between the implants and preserving the gingival papilla.
7. Healing Caps should be left in the oral cavity for approximately 15 days.
8. Remove component of its packaging and adapt it to the implant head with the help of digital keys, contra-angle keys or ratchet wrenches. Thread over the implant until it is fully set with digital torque of 10N.cm.

ATTENTION

The S.I.N. Components 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 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 S.I.N. Components 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 S.I.N. Components 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 Components S.I.N., it is recommended that the professional have a specialization course in the area and prepare a prosthetic execution plan.
Inadequate planning and/or lack of occlusal adjustment may compromise the performance of the implant/prosthesis combination resulting in system failure, such as implant loss or fracture, loosening or fracture of the prosthetic screws.
The diameter and the angulation of the implant, as well as the gingival height, must be taken into account when choosing the model of Components S.I.N. to be used.
The S.I.N. does not recommend implant installation in patients with inadequate oral hygiene, uncooperative and unmotivated patients, drug or alcohol abuse, psychoses, chemical dependence, prolonged functional disorders that resist any drug treatment, xerostomia, low immune system, diseases which require the use of steroids regularly, endocrinological diseases, drug allergy, diabetes mellitus, anticoagulants/bleeding diathesis, bruxism, other parafunctional habits, tobacco abuse, installation in children and pregnant women and during breastfeeding.

CONTRAINDICATIONS

The use of S.I.N. Components 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 perimplant 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.
The reuse or re sterilization of this product may cause contagious infectious disease, deformation and wear of the product.

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 S.I.N. Components 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

The S.I.N. 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.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

The S.I.N. Components 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.

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).

COMPLEMENTARY INFORMATIONS

Single use product. Reprocessing prohibited. Product for exclusive dental use. In the event of an incident caused by the product, the professional must immediately inform the manufacturer.

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.

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
	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
EC REP	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	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

DEVELOPED AND MANUFACTURED BY:
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PRODUCT:
S.I.N. Component

ANVISA REGISTRATION 80108910025