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 REESTERILIZAR
	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:

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

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RESPONSIBLE TECHNICIAN:

Alessio Di Risio
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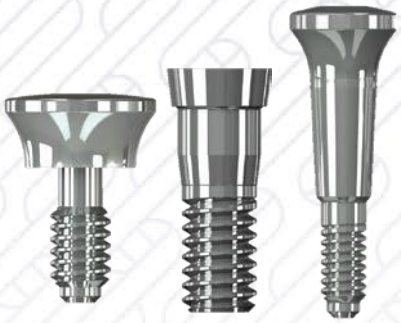
PRODUCT:

S.I.N. Components
Anvisa Registration: 80108910025

CE 2460

S.I.N. 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

S.I.N. Components are manufactured in Titanium (Grade 5) and used in the healing process of the gingiva keeping it visible for manipulation of the prosthesis and prevent accumulation of residues on it. When temporary, they must be removed when installing the prosthesis.

INDICATIONS OF USE

S.I.N. Components are indicated to heal the gingiva around the implant or Abutment leaving the implant platform or Abutment free for following procedures.
Healing Abutment: 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. Its use is indicated for soft tissue healing and for protection of the implant to prevent the invasion of the mucosa on top of it. Regarding this product, it is worth mentioning that the use in the healing period of soft tissue is valid, being replaced by one of the definitive Abutments according to the prosthetic solution chosen by the professional.
Protector Abutment: It consists of a cylindrical pillar that becomes adapted to the implant platform. They are available to professionals in STERILE form by Gamma Radiation. Its use is indicated for soft tissue healing and for protection of the mini-abutment to prevent the invasion of the mucosa on top of it. Regarding this product, it is worth mentioning that the use only in the healing period of soft tissue is valid, being replaced by one of the definitive Abutments according to the prosthetic solution chosen by the professional.

Cover Screw Abutment: 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. The use is indicated to protect the interior of the implant during the osseointegration period against any particles that may enter its orifice.

OPERATION PRINCIPLE

S.I.N. Components of Healing type base their working principle on the protection of the internal orifice of the implant during the osseointegration period. Also, they are used to the formation of emergency profile for correct settlement of the prosthesis.
S.I.N. Components of Protector and Cover Screw type base their working principle on the protection of the implant's internal orifice during the osseointegration period.

HOW TO USE

After implant installation or after reopening procedure.

Insertion of the S.I.N. Component:

1.Evaluate the fibromucosal tissue: thickness, type, and height of the back of the bag;
2.Evaluate the vestibular/palatal or vestibular/lingual thickness;
3.Use a x-ray to know the correct location of the implant with the professional's own technique;
4.Check the diameter of the implant through notes on the patient's chart on the implantation day;
5.Check the angulation that the implant was implanted into the bone;

6. Pre-calculate the height of the S.I.N. Components according to the thickness of the fibromucosa at its crest, which should be approximately 2mm higher than it;
7. Note that the diameter of S.I.N. Components has variations according to implanted tooth (greater or lesser), implant location, gap between teeth, implant diameter, border thickness, or space between implants, always preserving the gingival papilla;
8. Using a millimeter probe, measure the height between the implant head and the gingival border. This allows choosing the ideal height of S.I.N. Components, which should be approximately 2mm above the gingiva;
9. Remove the S.I.N. Component of its package and adapt it to the implant head with the help of digital, contra-angle, or ratchet wrenches. Thread over the implant until it is completely set;
10. S.I.N. Components should be left in the oral cavity for approximately 15 days;
11. Remove S.I.N. Components and install the prosthesis.

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 some side effects in the area where it was applied, such as pain, tenderness of short duration, tissue reaction or infection.

PRECAUTIONS AND RECOMENDATIONS

For the placement of S.I.N. Components, it is recommended that the professional has a specialization course in the area and 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 S.I.N. Components, the professional should submit the patient to a thorough visual inspection to diagnose cases cited in the contraindications. The use in patients with poor oral hygiene is not recommended.
The diameter and angulation of the implant, as well as the gingival height should be taken into consideration in the case of S.I.N. Components. If a correct diameter is not used, irritation of the soft tissue may occur. The settlement platform of the S.I.N. Components that adapt to the implant/abutment shall not be changed at all. S.I.N. Components are sent sterilized and have been designed to be used only once. The professional shall sterilize all surgical instruments before use, prepare the environment with proper 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 S.I.N. 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 and selection of the S.I.N. component is not appropriate and patients are not suitable for this type of surgery, the healer may not succeed and there shall be the loss of it.
Do not use the product if the package is damaged, as the sterilization is not ensured under these conditions.

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. 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

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.

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.