COMPONENT
HEALING ABUT AND ABUTMENTS PROTECTORS

INDICATIONS FOR USE

S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

PRODUCT DESCRIPTION

S.I.N. Dental Implant System Healing Abutments and Abutment Protectors are designed for the healing period between implant placement and abutment placement.

Healing Abutments are provided in three platform diameters (3.65, 4.1, and 5.0 mm) for the HE connection, two platform diameters (3.8 and 4.5 mm) for the HI connection, and three gingival heights (2.0, 4.0, and 6.0 mm). Healing Abutments are provided for Unitite Slim, Unitite, Unitite Compact, and Strong SW CM implants.

Healing abutments are used to contour trans gingival tissue during the healing period.

Abutment Protectors are provided with three interfaces for compatibility with the Conical Abutment and the Mini Abutment. They are designed to cover the screw hole of the abutment during healing to prevent foreign body impaction.

Healing Abutments and Abutment Protectors are manufactured from Ti-6Al-4V alloy conforming to ASTM F136.

Each abutment is provided with a Ti-6Al-4V alloy abutment screw for attachment to the dental implant. Provided STERILE. Sterilized by irradiation.

CONTRAINDICATIONS

S.I.N. Dental Implant System is contraindicated in the following conditions:

- The mandibular or maxillary bone quantity and quality is insufficient to provide initial stability to the implant.
- When the site or systemic conditions show inadequate or poor oral hygiene.
- Acute or chronic periodontal infection.
- Chemical dependence.
- Occlusal parafunction.
- Radiation history to the implant site.
- Inappropriate patient for prolonged or complicated oral surgery.
- Inability to build a functional prosthesis.
- Rehabilitation with dental implants is also contraindicated for children, pregnant women and during breastfeeding.
- In cases of immediate loading, inappropriate primary stability of the implant.

WARNINGS

The surgical technique of dental implant installation is highly specialized and the surgical procedure complex, it is recommended that the professionals be technically qualified so that the application of the S.I.N. implants is safe and efficient.

Product is for professional use only.

Product is sterilized by gamma radiation. Sterility is ensured except in cases where the package has been violated or damaged. Do not use if the package is damaged package or after the expiration date. Single use only. Do not resterilize.

The reuse or re-sterilization of this product can cause damage to health.

S.I.N. Dental Implant System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) Environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of S.I.N. Dental Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTIONS

Before implant installation, to obtain a predictable long-term outcome, the professional must submit the patient to a detailed and careful medical history, examination, radiographs, laboratory tests, and study models for appropriate planning.

ADVERSE EFFECTS

Loss of the implant and prosthesis is possible due to a number of reasons, including implant contamination, inappropriate surgical technique, poor bone quality, inappropriate oral hygiene, and parafunctional habits (tooth grinding).

SURGICAL COMPLICATIONS

The implant installation surgical procedure may bring risks during and after the surgery, such as: pain, edema, hemorrhage, dehiscence, paresthesia, and infection.

SHIPIMENT AND HANDLING

The S.I.N. implants are sent to professionals duly packaged, sealed and sterilized. Therefore, the package must be opened using sterile technique, and must be handled only with sterilized titanium instruments.

ATTENTION

In order to obtain technical support or additional information material about the product, contact: S.I.N. - Sistema de Implante Nacional S.A. Contact details are provided at the end of these instructions.

INSTRUCTIONS FOR USE

After implant installation (1-stage procedure) or after a period of delayed healing (2-stage procedure):

1. Assess tissue fibrous mucosa: thickness, type and height of the gum tissue.
2. Assess gum tissue thickness.
3. Take an x-ray to know the correct location of the implant with the professional's own technique.
4. Check the diameter of the implant through the note in the patient's chart on the day of implementation.
5. Check the angulation of the implant in the bone.
6. Pre-calculate the height of the S.I.N. Component according to the thickness of the crest of the mucosa.

   Select a component that is approximately 2 mm higher.
7. Note that the diameter of the S.I.N. Component has variations according to the implanted tooth (higher or lower), implant location, spacing between teeth, implant diameter, edge thickness or spacing between the implants. The gingival papilla must be preserved.
8. Using a millimeter probe, measure the height between the head of the implant and gingival edge. This enables the choice of the ideal height of the S.I.N. Component, which should be approximately 2 mm supragingival.
9. Remove the S.I.N. Component from its packaging and adapt it to the head of the implant with the aid of digital keys (CDH 1220 or CDH1224), handpiece keys (CTH1220 or CTH1224) or ratchet wrenches (CDHC 20 or CDHC 24). Thread the component onto the implant until it is fully seated onto the implant platform. Hand tighten.
10. Following the healing period, remove the component and install the final prosthesis (abutment) to the implant.

Note: Healing abutments attach directly to the implant. Abutment Protectors attach to a multi-unit abutment placed on the implant.

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
	ATTENTION	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	ATTENTION: 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
	SHELF-LIFE	USE-BY DATE	VIDA ÚTIL
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA

DEVELOPED AND MANUFACTURED BY:

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

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PRODUCT:

Healing Abutment and Abutment Protectors

510 (k) FDA-USA:

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