COMPONENT
Provisional Abutment (HE/ CM/ Conical)

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

The Provisional Abutment is designed to facilitate the fabrication of a custom restoration to be used between the time of abutment placement and final restoration placement. The Provisional Abutment is available in HE, CM and Conical Connection and is provided for Unitite Slim, Unitite, Unitite Compact, and Strong SW CM implants.

The Provisional Abutment is a straight abutment for screw-retained or cement-retained provisional restorations. The cylinder portion of the abutment can be reduced and is designed for adding material, such as acrylic or composite, when creating an esthetic provisional restoration.

The Provisional Abutment is provided in three platform diameters (3.65, 4.1, and 5.0 mm) for the HE connection, and provided in one multi-unit conical connection diameter (4.8 mm) for mini-conical abutments.

The Provisional Abutment is provided with screw for attachment of the abutment to the dental implant.

The Provisional Abutment is 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 NON-STERILE.

To be sterilized before use – see Section 10, Sterilization.

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

Sterilize the Provisional Abutment and screw using the instructions in Section 10 below.

1. Connect the Provisional Abutment to the implant and reduce if necessary.

   For the Provisional Abutment installation, the digital keys CDQ or CDH 1220 or 24, or contra-angle key CTQ or CTH1220 or 24 or CQTM ratchet wrenches or CDHC 20 or 24 should be used, applying the torque to 20 Ncm.

   NOTE: Always check if the key is compatible with the screw type (square or hexagonal).
2. Fill the screw access hole with a suitable material (*).
3. Place a temporary restoration.
4. Remove the material from the screw access hole and loosen the screw using the appropriate key (*).
5. Make final adjustments.
6. Connect the temporary restoration.

(*) In the case of provisional cemented abutments, skip steps 2 and 4.

STERILIZATION INSTRUCTIONS FOR PROVISIONAL ABUTMENT AND SCREW

Standard autoclave sterilization is recommended, using a gravity cycle, with an exposure time of 30 minutes at 121°C/ 250 °F with a drying time of 20 minutes, using a sterilization wrap that is FDA cleared for the indicated cycle.

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:

Provisional Abutment

510 (k) FDA-USA:

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