COMPONENT

Conical Abut/ Mini Abutment/ Micro Mini Abut

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

Conical Abutment is a straight abutment having an indexed (anti-rotational) or non-indexed cone, and is intended for a screw retained prosthesis. Two Conical/Prosthetic precision fit components (provisional and UCLA CoCr) are available for fabrication of the prosthesis. Conical Abutment is provided for HE (platform diameters 3.65 mm) and CM connection.

Mini Abutment is a straight multi-unit abutment. The Mini Abutment is provided for HE (platform diameters 3.65 and 4.1 mm), HI (platform diameters 3.8 and 4.5 mm) and CM connection.

Mini Micro Abutments are straight, non-indexed multi-unit abutments. Mini Micro Abutments are provided for the Unitite Slim implants, Unitite implants, and Strong SW CM implants.

Conical Abutments, Mini Abutments, and Mini Micro Abutments are manufactured from Ti-6Al-4V alloy conforming to ASTM F136.

Mini Abutment, Conical Abutment, and Micro Mini Abutment for Unitite implants are anodized to a pink color using standard electrolytic passivation processing.

Mini Abutment, Conical Abutment, and Micro Mini Abutment for Strong SW CM implants are anodized to a gold color using standard electrolytic passivation processing.

Mini Abutment, Conical Abutment, and Micro Mini Abutment for Strong SW CM implants are anodized to a gold color using standard electrolytic passivation processing.

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. Abutments with a prosthetic post height less than 4.0 mm are intended for multi-unit restorations only.

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):

Conical Abutments HI and HE connections

1. Remove the Conical Abutment from its packaging and adapt it to the head of the implant.
2. Thread the abutment retaining screw onto the implant until the screw is fully seated onto the implant platform.
3. With the aid of digital keys (CDA 20 or CDA 24), handpiece key (CTA1224) or ratchet wrench (CDAC 20), torque the abutment screw to 20 Ncm.

Conical Abutment CM connection

1. Remove the Conical Abutment from its packaging and adapt it to the head of the implant.
2. Thread the abutment retaining screw onto the implant until the screw is fully seated onto the implant platform.
3. With the aid of digital keys (CDA 20 or CDA 24), handpiece keys (CTA1224) or ratchet wrenches (CDAC 20 or CDHC 24), torque the abutment screw to 20 Ncm.

Mini Abutments HI and HE connections

1. Remove the Mini Abutment from its packaging and adapt it to the head of the implant.
2. Thread the abutment retaining screw onto the implant until the screw is fully seated onto the implant platform.
3. With the aid of 2.0 torque connection wrench and the Prosthetic Torque Wrench (CHTMA 24), torque the abutment screw to 20 Ncm.

Mini Abutments CM connections

1. Remove the Mini Abutment from its packaging and adapt it to the head of the implant.
2. Thread the abutment retaining screw onto the implant until the screw is fully seated onto the implant platform.
3. With the aid of digital keys (CDA 20 or CDA 24), handpiece key (CTA1224) or ratchet wrench (CDAC 20), torque the abutment screw to 20 Ncm.

Micro Mini Abutments

1. Remove the Micro Mini Abutment from its packing and adapt it to the head of the implant.
2. Thread the abutment retaining screw onto the implant until the screw is fully seated onto the implant platform.
3. With the aid of digital Keys (CDA 20 or CDA 24), handpiece key (CTA 1224) or ratchet wrench (CDAC 20), toque the abutment screw to 20 Ncm.

Prosthetics for Conical and Mini Abutments

1. Conical and Mini Abutment provisional and UCLA components are prosthetic components used to attach the prosthesis (restoration) to the abutment.
2. Upon completion of the prosthesis (restoration), attach the prosthesis to the abutment, and thread the prosthetic retaining screw onto the abutment until the screw is fully seated.
3. With the aid of 1.2 torque connection wrench and the Prosthetic Torque Wrench (CDHA 20, CDHC 24 or CHTMA 24), torque the retaining screw to 10 Ncm.

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

CNPJ: 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 2445 - Vila Rio Branco CEP: 03348-060 - São Paulo - SP - Brazil Phone/Fax: +55 (11) 2169-3000

SERVICE TO PROFESSIONALS

0800 770 8290 +55 (11) 2169-3000
www.sinimplante.com.br
Email: sin@sinimplante.com.br

TECHNICAL RESPONSIBLE:

Alessio Di Risio
CREA-SP: 5061207169

PRODUCT:

Conical Abutment
Mini Abutment
Micro Mini Abutment

510 (k) FDA-USA:

170207/ 170208