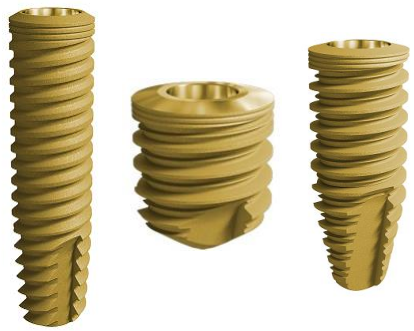
Unitite

The synergy between unique macro geometry and the most advanced nano surface activation has emerged Unitite®, a line of implants that has revolutionized the world market for its originality, innovation and high performance.



DEVICE DESCRIPTION

Unitite implants have a Morse taper prosthetic interface, and are manufactured from unalloyed titanium conforming to ASTM F67, Grade 4. Unitite Slim implants are provided with a double acid etched surface treatment, or hydroxyapatite surface coating (HAnano).

Provided STERILE. Sterilized by irradiation.

INDICATIONS OF 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.

IMPLANT LINE	BODY Ø (MM)	PF Ø (MM)	LENGTH (MM)
PRIME	3.5, 4.3, 5.0	3.5, 4.3, 5.0	8.5, 10, 11.5, 13, 15
SLIM	2.9	2.9	10, 11.5, 13
COMPACT	4.0, 5.0, 6.0	4.0, 5.0, 6.0	5, 6, 7

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

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.

SHIPMENT 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: SIN - Sistema de Implante Nacional S.A. Contact details are provided at the end of these instructions.

INSTRUCTIONS FOR USE

PRIME

Note: During all drilling to shape the implant site, avoid deflecting the drill sideways, and use continuous, copious irrigation.

Transfer of the implant from the package to insertion in the surgical site shall be carried out using the drivers with counter-angle fitting (CTUM 20 or CTUM 24). Drivers with a fitting for torque wrench (CCUM 20 or CCUM 24) do not perform implant capture, and shall only be used for final insertion torque Unitite implants were designed for a maximum torque of 60 Ncm. Higher torques may cause irreversible damage to the implants as well as surgical complications.

The torque for intermediary fixation (cemented abutment, conic abutment or mini-abutment) on the implant is 20 Ncm.

The torque for component fixation on the intermediaries is 10 Ncm.

Do not install the protection screw (cover screw) with the ratchet wrench or torque meter since this may damage the implant; tighten it manually with a hex driver.

Unitite Prime – Body Ø3.5 mm x Platform Ø3.5 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2005) (1200 RPM). Prepare the surgical site with the Ø2.0 mm helical drill (FHCD 2015) to the depth of the mark on the previously selected implant (1200 RPM).

   Use the specific conical drill for the Unitite implant Ø3.5 mm (FUM 3515) up to the height marking of the preselected implant (800 RPM).

   In a dense bone, types I and II, use a male thread for Unitite implants Ø3.5 mm (CMRU 35) up to the height marking of the preselected implant.
2. Remove the adhesive part of the package and the inner tray containing the dental implant.

   Place the inner tray over a surgical tray or organizer. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation (CTUM 20 or CTUM 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCUM 20 or CCUM 24).

   After placing the implant, remove the installation drive.
6. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224), and suture the gingiva.
7. For single-stage or immediate loading, install the selected prosthetic components.

Unitite Prime – Body Ø 4.3 mm x Platform Ø 4.3 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2005) (1200 RPM). Prepare the surgical site with the Ø 2.0 mm helical drill (FHCD 2015) to the depth of the mark on the previously selected implant (1200 RPM).

Use the specific conical drill for the Unitite implant Ø3.5 mm (FUM 3515) up to the height marking of the preselected implant (800 RPM).

Use specific conical drill for the Unitite implant Ø 4.3 mm (FUM 4315) up to the height marking of the preselected implant (800 RPM).

In a dense bone, types I and II, use a male thread for Unitite implants Ø 4.3 mm (CMRU 43) up to the height marking of the preselected implant.

2. Remove the adhesive part of the package and the inner tray containing the dental implant.

   Place the inner tray over a surgical tray or organizer.

   Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation (CTUM 20 or CTUM 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCUM 20 or CCUM 24).

   After placing the implant, remove the installation drive.
6. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224), and suture the gingiva.
7. For single-stage or immediate loading, install the selected prosthetic components.

Unitite Prime – Body Ø5.0 mm x Platform Ø5.0 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2005) (1200 RPM).

   Prepare the surgical site with the Ø2.0 mm helical drill (FHCD 2015) to the depth of the mark on the previously selected implant (1200 RPM).

   Use the specific conical drill for the Unitite implant Ø3.5 mm (FUM 3515) up to the height marking of the preselected implant (800 RPM).

   Use specific conical drill for the Unitite implant Ø4.3 mm (FUM 4315) up to the height marking of the preselected implant (800 RPM).

   Use specific conical drill for the Unitite implant Ø 5.0 mm (FUM 5015) up to the height marking of the preselected implant (800 RPM).

   In a dense bone, types I and II, use a male thread for Unitite implants Ø5.0 mm (CMRU 50) up to the height marking of the preselected implant.
2. Remove the adhesive part of the package and the inner tray containing the dental implant.

   Place the inner tray over a surgical tray or organizer.

   Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation (CTUM 20 or CTUM 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCUM 20 or CCUM 24).

   After placing the implant, remove the installation drive.
6. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224), and suture the gingiva.
7. For single-stage or immediate loading, install the selected prosthetic components.

SLIM

Note: During all drilling to shape the implant site, avoid deflecting the drill sideways, and use continuous, copious irrigation.

Transfer of the implant from the package to insertion in the surgical site shall be carried out using the drivers with counter-angle fitting (CTUS 20 or CTUS 24).

Drivers with a fitting for torque wrench (CCUS 20 or CCUS 24) do not perform implant capture, and shall only be used for final insertion torque Unitite Slim implants were designed for a maximum torque of 45 Ncm.

Higher torques may cause irreversible damage to the implants as well as surgical complications.

The torque for intermediary fixation (cemented abutment, conic abutment or mini-abutment) on the implant is 20 Ncm.

The torque for component fixation on the intermediaries is 10 Ncm.

Do not install the protection screw (cover screw) with the ratchet wrench or torque meter since this may damage the implant; tighten it manually with a hex driver.

Unitite Slim – Body Ø2.9 mm x Platform Ø 2.9 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2005) (1200 RPM).

Prepare the surgical site with the Ø 2.0 mm helical drill (FHCD 2015) to the depth of the mark on the previously selected implant (1200 RPM).

Use the specific helical drill for the Unitite Slim implant Ø 2.09 mm (FUM 2915) up to the height marking of the preselected implant (800 RPM).

In a dense bone, use a male thread for the Unitite Slim implant Ø 2.9 mm (CMRU 29) up to the height marking of the preselected implant.

2. Remove the adhesive part of the package and the inner tray containing the dental implant.

   Place the inner tray over a surgical tray or organizer.

   Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation (CTUS 20 or CTUS 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCUS 20 or CCUS 24).

   After placing the implant, remove the installation drive.
6. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224), and suture the gingiva.
7. For single-stage or immediate loading, install the selected prosthetic components.

COMPACT

During all drilling to shape the implant site, avoid deflecting the drill sideways, and use continuous, copious irrigation.

Transfer of the implant from the package to insertion in the surgical site shall be carried out using the drivers with counter-angle fitting (CTUC 20 or CTUC 24). Drivers with a fitting for torque wrench (CCUC 20 or CCUC 24) do not perform implant capture, and shall only be used for final insertion torque Unitite Compact implants were designed for a maximum torque of 60 Ncm. Higher torques may cause irreversible damage to the implants as well as surgical complications.

The torque for intermediary fixation (cemented abutment, conic abutment or mini-abutment) on the implant is 20 Ncm.

The torque for component fixation on the intermediaries is 10 Ncm.

Do not install the protection screw (cover screw) with the ratchet wrench or torque meter since this may damage the implant; tighten it manually with a hex driver.

Unitite Compact – Body Ø4.0mm x Platf Ø4.0mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2005) (1200 RPM).

   Prepare the surgical site with the Ø 2.0 mm helical drill (FHCD 2015) to the depth of the mark on the previously selected implant (1200 RPM).

   Use the specific helical drill for the Unitite Compact implant Ø 4.0 mm (FHCD 3215) up to the height marking of the preselected implant (800 RPM).

   Use the specific conical drill for the Unitite implant Ø 3.5 mm (FUM 3515) up to the height marking of the preselected implant (800 RPM).
2. Remove the adhesive part of the package and the inner tray containing the dental implant.

   Place the inner tray over a surgical tray or organizer.

   Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation (CTUC 20 or CTUC 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCUC 20 or CCUC 24).

   After placing the implant, remove the installation drive.
6. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224), and suture the gingiva.
7. For single-stage or immediate loading, install the selected prosthetic components.

Unitite Compact – Body Ø 5.0 mm x Platform Ø 5.0 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2005) (1200 RPM).

   Prepare the surgical site with the Ø 2.0 mm helical drill (FHCD 2015) to the depth of the mark on the previously selected implant (1200 RPM).

   Use the specific helical drill for the Unitite Compact implant Ø 4.0 mm (FHCD 3215) up to the height marking of the preselected implant (800 RPM).

Use the specific helical drill for the Unitite Compact implant Ø 5.0 mm (FHCD 4215) up to the height marking of the preselected implant (800 RPM).

Use the specific conical drill for the Unitite implant Ø 3.5 mm (FUM 3515) up to the height marking of the preselected implant (800 RPM).

2. Remove the adhesive part of the package and the inner tray containing the dental implant.

   Place the inner tray over a surgical tray or organizer.

   Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation (CTUC 20 or CTUC 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCUC 20 or CCUC 24).

   After placing the implant, remove the installation drive.
6. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224), and suture the gingiva.
7. For single-stage or immediate loading, install the selected prosthetic components.

Unitite Compact Implant – Body Ø 6.0 mm x Platform Ø 6.0 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2005) (1200 RPM).

   Prepare the surgical site with the Ø 2.0 mm helical drill (FHCD 2015) to the depth of the mark on the previously selected implant (1200 RPM).

   Use the specific helical drill for the Unitite Compact implant Ø 4.0 mm (FHCD 3215) up to the height marking of the preselected implant (800 RPM).

   Use the specific helical drill for the Unitite Compact implant Ø 5.0 mm (FHCD 4215) up to the height marking of the preselected implant (800 RPM).

   Use the specific helical drill for the Unitite Compact implant Ø 6.0 mm (FHCD 5215) up to the height marking of the preselected implant (800 RPM).

   Use the specific conical drill for the Unitite implant Ø 3.5 mm (FUM 3515) up to the height marking of the preselected implant (800 RPM).
2. Remove the adhesive part of the package and the inner tray containing the dental implant.

   Place the inner tray over a surgical tray or organizer.

   Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation (CTUC 20 or CTUC 24) attached to the contra-angle, press the drive onto the implant.
4. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
5. If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCUC 20 or CCUC 24).

   After placing the implant, remove the installation drive.
6. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224), and suture the gingiva.
7. For single-stage or immediate loading, install the selected prosthetic components.

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	VIDA ÚTIL
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA

DESENVOLVIDO E FABRICADO POR:
S.I.N. Sistema de Implante Nacional S/A
CNPJ: 04.298.106/0001-74
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PRODUCT:
Unitite Implant

510 (k) FDA-USA:
170207