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 (HA^{nano}).

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.

MRI SAFETY INFORMATION

Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. Dental Implant System devices are MR Conditional.
A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	S.I.N. Dental Implant System
Static Magnetic Field Strength (B_0)	≤ 3.0 T
Maximum Spatial Field Gradient	50 T/m (5,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head coil and body coil permitted. Extremity T/R coils permitted.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2.4 W/kg (15 minutes of scanning, Normal Operating Mode)
Maximum Head SAR	2.0 W/kg (15 minutes of scanning, Normal Operating Mode)
Scan Duration	15 minutes
Temperature Rise	Maximum temperature rise of 0.45 °C/(W/kg), after 15 minutes of continuous scanning in a static magnetic field of 3 T with either head type or body type coils
Artifact	when imaged using a gradient-echo sequence and a 3 T MR system, image artifact can extend up to approximately 12 mm with a body coil type, and up to approximately 32 mm with a head coil type

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.

Symbols Glossary

ANSI/AAMI/ ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol6	Title of Symbol (References Number)	Meaning of Symbol
	Caution (5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Keep away from sunlight (5.3.2)	Indicates a medical device that needs protection from light sources.
	Upper limit of temperature (5.3.6)	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	Keep dry (5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Do not use if package Damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not re-use (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Date of manufacture (5.1.3)	Indicates the date when the medical device was manufactured
	Manufacturer (5.1.1)	Indicates the medical device manufacturer.
	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	MR Conditional (n/a)	Conditions under which a medical device can safely enter the MR environment

DESENVOLVIDO E FABRICADO POR:
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PRODUCT:
Unitite Implant

510 (k) FDA-USA:
K170392