

The versatility of the Strong SW line that you already know, with HAnano® surface.



Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

PRODUCT DESCRIPTION

Strong SW Plus implants have macrogeometry of the implant is hybrid, with cervical micro threads and external hexagon (EH), internal hexagon (IH) and morse taper (MT) prosthetic coupling interface and are manufactured from unalloyed titanium conforming to ASTM F67, Grade 4. Strong SW Plus implants are provided with a double acid etched surface treatment and 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 S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

All digitally-designed custom abutments for use with Interface CAD-CAM abutments are to be sent to a S.I.N.-validated milling center for manufacture.

IMPLANT LINE	BODY Ø (MM)	PF Ø (MM)	LENGTH (MM)
MT	3.5, 3.8, 4.5, 5.0.	3.5, 3.8, 4.5, 5.0.	8.5, 10, 11.5, 13, 15.
HE	3.5, 3.75, 4.0, 4.5, 5.0.	3.65, 4.1, 4.5, 5.0.	7.0, 8.5, 10, 11.5, 13, 15, 18.
HI	3.8, 4.5, 5.0.	3.8, 4.5, 5.0.	8.5, 10, 11.5, 13, 15.

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 Strong SW Plus Dental implants are only intended for straight placement with no angulation correction or divergence correction.

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.

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

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 for morse tapper (CTMD 20 or CTMD 24), for H.E. (CTWD 20 or CTWD 24).

Drivers with a fitting for torque wrench for C.M (CCM 20 or CCM 24) and H.E (CCW 20 or CCW 24) do not perform implant capture, and shall only be used for final insertion torque Strong SW implants were designed for a maximum torque of 80Ncm. 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 for C.M and H.E connection. For H.I connection the torque for componente fixation on the intermediaries is 0 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 digital driver.

Strong SW MT Implant – Body Ø 3.5 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD 2015) to the depth of the mark on the previously selected implant (1500 RPM).
Use the conical drill specifically designed for Ø 3.5 mm Strong SW MT implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).
In high-density bone use the male thread for Ø 3.5 mm Strong SW MT implants (CMRIW 35) to the depth of the mark on the previously selected implant (25 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 (CTMD 20 or CTMD 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 (CCM 20 or CCM 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.

Strong SW MT Implant – Body Ø 3.8 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD 2015) to the depth of the mark on the previously selected implant (1500 RPM).

Use the conical drill specifically designed for Ø 3.5 mm Strong SW MT implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).

Use the conical drill specifically designed for Ø 3.8 mm Strong SW MT implants (FRWD 38) to the depth of the mark on the previously selected implant (800 RPM).

In high-density bone use the male thread for Ø 3.8 mm Strong SW MT implants (CMRIW 38) to the depth of the mark on the previously selected implant (25 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 (CTMD 20 or CTMD 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 (CCM 20 or CCM 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.

Strong SW MT Implant – Body Ø 4.5 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD 2015) to the depth of the mark on the previously selected implant (1500 RPM).
Use the conical drill specifically designed for Ø 3.5 mm Strong SW MT implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).
Use the conical drill specifically designed for Ø 3.8 mm Strong SW MT implants (FRWD 38) to the depth of the mark on the previously selected implant (800 RPM).
Use the conical drill specifically designed for Ø 4.5 mm Strong SW MT implants (FRWD 45) to the depth of the mark on the previously selected implant (800 RPM).

In high-density bone use the male thread for Ø 4.5 mm Strong SW MT implants (CMRIW 45) to the depth of the mark on the previously selected implant (25 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 (CTMD 20 or CTMD 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 (CCM 20 or CCM 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.

Strong SW MT Implant – Body Ø 5.0 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2020) (1500 RPM). Prepare the surgical site with the Ø 2.0 mm helical drill (FHD 2015) to the depth of the mark on the previously selected implant (1500 RPM).
Use the conical drill specifically designed for Ø 3.5 mm Strong SW MT implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).
Use the conical drill specifically designed for Ø 3.8 mm Strong SW MT implants (FRWD 38) to the depth of the mark on the previously selected implant (800 RPM).
Use the conical drill specifically designed for Ø 4.5 mm Strong SW MT implants (FRWD 45) to the depth of the mark on the previously selected implant (800 RPM).
In high-density bone use the male thread for Ø 4.5 mm Strong SW MT implants (CMRIW 45) to the depth of the mark on the previously selected implant (25 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 (CTMD 20 or CTMD 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 (CCM 20 or CCM 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.

Strong SW HE – Implant Body Ø 3.5 mm/ Platform Ø 3.65 mm

1. At the surgical site penetrate the cortical bone with the initial drill, spear drill (FRLD2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD2015) up to the depth of the mark on the previously selected implant (1500 RPM).
Use the conical drill specifically designed for Ø 3.5 mm Strong SW implants (FRWD 35) to the depth of the mark on the previously selected 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 (CTWD 20 or CTWD 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 (CCW 20 or CCW 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.

Strong SW HE – Implant Body Ø 3.75 mm/ Platform Ø 4.1 mm

- At the surgical site penetrate the cortical bone with the initial drill, spear drill (FRLD2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD2015) up to the depth of the mark on the previously selected implant (1500 RPM).
Use the conical drill specifically designed for Ø 3.5 mm Strong SW implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).
Use conical drill specifically designed for Ø 3.75 mm Strong SW implants (FRWD 38) up to the depth of the mark on the previously selected implant (800 RPM).
Use countersink drill for Ø 4.1 mm Strong implants (FCWD 41) up to the depth of the mark (800 RPM).
In high-density bone (types I and II), use the male thread for Ø 3.75 Strong implants (CMRIW 37) up to the depth of the mark on the previously selected implant (25 RPM)
- 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.
- With the drive for implant installation (CTWD 20 or CTWD 24) attached to the contra-angle, press the drive onto the implant.
- Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
- If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCW 20 or CCW 24).
After placing the implant, remove the installation drive.
- 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.
- For single-stage or immediate loading, install the selected prosthetic components.

Strong SW HE – Implant Body Ø 4.0 mm / Platform Ø 4.1 mm

- At the surgical site penetrate the cortical bone with the spear drill (FRLD 2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD 2015) to the depth of the mark on the previously selected implant (1500 RPM).

Use the conical drill specifically designed for Ø 3.5 mm Strong SW implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).

Use conical drill specifically designed for Ø 3.75 mm Strong SW implants (FRWD 38) up to the depth of the mark on the previously selected implant (800 RPM).

Use countersink drill for Ø 4.1 mm Strong implants (FCWD 41) up to the depth of the mark (800 RPM).

In high-density bone (types I and II), use the male thread for Ø 3.75 Strong implants (CMRIW 37) up to the depth of the mark on the previously selected implant (25 RPM).

- 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.
- With the drive for implant installation (CTWD 20 or CTWD 24) attached to the contra-angle, press the drive onto the implant.
- Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (20 RPM).
- If required, complete the installation with the surgical torque meter (TMECC 02) attached to the ratchet drive (CCW 20 or CCW 24).
After placing the implant, remove the installation drive.
- 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.
- For single-stage or immediate loading, install the selected prosthetic components.

Strong SW HE – Implant Body Ø 4.5 mm/ Platform Ø 4.5 mm

- At the surgical site penetrate the cortical bone with the initial drill, spear drill (FRLD2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD2015) up to the depth of the mark on the previously selected implant (1500 RPM).
Use the conical drill specifically designed for Ø 3.5 mm Strong SW implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).
Use conical drill specifically designed for Ø 3.75 mm Strong SW implants (FRWD 38) up to the depth of the mark on the previously selected implant (800 RPM).

Use conical drill designed for Ø 4.5 mm Strong implants (FRWD 45) up to the depth of the mark on the previously selected implant (800 RPM).

In high-density bone (types I and II), use the male thread for Ø 4.5 Strong implants (CMRIW 45) up to the depth of the mark on the previously selected implant (25 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 (CTWD 20 or CTWD 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 (CCW 20 or CCW 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.

Strong SW HE – Implant Body Ø 5.0 mm/ Platform Ø 5.0 mm

1. At the surgical site penetrate the cortical bone with the initial drill, spear drill (FRLD2020) (1500 RPM).
At the surgical site penetrate the cortical bone with the initial drill, spear drill (FRLD2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD2015) up to the depth of the mark on the previously selected implant (1500 RPM).
Use the conical drill specifically designed for Ø 3.5 mm Strong SW implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).
Use conical drill specifically designed for Ø 3.75 mm Strong SW implants (FRWD 38) up to the depth of the mark on the previously selected implant (800 RPM).
Use conical drill designed for Ø 4.5 mm Strong implants (FRWD 45) up to the depth of the mark on the previously selected implant (800 RPM).

Use conical drill designed for Ø 5.0 mm Strong SW implants (FRWD 50) up to the depth of the mark on the previously selected implant (800 RPM).

In high-density bone (types I and II), use the male thread for Ø 5.0 Strong implants (CMRIW 50) up to the depth of the mark on the previously selected implant (25 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 (CTWD 20 or CTWD 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 (CCW 20 or CCW 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.

Strong SW HI Implants – Body Ø 3.8 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2020) (1500 RPM).
Prepare the surgical site with the Ø 2.0 mm helical drill (FHD 2015) to the depth of the mark on the previously selected implant (1500 RPM).
Use the conical drill specifically designed for Ø 3.5 mm Strong SW HI implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM).
Use the conical drill specifically designed for Ø 3.8 mm Strong SW HI implants (FRWD 38) to the depth of the mark on the previously selected implant (800 RPM).
In high-density bone (types I and II) use the male thread for Ø 3.8 mm Strong SW HI implants (CMRIW 38) to the depth of the mark on the previously selected implant (25 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. Attach the drive for implant installation (CMHI 01 or CMHI 02) to the contra- angle, and 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 (CCIH 20 or CCIH 24).
6. For delayed loading procedures, after placing the implant, remove the installation drive and use the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224) to place the Cover Screw. After installation of the appropriate Cover Screw, suture the gingiva.
7. For immediate loading, install the Titanium Temporary Cylinder with 20 N-cm torque, and install the temporary restoration on the cylinder.

Strong SW HI Implants – Body Ø 4.5 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2020) (1500 RPM). Prepare the surgical site with the Ø 2.0 mm helical drill (FHD 2015) to the depth of the mark on the previously selected implant (1500 RPM). Use the conical drill specifically designed for Ø 3.5 mm Strong SW HI implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM). Use the conical drill specifically designed for Ø 3.8 mm Strong SW HI implants (FRWD 38) to the depth of the mark on the previously selected implant (800 RPM). Use the conical drill for Ø 4.5 mm Strong SW HI implants (FRWD 45) to the depth of the mark on the previously selected implant (800 RPM). In high-density bone (types I and II) use the male thread for Ø 4.5 mm Strong SW HI implants (CMRIW 45) to the depth of the mark on the previously selected implant (25 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. Attach the drive for implant installation (CMHI 01 or CMHI 02) to the contra- angle, and 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 (CCIH 20 or CCIH 24).

6. For delayed loading procedures, after placing the implant, remove the installation drive and use the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224) to place the Cover Screw. After installation of the appropriate Cover Screw, suture the gingiva.
7. For immediate loading, install the Titanium Temporary Cylinder with 20 N-cm torque, and install the temporary restoration on the cylinder.

Strong SW HI Implants – Body Ø 5.0 mm

1. At the surgical site penetrate the cortical bone with the spear drill (FRLD 2020) (1500 RPM). Prepare the surgical site with the Ø 2.0 mm helical drill (FHD 2015) to the depth of the mark on the previously selected implant (1500 RPM). Use the conical drill specifically designed for Ø 3.5 mm Strong SW HI implants (FRWD 35) to the depth of the mark on the previously selected implant (800 RPM). Use the conical drill specifically designed for Ø 3.8 mm Strong SW HI implants (FRWD 38) to the depth of the mark on the previously selected implant (800 RPM). Use the conical drill for Ø 4.5 mm Strong SW HI implants (FRWD 45) to the depth of the mark on the previously selected implant (800 RPM). Use the conical drill for Ø 5.0 mm Strong SW HI implants (FRWD 50) to the depth of the mark on the previously selected implant (800 RPM). In high-density bone (types I and II) use the male thread for Ø 5.0 mm Strong SW HI implants (CMRIW 50) to the depth of the mark on the previously selected 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. Attach the drive for implant installation (CMHI 01 or CMHI 02) to the contra- angle, and 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 (CCIH 20 or CCIH 24).
6. For delayed loading procedures, after placing the implant, remove the installation drive and use the 1.2 mm hexagonal drive (CDH 1220 or CDH 1224) to place the Cover Screw. After installation of the appropriate Cover Screw, suture the gingiva.
7. For immediate loading, install the Titanium Temporary Cylinder with 20 N-cm torque, and install the temporary restoration on the cylinder.

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 re-sterilize (5.2.6)	Indicates a medical device that is not to be re-sterilized.
	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

DEVELOPED AND MANUFACTURED BY:

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

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
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RESPONSIBLE TECHNICIAN:

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PRODUCT:

Strong SW Implant
510 (k) FDA-USA:
 K170392
 K170398