The line of Epikut Plus implants arrives on the market in order to optimize the daily clinical practice, bringing a more cutting macrogeometry, making bone installation easier and with a high primary stability combined with the HAnano surface that helps in better osseointegration.

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

PRODUCT DESCRIPTION

Epikut Plus implants are manufactured from unalloyed titanium conforming to ASTM F67, Grade 4, and are provided with a double acid etched surface treatment and hydroxyapatite surface coating (HAnano).
Epikut Plus implants have an 11.5° Morse taper (CM) connection, or an external hexagon connection (HE). Provided STERILE. Sterilized by irradiation.

Implant Diameters (mm)	Length (mm)
3.5, 3.8, 4.5, 5.0	7, 8.5, 10, 11.5, 13, 15.

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.

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.

WARNING

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.

Epikut Plus HE implants are not for use with angled abutments.
Epikut Plus CM Ø 3.5mm implants with angled abutments are recommended for incisors region only. Small diameter implants and angled abutments are not recommended for the posterior region.

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 or after the expiration date.

Single use only. Do not resterilize.

The reuse or re-sterilization of this product can cause damage to health.

MRI Safety Information

S.I.N. Dental Implant System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of S.I.N. Dental Implant System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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

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 morse connection (CTUM 20 or CTUM 24) and (CTWD 20 or CTWD 24) for HE connection. Drivers with a fitting for torque wrench for morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE, they do not perform implant capture, and shall only be used for final insertion torque Epikut and Epikut Plus implants were designed for a maximum torque of 80 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 digital driver.

For all Epikut Plus CM implants (Morse taper) it is recommended to place the implant 1.5 mm intra-bony (sub-crestal), and for HE (external hexagon) it is recommended to place the implant at bone level.

All Epikut Plus dental implants (CM and HE) are intended for placement in all bone types (I, II, III, and IV; Lekholm and Zarb classification).

Epikut Plus Implants (HE and CM) –Body Ø 3.5 mm

For Type IV bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM). Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).

For Type II and Type III bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM).

Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).

Follow for the helical drill Ø 3.0 mm (FHI 30) and optionally the countersink drill Ø 3.3 mm (FHI 33) (1500 RPM).

For Type I Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM). Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).

Follow for the helical drill Ø 3.0 mm (FHI 30) and the countersink drill Ø 3.3 mm (FHI 33) (1500 RPM).

1. 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.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTUM 20 or CTUM 24) and for hexagon external connection (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 Morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE.
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

For single-stage or immediate loading, install the selected prosthetic components.

Epikut Plus Implants (CM) – Body Ø 3.8 mm
For Type IV Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant, follow for the helical drill Ø 3.0 mm (FHI 30) (1500 RPM).

For Type II and III Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant.
Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), optionally use the drill Ø 3.6 mm (FHI 36) (1500 RPM).

For Type I Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).
Follow for the helical drill Ø 3.0 mm (FHI 30) and the countersink drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36) (1500 RPM).

1. 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.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTUM 20 or CTUM 24) and for hexagon external connection (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 Morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE.
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

For single-stage or immediate loading, install the selected prosthetic components.

Epikut Plus Implants (HE and CM) –Body Ø 4.5 mm
For Type IV Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant, follow for the helical drill Ø 3.0 mm (FHI 30), use the drill Ø 3.6 mm (FHI 36) (1500 RPM)

For Type II and Type III Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant.
Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36), follow to drill Ø 4.0 mm (FHI 40), optionally use the drill Ø 4.3 mm (FHI 43) (1500 RPM).

For Type I Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).
Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36), follow to drill Ø 4.0 mm (FHI 40), use the drill Ø 4.3 mm (FHI 43) (1500 RPM).

1. 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.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTUM 20 or CTUM 24) and for hexagon external connection (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 Morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE.
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

For single-stage or immediate loading, install the selected prosthetic components.

Epikut Plus Implants (HE and CM) – Body Ø 5.0 mm
For Type IV Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant, follow for the helical drill Ø 3.0 mm (FHI 30), use the drill Ø 3.6 mm (FHI 36) and the drill Ø 4.0 mm (FHI 40) (1500 RPM).

For Type II and Type III Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20). Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant.
Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36), follow to drill Ø 4.0 mm (FHI 40) and the drill Ø 4.3 mm (FHI 43), optionally use the drill Ø 4.8 mm (FHI 48) (1500 RPM).

For Type I Bone

At the surgical site penetrate the cortical bone with the spear drill (FLI 20) (1500 RPM).
Prepare the surgical site with the Ø 2.7 mm helical drill (FHI 27) to the depth of the mark on the previously selected implant (1500 RPM).
Follow for the helical drill Ø 3.0 mm (FHI 30) and the drill Ø 3.3 mm (FHI 33), use the drill Ø 3.6 mm (FHI 36), follow to drill Ø 4.0 mm (FHI 40), use the drill Ø 4.3 mm (FHI 43) (1500 RPM), follow to use the drill Ø 4.8 mm (FHI 48) (1500 RPM).

1. 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.
2. Remove the Tyvek label, exposing the implant.
3. With the drive for implant installation for Morse taper connection (CTUM 20 or CTUM 24) and for hexagon external connection (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 Morse connection (CCUM 20 or CCUM 24) and (CCW 20 or CCW 24) for HE.
6. After placing the implant, remove the installation drive.
7. For delayed loading procedures, apply the appropriate Cover Screw using the 1.2 mm hexagonal drive (CDH 1224), and suture the gingiva.

For single-stage or immediate loading, install the selected prosthetic components.

Lekholm UR and Zarb GA, Patient selection and preparation, in Brånemark P-I, Zarb GA, Albrektsson T (eds): Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chicago IL, Quintessence, 1985, 199-209.

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.

Symbol	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.

DEVELOPED AND MANUFACTURED BY:

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

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PRODUCT:

Epikut Plus dental implants

510 (k) FDA-USA:

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