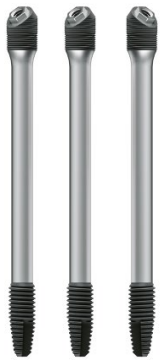
S.I.N's Zygomatic Implants External Hexagon (HE) connection are a great option for patients with atrophic maxilla, without the need for bone graft and with high stability prosthetic fixation.



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

PRODUCT DESCRIPTION

Zygomatic implants are manufactured from unalloyed titanium conforming to ASTM F67, Grade 4, and are provided with an acid-etched surface treatment.
Provided STERILE. Sterilized by irradiation.

INDICATIONS OF USE

S.I.N. Dental Implant System Zygomatic implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System Zygomatic implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

BODY Ø (MM)	PF Ø (MM)	LENGTH (MM)
4.5 (coronal) 3.85 (apical)	4.1	34, 36.5, 39, 41.5, 44, 46.5, 49, 51.5, 54, 56.5, 59.

Zygomatic implants are for conventional 1-stage and 2-stage surgical technique and immediate loading.

CONTRAINDICATIONS

S.I.N. Dental Implant System is contraindicated in the following conditions:

- the maxillary bone quantity and quality is insufficient to provide initial stability to the implant
- inadequate bone volume for zygomatic or conventional implants, or where adequate numbers of implants cannot be placed to achieve full functional support of a prosthesis
- when the site or systemic conditions show inadequate or poor oral
- 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.

Implant failure increases when implants are placed in irradiated bone as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity. The use of zygomatic implants in bone tissue which has been irradiated as part of cancer therapy may result in the following:

delayed or failed osseointegration of implants due to reduced bone vascularity, clinically expressed as osteoradionecrosis;

Tissue dehiscence and osteoradionecrosis;

Implant failure and loss.

Implant treatment of irradiated patients is dependent upon the timing of implant placement in relation to the

radiation therapy, the anatomic sites chosen for implant placement, the radiation dosage at that selected sites, and consequent risk of osteoradionecrosis.

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.

MRI Safety Information

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.

Before surgery, a clinical, physical and radiological examination has to be performed to determine adequate bone dimensions, anatomical landmarks, occlusal conditions, and periodontal health.

The patient must have clinically symptom-free sinuses and no pathology in surrounding bone or soft tissue.

It is recommended that a CT scan and or CBCT analysis be performed as part of the planning process for the following reasons:

- to detect the presence of any pathology in the maxillary sinuses;
- to evaluate the bone volume and condition;
- to assess the relationship/occlusion of the mandible and maxilla.

Zygomatic implants are recommended for the posterior (premolar/molar) region, with one zygomatic implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration.

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 implant fitter for external hexagon connection (MIZ 41). Drivers with a fitting for connection (CMZ or CQCA 27), shall only be used for final installation.

Zygomatic 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 (Abutment mini Zygomatic conical and abutment zygomatic standard) 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.

Zygomatic Implants

1. At the surgical site penetrate the cortical bone with the Ø 2.95 mm spherical drill (FLEZ 03) (1200 RPM) to make the entry mark on the maxillary sinus posterior-upper roof. Continue drilling with the spherical drill, until penetration of the outer cortical layer of the zygomatic bone.

   Use the straight depth probe to achieve the desired length of the Zygomatic implant to be used.

   Prepare the surgical site with the Ø 2.95 mm helical drill (FHZ 295) to the depth of the mark on the previously selected implant (1200 RPM). Use the Ø 2.95 mm/ Ø 3.55 mm pilot drill (FPZ 2533); the pilot is used to prepare a guide for the next drill to be used.

   Use the Ø 3.55 mm helical drill observing the drilling length.
2. Check the depth of the prepared surgical site with the depth probe to ensure that the selected implant has the length that can be completely inserted without apical bone interference.
3. 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.
4. Remove the Tyvek label, exposing the implant.
5. Make sure that the motor is parameterized between 40 RPM and 50 RPM and a maximum torque of 45 N.cm; with the implant in position, start the installation with the contra-angle. Do not move the implant vertically or laterally; this can damage the surgical site and the stability of the implant.
6. With the driver for implant installation for H.E connection (CMZ or CQCA 27) attached to the contraangle, press the driver onto the implant.
7. Take the assembled implant set to the previously prepared surgical site, and start the implant installation at a low speed (40 RPM).
8. If required, complete the installation with the fixation driver (CMZ).
9. After placing the implant, remove the fixation driver.
10. For delayed loading procedures, apply the appropriate Implant Cover Zygomatic (TIZ) using 1.2 mm hexagonal driver (CQCA 27), tighten to 5-10 N-cm, and suture the gingiva.

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

DEVELOPED AND MANUFACTURED BY:
S.I.N. Sistema de Implante Nacional S/A
CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 421 - Vila Rio Branco CEP: 03348-060 - São Paulo - SP - Brazil

SERVICE TO PROFESSIONALS
0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com email: sin@sinimplante.com.br

RESPONSIBLE TECHNICIAN:
Alessio Di Risio
CREA-SP: 5061207169

PRODUCT:
Zygomatic Implant

510 (k) FDA-USA:
K203725