Zygomatic Plus implants are a great option for patients with atrophic maxilla, without the need for bone graft and with highly stable prosthetic fixation.

PRODUCT DESCRIPTION

Zygomatic Plus implants are produced in commercially pure Titanium (Grade 4). The macrogeometry of the implant is cylindrical, with cervical micro threads and cone morse (CM) prosthetic coupling, available in lengths from 30.0mm to 62.5mm with 2.5mm intervals between each model. The surface of the implant threads has moderate roughness obtained by acid etching and composed of an ultra-thin layer of hydroxyapatite. It comes with the cover screw as an accessory.

Thread Diameter "X1" (mm)	4.0
Lenght "Y1" (mm)	30.0; 32.5; 35.0; 37.5; 40.0; 42.5; 45.0; 47.5; 50; 52.5; 55.0; 57.5; 60.0 e 62.5.

The chemical composition of the Dental Components is according to ASTM F67:

Chemical Element	Composition % (mass/mass)
Nitrogen	≤ 0.05
Carbon	≤ 0.08
Hydrogen	≤ 0.015
Iron	≤ 0.50
Oxygen	≤ 0.40
Titanium	Balance
Hydroxyapatite Coating	< 1.0

The coating is Hydroxyapatite (HAnano), composed of $Ca_5(PO_4)_3OH$, also known as Calcium Phosphate. It has a Ca/P ratio of 1.67.

The cover screw is according ASTM F136:

Chemical Element	Composition % (mass/mass)
Nitrogen	≤ 0.05
Carbon	≤ 0.08
Hydrogen	≤ 0.012
Iron	≤ 0.25
Oxygen	≤ 0.13
Aluminum	5.5 - 6.5
Vanadium	3.5 - 4.5
Titanium	Balance

INDICATIONS OF USE

The Zygomatic Plus are indicated for surgical procedure in the maxillary and zygomatic bones in case of severe maxillary resorption and in total edentulism, in clinical situations where the installation of conventional implants is impossible. This implant has its emergence indicated in the posterior region of the maxilla, pre-molar and molar regions and with other implants gives support to a fixed total rehabilitation. It can be used in 1 or 2 stages, depending on primary stability and adequate occlusal load.

PURPOSE AND OPERATION PRINCIPLE

The purpose is to replace missing, condemned teeth or conventional prostheses, with the aim of restoring aesthetics and masticatory function, stopping bone resorption and reducing overload on remaining teeth.

HOW TO USE THE ZYGOMATIC PLUS CONE MORSE

Zygomatic Plus implants are indicated for surgical installation in all bone densities in the maxilla, provided that the maximum insertion torque (80N.cm) is respected. For the external hexagon implants the installation must be done at bone level.

- Start the surgical protocol with the Ø2.70mm lance drill at 1200 RPM to mark the osteotomy site.
- According to the technique chosen by the professional, diamond drills can be used after the lance drill, Ø4.0mm Diamond Drill or Ø4.0mm Diamond Spherical Drill.
- Prepare the surgical site with the Ø3.9mm/Ø4.0mm Helical Drill at 1200 RPM followed by the Ø3.2mm/Ø4.0mm Helical Drill and the Ø3.4mm/Ø4.0mm Helical Drill. For implant depth, check the depth of the prepared surgical site with the depth probe to make sure that the selected implant has the length that can be completely inserted without apical bone interference.

NOTE: The mucosa of the maxillary sinus must be kept apart without contact with the implant to avoid problems with osseointegration. Ensure correct angulation and avoid milling drill oscillation, to maintain the integrity of the surgical alveolus.

- Make sure the motor is set between 40RPM and 50RPM and maximum torque of 45N.cm.
- Remove the blister from the outer cartridge.
- Reserve the traceability labels that come with the product.
- With the implant in position, start the installation with the contra angle. Do not move the implant vertically or laterally, as this may damage the alveolus and the implant stability.
- The finalization of the implant can be performed with the manual driver. To do this, disconnect the contra-angle pen with the driver and finish the implant installation with the manual driver.
- When installing the implant, carefully observe the maximum installation torque of 80 N.cm. If this torque is reached during installation, stop the procedure and confirm that the drilling system has been correctly performed and that the chosen implant length is according to plan. In situations of high torque during Zygomatic Plus implant insertion, surgical maneuvers should be performed to reduce the torque, to preserve the implant platform and the screw.

NOTE: Torque above 80 N.cm on the implants can damage their prosthetic connection or cause the assembler and its screw to fracture, implying the non-adaptation of the prosthetic components in the subsequent rehabilitation.

⚠ ATTENTION

Zygomatic Plus implants are intended for specialized procedures, which must be performed by qualified professionals in Implantology. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTION

Observe the conditions of intraoral tissues, bone quality and bone quantity of the Implant receptor site, through radiographic and/or tomographic exams. Failure to perform the pre-surgical assessment can lead to the impossibility of finding pre-existing diseases. Consider the general health conditions of the patient. Patients that present local or systemic factors that may interfere with the healing processes of bone or soft tissues or in the integration process should receive special care. Handle the material only in sterile field. All materials used in the procedure must be sterile. Sterilization is only ensured if the secondary packaging (blister) is not damaged. Do not use the product if the package is damaged. Only open the package at the time of surgery and use the product immediately. Implants not used after opening the carton should be discarded Expired products should not be used. A Insertion torque higher than the recommended maximum can damage the product, causing the loss of its primary function. Observe the conditions of use of surgical instruments. Drills and other instruments with low cutting power can generate heating during use, which hinders the osseointegration process. 'Replace instruments in case of damage, erasure of marks, impaired sharpening, deformation, and wear. The surgical motor used in the procedure should be adjusted according to the specification of the implant to be used (torque and RPM). Check your motor and angling conditions before surgery. If necessary, perform preventive/corrective maintenance with the manufacturer. Deregulated equipment may directly interfere with the product performance. During the surgical and prosthetic procedure, only use components and instruments specified by S.I.N.; they have specific dimensions and tolerances for each implant system to ensure the product longevity. Other brand components or adapted to implant models may reduce the life time of the system and cause irreversible damage. The professional should ensure that the patient does not aspirate the product. The professional is responsible for using S.I.N. in accordance with the instructions for use, as well as determining if it suits the individual situation

of each patient. The patient should be informed about all possible surgical complications, contraindications, warnings, precautions, and side effects. All documentation accompanying the product should also be made available to the customer. The form of use is inherent to the training of the professional who will use the material. It can only be used and/or applied by dentists specialized in surgery/implant dentistry.

RECOMMENDATION

S.I.N recommends prior planning of the installation surgery for Zygomatic Plus implants. Inadequate planning and/or lack of occlusal adjustment may compromise the performance of the implant/prosthesis combination resulting in system failure, such as implant loss or fracture, loosening or fracture of the prosthetic screws. S.I.N does not recommend the installation of the implant in patients with inadequate oral hygiene, uncooperative and unmotivated patients, with drug or alcohol abuse, psychoses, chemical dependence, prolonged functional disorders that resist any drug treatment, xerostomia, bruxism, other parafunctional habits, tobacco abuse. Diseases that can compromise the immune system, diseases that require the use of steroids regularly, endocrine disorders, drug allergy, diabetes mellitus, anticoagulation/ bleeding diathesis medications, should be evaluated with the primary medical for a combination of the treatment plan

CONTRAINDICATION

S.I.N. does not recommend the installation of implants in patients with: acute inflammatory or infectious processes of living tissues, inadequate bone volume or quality (as assessed by the clinician), root remains in the surgical site, serious medical issues, including bone metabolism disorders, blood coagulation disorders, poor healing capacity, incomplete maxillary growth, allergy or hypersensitivity to titanium, patients with a history of head and neck irradiation, bone condition anatomically unfavorable for implant stability, acute periodontitis, treatable pathological maxillary diseases and alterations of the oral mucosa. S.I.N. does not recommend the installation of dental implants in children, and pregnant or lactating women.

SIDE EFFECTS

Because it is a surgical procedure, the installation of implants can cause side effects such as irritation at the site of implantation, mild bleeding, mild inflammation, localized pain, sensitivity, edema and ecchymosis. In case of failure in the planning or execution of the surgical procedure adverse effects such as chronic pain, paresthesia, paralysis, infection, hemorrhage, oro-antral or orosinusal fistula, sinusitis, affected adjacent teeth, bone necrosis, fractures of the implant or prosthesis, bone loss around the implant, or implant loss (non-ossointegration) can occur.

WARNING

Implants should receive components with compatible geometry and installation indication. S.I.N. suggests an application table of implants and components according to the region to be applied, but it is up to the dentist, trained in the specialty, the choice and arbitration with regards the diameter and length of the implant installation in relation to the region and anatomy. S.I.N. Implants are designed to withstand the maximum torque of 80N.cm. Torques above this value can cause irreversible damage, as well as surgical complications. This product is for single use and cannot be reused nor reesterelized. The reuse or re sterilization of this

product may cause loss of the implant (non Osseointegration), contagious infectious disease, deformation and wear of the product. The torque for fixation of the intermediates on the implant is 20N.cm. The torque for fixation of components above intermediates is 10 N.cm. Do not install the protective screw (implant cap) with ratchet driver or torque driver in order to not damage the implant; the tightening must be performed manually through digital driver. During prosthesis maintenance, the recommended torque value for each component must be respected. Higher values can damage/fracture the implant, reducing its useful life.

TRACEABILITY

All S.I.N. products have sequential batches that allow traceability, which promotes greater safety for the professional qualified to the procedure. Through this batch number it is possible to know the entire history of the product from the manufacturing process until the moment of distribution. The implants are available with three (3) traceability labels.

STORAGE

The S.I.N. medical device should be stored in a cool dry place at a temperature of 15°C to 35°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

S.I.N implants are sent to the professionals properly packaged, sealed and sterilized. Therefore, its packaging (blister) should be opened in a sterile surgical field, and the implant should be handled only with the specific instruments available in the Zygomatic kit.

DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

TRANSPORTATION

Zygomatic Plus implant must be transported adequately to avoid falling and stored under a maximum temperature of 35°C, protected from heat and moisture. Carriage must be carried out in its original packaging.

COMPLEMENTARY INFORMATION

Magnetic Resonance Imaging (MRI): Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. devices are MR Conditional.

CAUTION: Patient imaging can only be obtained by delimiting at least 30cm from the implant or ensuring that the implant is located outside the radiofrequency coil.

A patient with this device can be safely scanned on an MRI system under the following conditions:

Device Name	S.I.N. Implant System
Static Magnetic Field Strength (B0)	≤ 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

Exclusive Product for Dental use. Reprocessing not allowed. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed version of this instruction for use or a copy of the safety and clinical performance summary (SSCP), at no cost, please request it by email to sin@sinimplantsystem.com or call 0800 770 8290 and you will receive it within 7 calendar days.

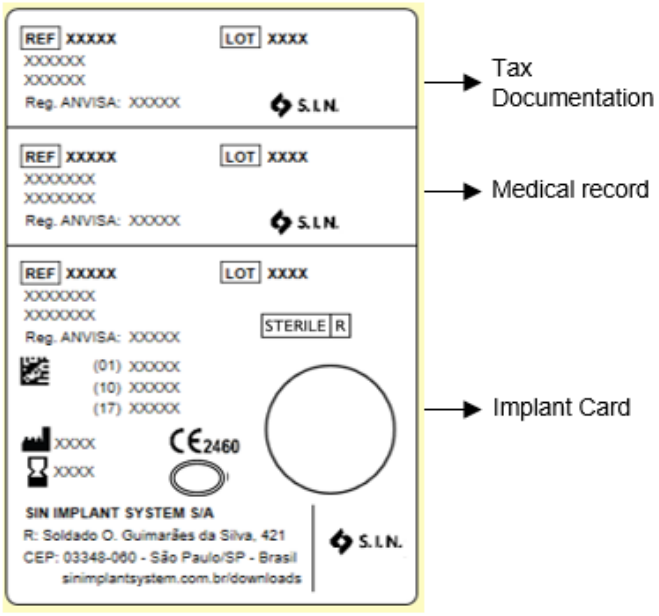
TRACEABILITY LABELS

The Zygomatic Plus line implants are available from S.I.N. with 3 (three) labels containing product information. The labels must be used as follows:

Tax label: The dental surgeon must stick a label on the implant's tax documentation.

Medical record label: The dental surgeon must paste a label in the patient's medical record in order to maintain traceability of the products used.

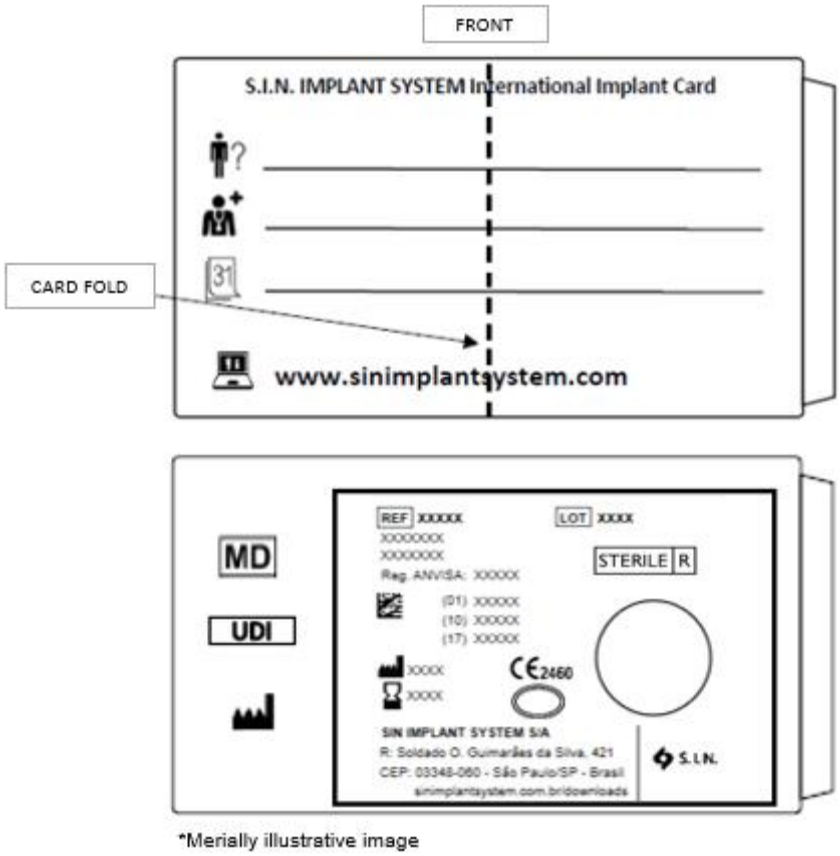
Implant card label: The dental surgeon must attach a label to the implant card to inform which products have been used.



*Merially illustrative image

IMPLANT CARD

The Zygomatic Plus line implants are provided by S.I.N. with an implant card. This card must be given to the patient, who must be instructed on how to keep and preserve this information.



*Merially illustrative image

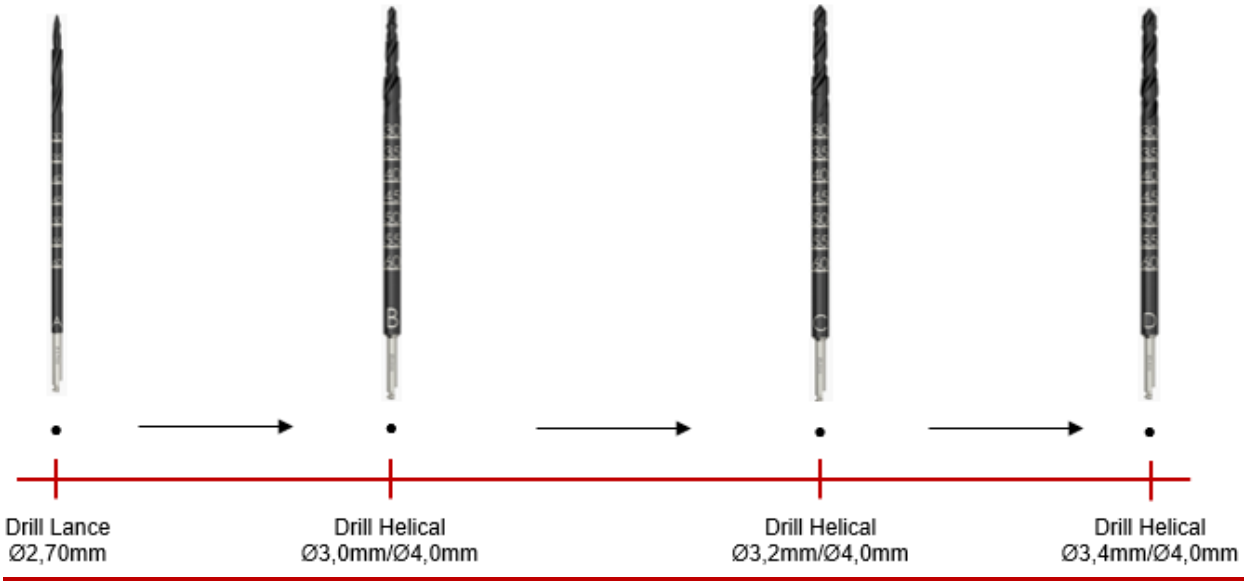
STERILE R FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and single-use (sterilization method: gamma radiation) packaged in a unit that offers triple protection: tertiary packaging (cardboard), secondary blister packaging (PET film and surgical grade paper), and primary packaging (clear tube).

EXPIRATION DATE

The information regarding the expiration date can be found on the labeling of the product. After installation on the patient, the product must be monitored by the professional.

DRILLING SEQUENCE ZYGOMATIC PLUS IMPLANT



	PRODUTO ESTERILIZADO POR RADIAÇÃO GAMA	PRODUCT STERILIZED THROUGH GAMMA RAYS	PRODUIT STÉRILISÉ AUX RAYONS GAMMA
	NÃO REUTILIZAR	DO NOT REUSE	NE PAS RÉUTILISER
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTER LE MODE D'EMPLOI
	MARCAÇÃO CE	CE MARK	CE MARQUE
	MANTENHA SECO	KEEP DRY	GARDER AU SEC
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	TENIR À L'ABRI DE LA LUMIÈRE DU SOLEIL
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NE PAS UTILISER SI L'EMBALLAGE EST ENDOMMAGÉ
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NON RI-STERILIZZARE
	ATENÇÃO	CAUTION	ATTENTION
EU REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRÉSENTANT AUTORISÉ DANS LA COMMUNAUTÉ EUROPÉENNE
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LIMITE DE TEMPÉRATURE
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.	ATTENTION: LES LOIS FÉDÉRALES (AMÉRICAINES) LIMITENT LA VENTE DE CET APPAREIL PAR OU SUR ORDRE D'UN PROFESSIONNEL DE LA SANTÉ AGRÉÉ.
	FABRICANTE	MANUFACTURER	FABRICANT
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	DATE DE FABRICATION
	VALIDADE	USE-BY DATE	VALIDITÉ
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CODE DE RÉFÉRENCE
MD	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIF MÉDICAL
UDI	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICATEUR UNIQUE DE L'APPAREIL
	SISTEMA DE BARREIRA DUPLO ESTÉRIL	DOUBLE STERILE BARRIER SYSTEM	SYSTÈME STÉRILE À DOUBLE BARRIÈRE
	IMPORTADOR	IMPORTER	IMPORTATEUR
	DISTRIBUIDOR	DESTRIBUTOR	DISTRIBUTEUR

	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAYS DE FABRICATION
	LOTE	BATCH CODE	CODE DE LOT
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALLAGE RECYCLABLE
	MR CONDICIONAL	MR CONDITIONAL	MR CONDITIONNEL
	DATA DA IMPLANTAÇÃO	DATE OF IMPLANTATION	DATE D'IMPLANTATION
	NOME E ENDEREÇO DA INSTITUIÇÃO	NAME AND ADDRESS OF THE IMPLANTING HEALTHCARE INSTITUTION	NOM ET ADRESSE DE L'ÉTABLISSEMENT DE SANTÉ IMPLANTEUR
	NOME DO PACIENTE OU IDENTIFICAÇÃO DO PACIENTE	PATIENT NAME OR PATIENT ID	NOM DU PATIENT OU IDENTIFIANT DU PATIENT
	SITE DE INFORMAÇÕES PARA OS PACIENTES	INFORMATION WEBSITE FOR PATIENTS	SITE D'INFORMATION POUR LES PATIENTS
DESCRIPTION ON THE LABEL	MAT. TITANIUM	MAT. TITANIUM	MAT. TITANIO
DESCRIPTION ON THE LABEL	CONTÉM: 1 UNIDADE	CONTENT: 1 UNIT	CONTENU: 1 UNITÉ
DESCRIPTION ON THE LABEL	PRODUTO ESTÉRIL	STERILE PRODUCT	PRODUIT STÉRILE
DESCRIPTION ON THE LABEL	PROIBIDO REPROCESSAR	REPROCESSING NOT ALLOWED	RETRAITEMENT NON AUTORISÉ

MANUFACTURER
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SYSTEM
Zygomatic Plus Implant

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