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

PRODUCT DESCRIPTION

Zygomatic implants are produced in commercially pure Titanium (Grade 4). The macrogeometry of the implant is cylindrical, with cervical micro threads and external hexagon (HE) prosthetic coupling. The surface of the implant threads has moderate roughness obtained by acid etching. The product is composed by implant plus assembler. It comes with the implant cover as an accessory.

Implant Diameters (mm)	Lenght (mm)
3.85	32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60, 62.5

INDICATIONS OF USE

Zygomatic implants are indicated for surgical procedure in the jaw and zygomatic bones in case of severe resorption of the jaw. This implant is recommended for the posterior maxillary region (premolar and molar), and one implant is installed in a hemi-arch house and with at least two conventional implants in the anterior region as support for fixed total rehabilitations. It can be used in 1 or 2 stages depending on primary stability and adequate occlusal load.

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.

ZYGOMATIC IMPLANT INSTALLATION

- Use the Ø2.9mm spherical cutter with rotation of 1200RPM to make the entry mark on the maxillary sinus posterior-upper roof;
- Continue drilling with the spherical cutter, until it penetrates the outer cortical layer of the zygomatic bone.
- Use the straight depth gauge to determine the desired length of the Zygomatic Implant to be used.
- Program the drilling unit at a speed of 1200 rpm. Use the Ø2.95mm helical cutter observing the drilling length;
- Use the Ø2.95mm/Ø3.55mm pilot cutter. The pilot cutter is used to prepare a guide for the next cutter to be used;
- Use the Ø3.55mm helical cutter observing the drilling length.
- Check the depth of the prepared socket with the depth shank to ensure that the selected implant length can be completely inserted without apical bone interference.
- Note: The sinus mucosa must be kept clear without contact with the implant, so that there are no problems with osseointegration of the implant. Ensure correct angulation and avoid drilling oscillation, in order to maintain the integrity of the surgical socket.
- Make sure that the motor is parameterized between 40RPM and 50RPM and a maximum torque of 45N.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 socket and the stability of the implant.
- Finalization of the implant can be performed with the manual key. To do this, disconnect the pen against

the angle with the key and finish the installation of the implant with the manual key.

- When installing the implant, carefully observe the maximum installation torque of 80N.cm. If this torque is reached during installation, stop the procedure and confirm that the drilling system was performed correctly and the chosen implant length is in accordance with the plan. In situations of high torque during the insertion of the Zygomatic implant, surgical maneuvers should be performed to decrease it, aiming at preserving the implant platform and the Screw/Monrador set.
- *Torque above 80N.cm in implants, may damage their prosthetic connection or cause the assembler and screw to fracture, implying the non-adaptation of prosthetic components in the subsequent rehabilitation.
- At the end of the installation, use a 1.2mm hex wrench to remove the screw that holds the mount to the implant;
- Pay special attention to removing the screw, preventing it from falling into your mouth. Its reduced size can cause surgical complications if aspirated by the patient.

ATTENTION

Zygomatic 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.

PRECAUTIONS

Observe the conditions of intra-oral 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. The patient must undergo a thorough clinical and radiological analysis before the surgery to assess the physical and psychological 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.

RECOMMENDATIONS

S.I.N recommends prior planning of the installation surgery for Zygomatic 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. The 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, low levels in the immune system

diseases that require the use of steroids regularly, endocrine disorders, drug allergy, diabetes mellitus, anticoagulation/ bleeding diathesis medications, bruxism, other parafunctional habits, tobacco abuse, installation in children, or pregnant or lactating women.

CONTRAINDICATIONS

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, root remnants in the local, serious medical problems such as: disorders of bone metabolism, blood clotting 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 to implant stability, acute periodontitis, treatable pathological maxillary diseases and alterations of the oral mucosa.

SIDES 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.

WARNINGS

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 wrench or torque wrench in order to not damage the implant; the tightening must be performed manually through digital wrench. 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. - Implante System 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 Implant card is sent in 3 ways, which one way belongs to the patient.

STORAGE

The Zygomatic implant should be stored in a cool dry place at a maximum temperature of 35°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

S.I.N implants are sent tothe 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 implant must be transported adequately to avoid falling and stored under a maximum temperatureof 35°C, protected from heat and moisture. Carriage must be carried out in its original packaging.

COMPLEMENTARY INFORMATION

Magnetic Resonance Imaging (MRI): The safety and compatibility of S.I.N. dental implants with the MRI environment were not evaluated. The heating, displacement or distortion suffered by S.I.N. dental implants in the MRI environment were not tested. The safety of SIN dental implants in the MRI environment is unknown. Performing an MRI on a patient with this device may harm the patient. Exclusive Product for Dental Use. In case of an incident caused by the product, the professional must immediately inform the manufacturer. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplante.com.br or call to 0800 770 8290 will receive until 7 days calendar.

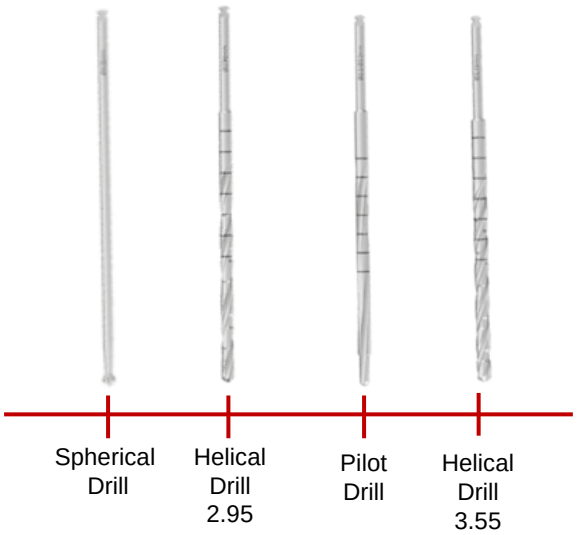
STERILE R FORM OF PRESENTATION AND STERILIZATION

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.

TABLE 1: ZYGOMATIC DRILLING SEQUENCE



STERILE R	PRODUTO ESTERILIZADO POR RADIAÇÃO GAMA	PRODUCT STERILIZED THROUGH GAMMA RAYS	PRODUCTO ESTERILIZADO POR RADIACIÓN GAMA
	NÃO REUTILIZAR	DO NOT REUSE	NO LO REUTILICE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO LEJOS DE LA LUZ SOLAR
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NO LO UTILICE SI EL ENVOLTORIO ESTÁ DAÑADO
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO REESTERILIZAR
	ATENÇÃO	CAUTION	PRECAUCIÓN
EC REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
	LIMITE SUPERIOR DE TEMPERATURA	UPPER LIMIT OF TEMPERATURE	LÍMITE SUPERIOR DE TEMPERATURA
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.	PRECAUCIÓN: LAS LEYES FEDERALES (USA) RESTRINGEN LA VENTA DE ESTE DISPOSITIVO POR O EN EL ORDEN DE UN PROFESIONAL DE LA SALUD LICENCIADO.
	FABRICANTE	MANUFACTURE	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDEZ
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA
MD	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
UDI	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	SISTEMA DE BARREIRA DOUPLO ESTÉRIL	DOUBLE STERILE BARRIER SYSTEM	SISTEMA DE DOBLE BARRERA ESTÉRIL
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
LOT	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE

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, 2445 - 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

EC REP

OBELIS S.A.
Bd. Général Wahis 53
1030 Brussels, Belgium

CE 2460

RESPONSIBLE TECHNICIAN:
Alessio Di Risio
CREA-SP (register): 5061207169

PRODUCT: Zygomatic Implant

ANVISA REGISTRATION: 80108910019