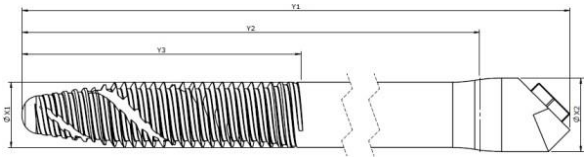
Zygomatic

Zygomatic implants are an excellent option for patients with atrophic maxilla, without the need for bone grafting and with highly stable prosthetic fixation.

PRODUCT DESCRIPTION

Zygomatic Implants are produced in commercially pure Titanium (Grade 4). The macro geometry of the implant is hybrid and external hexagon-type prosthetic coupling. The implant surface has moderate roughness obtained by an acid etching process. The product consists of implant plus assembler. Comes with the implant cap as an accessory.



Thread Diameter "X1" (mm)	4.0
Diameter "X2" (mm)	4.5
Length "Y1" (mm)	38, 40.5, 43, 45.5, 48, 50.5, 53, 55.5, 58, 60.5, 63, 65.5, 68.
Length "Y2" (mm)	32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60, 62.5
Length "Y3" (mm)	17.10

Implant Chemical Composition according ASTM F67:

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

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 FOR USE

The Zygomatic are indicated for human adults and elderly with good general health, for the 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, regions of premolars and molars, and with other implants they support total rehabilitation fixed. It can be used in 1 or 2 stages, depending on primary stability and adequate occlusal loading.

PURPOSE AND OPERATING PRINCIPLE

The purpose is to replace missing teeth, condemned teeth or conventional prostheses, with the aim of recovering aesthetics and chewing function, curbing bone resorption and reducing the overload on remaining teeth. They are based on the mechanical principles of load transmission system assembly.

HOW TO USE THE ZYGOMATIC EXTERNAL HEXAGON IMPLANT

The Zygomatic implants are indicated for surgical installation in all bone density in the maxilla, as long as the maximum insertion torque (80N.cm) is respected. For external hexagon implants, the installation must be carried out at the bone level.

- Use the Ø4.0mm ball cutter with 1200RPM rotation to mark the zygomatic bone entry.
- Continue milling with the Helical A Ø2.35mm, until it penetrates the outer cortical layer of the zygomatic bone.
- Use the straight depth indicator to determine the desired length of the Zygomatic implant to be used.
- Use the cylindrical diamond cutter Ø4.0mm at 1200RPM to prepare the edge for better fitting of the cervical portion in the case of the classic technique, or to make the groove in the case of the externalized technique.
- Program the drill unit at a speed between 600 and 800 RPM. Use the B Ø2.75mm screw cutter observing the milling length, following the same procedure for the C Ø3.0 mm screw cutters and, if necessary, the D Ø3.2mm cutter.

- Check the depth of the prepared socket with the depth rod to ensure that the length of the selected implant can be completely inserted without apical bone interference; The implant must be installed at the bone level.

NOTE: The maxillary sinus mucosa should be kept away without contact with the implant, so that there are no problems with osseointegration. Ensure correct angulation and avoid milling cutter oscillation in order to maintain the integrity of the surgical socket.

- Make sure the engine 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 contraangle. Do not move the implant vertically or laterally, as this can damage the socket and the stability of the implant.
- The implant can be completed with the manual key. To do this, disconnect the counter-angle pen with the wrench and finish the implant installation with the manual wrench.
- At the time of implant installation, carefully observe the maximum installation torque of 80N.cm. If this torque is achieved during installation, stop the procedure and confirm that the drilling system has been performed correctly and the length of the implant chosen is according to plan. In situations of high torque during the insertion of the Zygomatic implant, surgical maneuvers should be performed be performed to reduce it, aiming at preserving the implant platform and the screw/assembler assembly.
- At the end of the installation, use a 1.2mm hex wrench to remove the screw that holds the assembler to the implant.
- Pay extra attention to the removal of the screw, preventing it from falling into the mouth. Its small size can cause surgical complications if aspirated by the patient.

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

⚠ ATTENTION

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

PRECAUTIONS

Observe the conditions of the intra-oral tissues, bone quality and bone quantity of the implant recipient site, through radiographic and/or tomographic examinations. Failure to perform the pre-surgical evaluation may lead to the impossibility of finding pre-existing diseases. Consider the patient's general health conditions. The patient must undergo a thorough clinical and radiological analysis prior to surgery to assess the patient's physical and psychological conditions. Patients who have local or systemic factors that may interfere with the healing processes of the bones or soft tissues or in the process of integration should receive special care. Handle the material only in a 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 packaging is damaged. Only open the package at the time of surgery and use the product immediately. Implants not used after opening the outer pack should be disposed of, expired products should not be used. In one-stage surgical rehabilitations (immediate loading), primary stability should

reach at least 45 N.cm. The maximum permissible angle for S.I.N. is up to 30 degrees. An insertion torque higher than the recommended maximum may damage the product, causing it to lose its primary function. Observe the conditions of use of surgical instruments. The drill and other instruments with low cutting power can generate heat during use, which hinders the osseointegrated process. Replace instruments in case of damage, erasing of marks, impaired sharpness, deformation and wear. The surgical motor used in the procedure must be adjusted according to the specification of the implant to be used (torque and RPM). Check your motor and fishing conditions before surgery. If necessary, perform preventive/corrective maintenance with the manufacturer. Unregulated equipment can directly interfere with the performance of the product during the surgical and prosthetic procedure, using only components and instruments specified by S.I.N.. They have specific dimensions and tolerances for each implant system to ensure the longevity of the product. Other components of the brand or adapted implant models can reduce the life of the system and cause irreversible damage. The professional must ensure that the patient does not aspirate the product. The practitioner is responsible for using the S.I.N. in accordance with the instructions for use, as well as determining whether it is suitable for each patient's individual situation. The patient should be informed about all possible surgical complications, contraindications, warnings, precautions, and side effects. All documentation that comes with the product must 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 who specialize in surgery/implantology.

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. 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

As it is a surgical procedure, the installation of implants can cause side effects such as irritation at the implantation site, slight bleeding, slight inflammation, localized pain, tenderness, 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, oroantral or oronasal fistula, affected adjacent teeth, bone necrosis, fractures of the implant or prosthesis, bone loss around the implant or loss of the implant (non-osseointegration) may 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 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, thus promoting greater safety for the professional qualified for the procedure. Through this batch number, it is possible to know the entire history of the product from the manufacturing process to the moment of distribution. The implants are available with 3 (three) copies of 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 professionals properly packaged, sealed and sterilized. Therefore, its packaging (blister) must be opened in a sterile surgical field, and the implant must be handled only with the specific instruments available in the Zygomatic Surgical Kit.

DISPOSAL OF MATERIALS

The disposal of materials must be carried out in accordance with hospital standards and current local legislation.

TRANSPORTATION

Zygomatic implants must be transported properly, to prevent falling, and stored at a maximum temperature of 35ºC, away from heat and humidity. Transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATION

Magnetic Resonance Imaging (MRI): Non-clinical tests and simulations in an MRI environment performed in vitro have demonstrated that S.I.N. devices are MRI conditional.

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

A patient with this device can be safely scanned in 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 (5.00 gauss/cm).
RF Excitation	Circular Polarization (CP)
RF Transmission Coil Type	Head coil and body coil allowed. T/R end coils allowed.
Mode of Operation	Normal operating mode in the allowed image zone.
Specific Absorption (SAR) Maximum Rate Body Type Coil	2.0 W/kg (15 minutes scanning, normal operation mode)
Specific Absorption (SAR) Rate Maximum Coil Type Head	15 minutes
Scanning Time.	15 minutes
Temperature Rise	Maximum temperature rise of 0.45°C/(W/kg), after 15 minutes of continuous scanning in a static magnetic field and 3 T with head-type or body-type coils.
Artifacts	When scanned using a gradient-echo sequence and a 3 T MR system, the image artifact can extend to approximately 12 mm with a body-type coil, and up to approximately 32 mm with a head-type coil.

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.

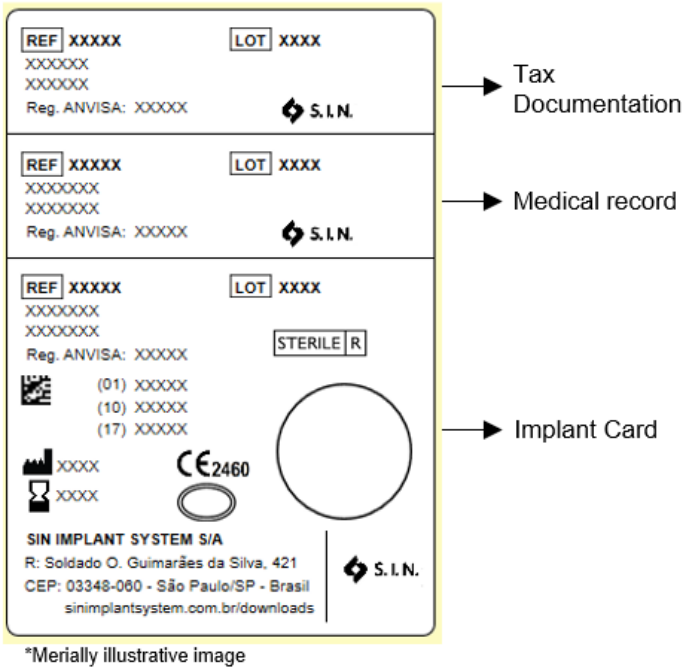
TRACEABILITY LABELS

The implants of the Zygomatic line are available through S.I.N. com 3 (three) labels containing the product information. Labels should be used as follows:

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

Label of the medical record: The dental surgeon must stick a label on the patient's record in order to maintain the traceability of the products used

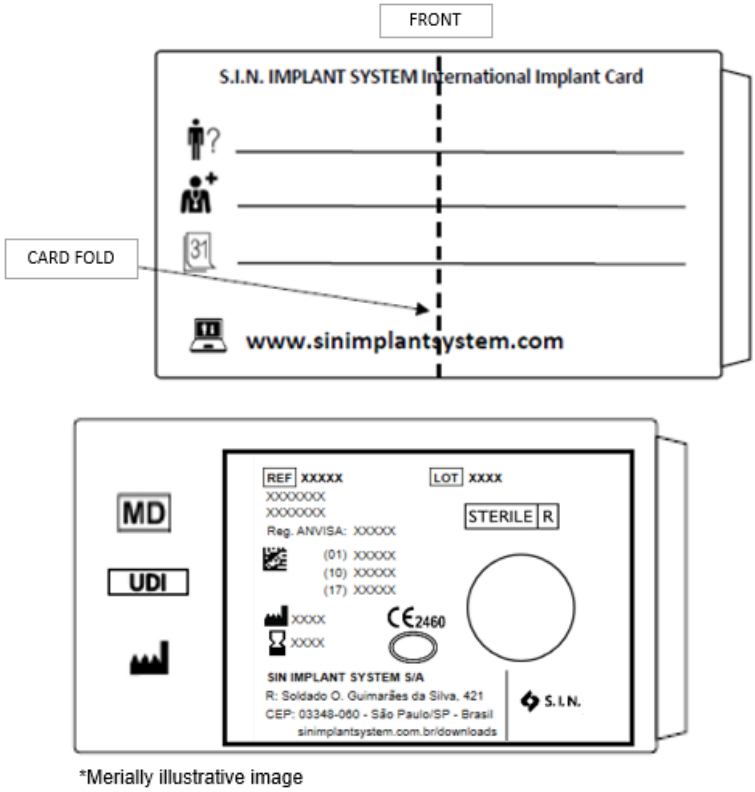
Implant card label: The dentist should stick a label on the implant card in order to inform about which products were used.



*Merially illustrative image

IMPLANT CARD

Zygomatic implants are provided by S.I.N. com an implant card. This card must be given to the patient, who must be instructed on the safekeeping and conservation of this information.



*Merially illustrative image

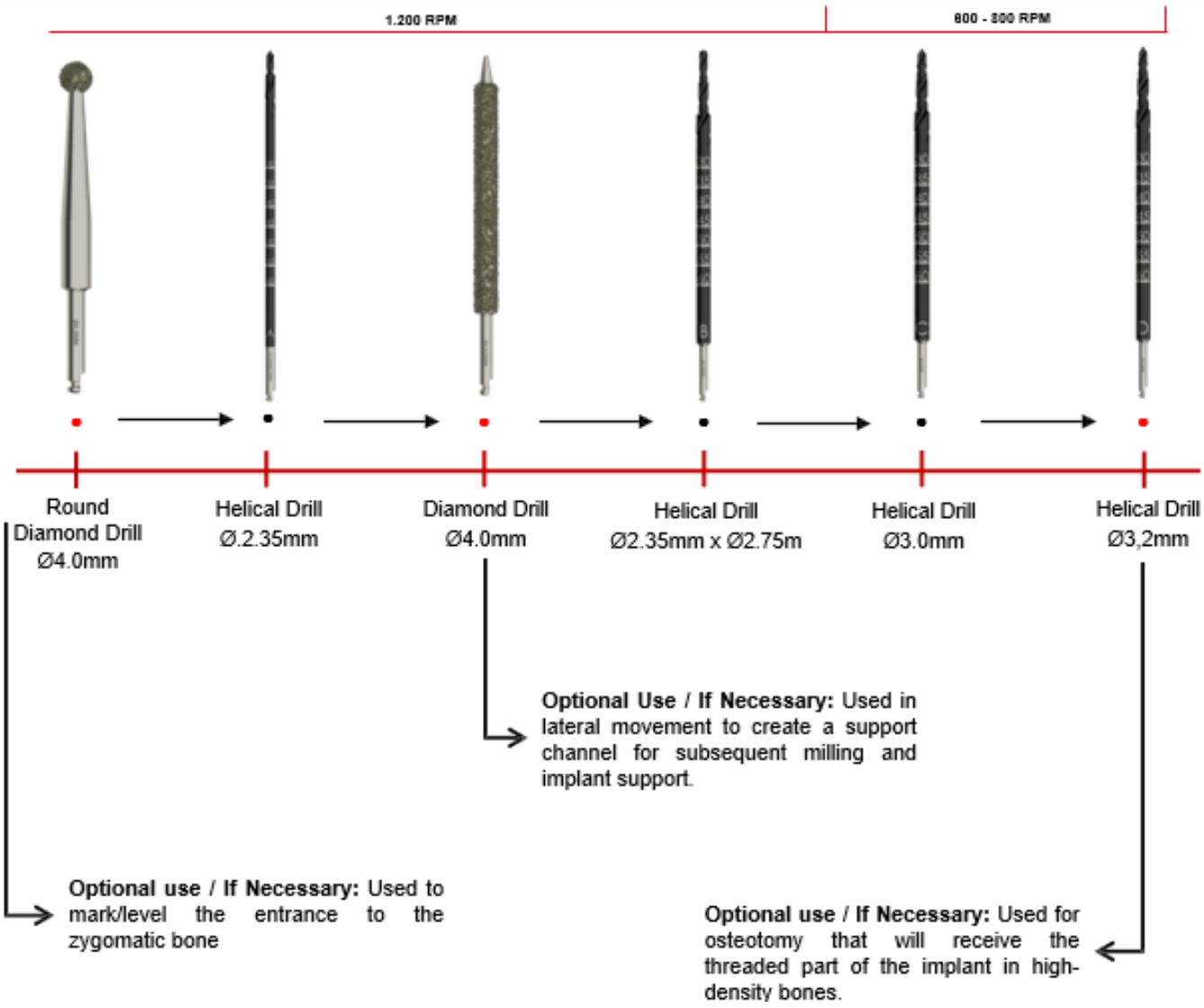
STERILE R FORM OF PRESENTATION AND STERILIZATION

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

EXPIRATION DATE

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

DRILLING SEQUENCE OF ZYGOMATIC IMPLANT



	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
EU REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LÍMITE 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	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDEZ
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
MD	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
UDI	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	SISTEMA DE BARREIRA DUPLO ESTÉRIL	DOUBLE STERILE BARRIER SYSTEM	SISTEMA DE DOBLE BARRERA ESTÉRIL
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DESTRIBUTOR	DISTRIBUIDOR

	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE
	MR CONDICIONAL	MR CONDITIONAL	MR CONDICIONAL
	DATA DA IMPLANTAÇÃO	DATE OF IMPLANTATION	FECHA DE APLICACIÓN
	NOME E ENDEREÇO DA INSTITUIÇÃO	NAME AND ADDRESS OF THE IMPLANTING HEALTHCARE INSTITUTION	NOMBRE Y DIRECCIÓN DE LA INSTITUCIÓN
	NOME DO PACIENTE OU IDENTIFICAÇÃO DO PACIENTE	PATIENT NAME OR PATIENT ID	NOMBRE DEL PACIENTE O IDENTIFICACIÓN DEL PACIENTE
	SITE DE INFORMAÇÕES PARA OS PACIENTES	INFORMATION WEBSITE FOR PATIENTS	PÁGINA WEB DE INFORMACIÓN AL PACIENTE

MANUFACTURER
S.I.N. Implant System LTDA.
CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
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PRODUCT
Zygomatic Implant

ANVISA REGISTRATION
80108910019