Strong sw

The Strong SW implant line offers an inseparable set of experiences for those seeking excellent results. With exceptional clinical practicality, Strong SW has a complete line of implants.

PRODUCT DESCRIPTION

Strong SW implants are produced from commercially pure titanium (Grade 4). The macrogeometry of the implant is hybrid, with cervical microthreads and prosthetic coupling of the external hexagon (HE), internal hexagon (HI) and morse taper (CM) types. The implant surface is moderately rough obtained by acid etching process. Comes with the implant cover as an accessory.

Diameters of the Implants (mm)	Length (mm)
3.5, 3.75, 3.8, 4.5, 5.0	7, 8.5, 10, 11.5,13, 15, 18, 20, 22, 24.

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 Strong SW are indicated for human adults and elderly with good general health, surgical procedures in maxillary or mandibular bones, generating a support platform for the installation of prosthetic components that will receive artificial teeth, restoring the patient's masticatory function. They can be used in conventional procedures (1 and 2 surgical stages) and immediate loading (activation within 48 hours) when there is acceptable primary stability (above 45 N.cm) and adequate occlusal loading. They can be used in single or multiple restorations.

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 STRONG SW IMPLANT EXTERNAL HEXAGON, INTERNAL HEXAGON AND MORSE TAPER

The implants of the Strong SW line are indicated for surgical installation in all bone densities, in maxilla or mandible, as long as the maximum insertion torque (80N.cm) is respected. If the installation reaches torque that exceeds the limit, it is recommended to use a specific thread tap for each model before the end of the installation. The Thread Taps can be used in the surgical socket with ratchet or counter angle depending on the fit of the purchased product. For implants with Morse taper connection, 1.5mm intraosseous installation must be performed, while for implants with internal and/or external hexagon connection, the installation must be performed at the bone level. Remove the blister from the outer cartridge.

- Remove the blister from the outer cartridge.
- Reserve the traceability labels that come with the product.
- In a sterile surgical field and, after breaking the sterility seal of the blister, hold the primary package (tube) with your non-dominant hand and open the cap.
- The implant will be exposed inside the tube for capture with the key.
- For the installation with a motor, use the counter angle wrench.
- Capture the implant by keeping the key still and slightly rotating the internal support, seeking the perfect fit between the connection and the implant. Press the key on the implant for better fixation.
- Transport the implant to the bone bed.
- In the surgical motor, use maximum torque of 35N.cm and rotation between 20-40 RPM.
- Preferably, complete the implant installation with the surgical torque wrench or a ratchet wrench.
- The maximum recommended installation torque is 80N.cm.
- The choice between the installation of the implant cover, healer or prosthetic component is at the discretion of the professional.
- Select the intermediaries between the implant and the prosthesis, observing their indications and limitations, according to the applicable literature.

HOW TO USE STRONG SW IMPLANT EXTERNAL HEXAGON, INTERNAL HEXAGON AND MORSE TAPER WITH GUIDED SURGERY KIT

- Remove the blister from the outer cartridge.
- Maintain the traceability labels that come with the product.
- In the sterile surgical field and after breaking the sterile seal of the blister, grasp the primary packaging (tube) with your non-dominant hand and open the cap.
- The implant will be exposed inside the tube to capture the conductor.
- For motorized installation, use the driver for contra-angle according to the choice of external hexagon, internal hexagon or morse taper implant system and observing the diameter of the chosen implant.
- Hold the implant while keeping the conductor immobilized and slightly rotating the internal support, looking for the perfect fit between the connection and the implant. Press the driver into the implant for better fixation.
- Fit one of the implant guides according to the implant diameter selected in the washing machine of the surgical guide prototype.
- Transport the implant to the implant guide already attached.
- On the surgical motor, use a maximum torque of 35 N.cm and rotation between 20-40 RPM.
- Preferably, complete the implant installation with the surgical torque driver or a ratchet adjusting the length of the driver (short or long) according to the adjacent dental crown and the available mouth opening. Remember that the connection of this driver must be the same as the driver pre-used for contra-angle.
- The recommended maximum installation torque is 80 N.cm.
- The choice between installing the implant cap, healing or prosthetic component is at the discretion of the professional.
- Select the intermediaries between the implant and the prosthesis, observing their indications and limitations, according to the applicable literature.
- The patient should be informed of all possible surgical complications, contraindications, warnings, precautions, and adverse effects. All documentation must also be made available to the patient.
- The use of the product and surgical techniques are inherent to the training of the professional. It can only be used and/or applied by dentists specialized in surgery/Implantology.

⚠ ATTENTION

Strong SW 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 intraoral 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 packaging should be discarded. 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 to implant models they can shorten the lifespan of the system and cause irreversible damage. The professional must ensure that the patient does not aspirate the product. The professional is responsible for using the S.I.N. according to the instructions for use, as well as determine if it suits the individual situation of each patient. The patient should be informed of 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 Unitite 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 Strong SW Surgical Kit and Strong SW Guided Surgery Kit.

DISPOSAL OF MATERIALS

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

TRANSPORTATION

Strong SW 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 INFORMATIONS

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 summary of safety and clinical performance (SSCP), without any cost, please request by e-mail to sin@sinimplantsystem.com or call to 0800 770 8290 will receive until 7 days calendar.

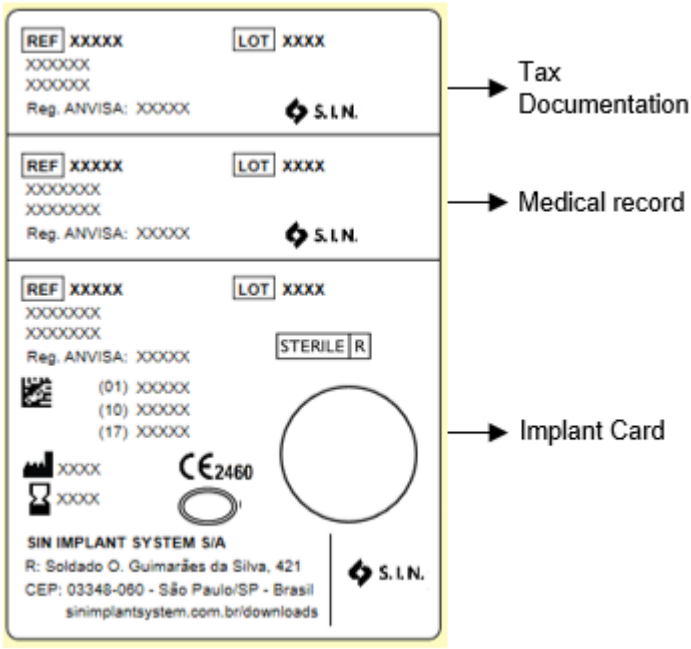
TRACEABILITY LABELS

The implants of the Strong SW line are available by 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

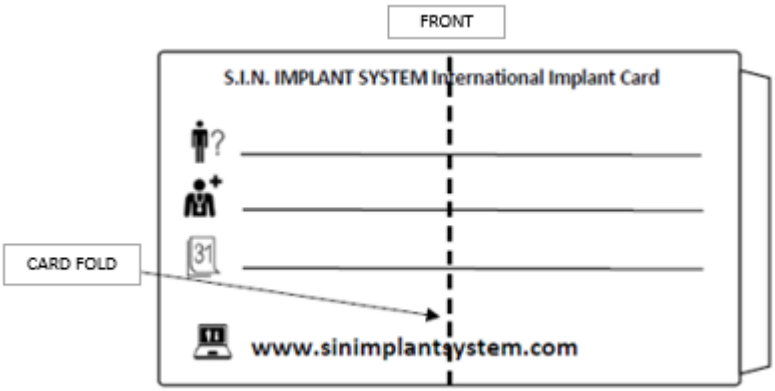
Implant card label: The dentist should stick a label on the implant card in order to inform about which products were used.

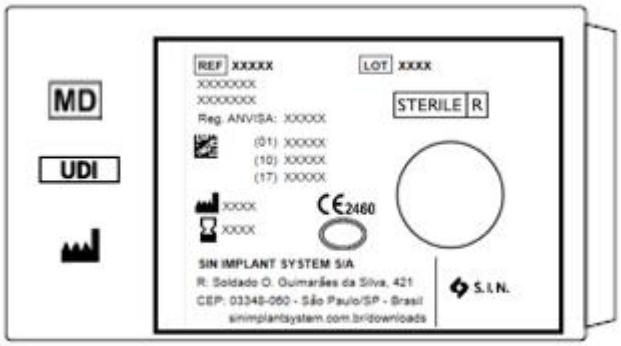


*Merially illustrative image

IMPLANT CARD

Strong SW 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

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.

INDICATION OF IMPLANT APPLICATION BY REGION

				Cone Morse		External Hexagon			Internal Hexagon	
Arch	Position		Tooth	Implant diameter	Component Diameter	Implant diameter	Implant platform	Component Diameter	Implant diameter	Component Diameter
MAXILAR	11	21	CENTRAL INCISOR	Ø3.5 / Ø3.8 / Ø4.5	Ø3.3 / Ø3.5 / Ø4.5	Ø3.5 / Ø3.75 / Ø4.5	Ø3.6 / Ø4.1 / Ø4.5	Ø3.6 / Ø4.1	Ø3.8 / Ø4.5	Ø3.8 / Ø4.5
	12	22	LATERAL INCISOR	Ø3.5 / Ø3.8	Ø3.3 / Ø3.5	Ø3.5 / Ø3.75	Ø3.6 / Ø4.1	Ø3.6 / Ø4.1	Ø3.8	Ø3.8
	13	23	CANINE	Ø3.5 / Ø3.8 / Ø4.5	Ø3.3 / Ø3.5 / Ø4.5	Ø3.5 / Ø3.75	Ø3.6 / Ø4.1 / Ø4.5	Ø3.6 / Ø4.1	Ø3.8 / Ø4.5	Ø3.8 / Ø4.5
	14	24	1st PRE-MOLAR	Ø3.8 / Ø4.5 / Ø5.0	Ø3.3 / Ø3.5 / Ø4.5	Ø3.75 / Ø4.5 / Ø5.0	Ø4.1 / Ø4.5	Ø4.1	Ø3.8 / Ø4.5 / Ø5.0	Ø3.8 / Ø4.5
	15	25	2nd PRE-MOLAR	Ø3.8 / Ø4.5 / Ø5.0	Ø4.5	Ø3.75 / Ø4.5 / Ø5.0	Ø4.1 / Ø4.5	Ø4.1	Ø3.8 / Ø4.5 / Ø5.0	Ø3.8 / Ø4.5
	16	26	1st MOLAR	Ø4.5 / Ø5.0	Ø4.5	Ø4.5 / Ø5.0	Ø4.5 / Ø5.0	Ø4.1 / Ø5.0	Ø4.5 / Ø5.0	Ø3.8 / Ø4.5
	17	27	2nd MOLAR	Ø4.5 / Ø5.0	Ø4.5	Ø4.5 / Ø5.0	Ø4.5 / Ø5.0	Ø4.1 / Ø5.0	Ø4.5 / Ø5.0	Ø4.5
	18	28	3rd MOLAR	Ø4.5 / Ø5.0	Ø4.5	Ø4.5 / Ø5.0	Ø4.5 / Ø5.0	Ø4.1 / Ø5.0	Ø4.5 / Ø5.0	Ø4.5
MANDIBLE	41	31	CENTRAL INCISOR	Ø3.5	Ø3.3 / Ø3.5	Ø3.5	Ø3.6	Ø3.6	Ø3.8	Ø3.8
	42	32	LATERAL INCISOR	Ø3.5	Ø3.3 / Ø3.5	Ø3.5	Ø3.6	Ø3.6	Ø3.8	Ø3.8
	43	33	CANINE	Ø3.5 / Ø3.8 / Ø4.5	Ø3.3 / Ø3.5 / Ø4.5	Ø3.5 / Ø3.75	Ø3.6 / Ø4.1 / Ø4.5	Ø3.6 / Ø4.1	Ø3.8 / Ø4.5	Ø3.8 / Ø4.5
	44	34	1st PRE-MOLAR	Ø3.8 / Ø4.5 / Ø5.0	Ø3.3 / Ø3.5 / Ø4.5	Ø3.75 / Ø4.5	Ø4.1 / Ø4.5	Ø3.6 / Ø4.1	Ø3.8 / Ø4.5 / Ø5.0	Ø3.8 / Ø4.5
	45	35	2nd PRE-MOLAR	Ø3.8 / Ø4.5 / Ø5.0	Ø4.5	Ø3.75 / Ø4.5	Ø4.1 / Ø4.5	Ø3.6 / Ø4.1	Ø3.8 / Ø4.5 / Ø5.0	Ø3.8 / Ø4.5
	46	36	1st MOLAR	Ø4.5 / Ø5.0	Ø4.5	Ø4.5 / Ø5.0	Ø4.5 / Ø5.0	Ø4.1 / Ø5.0	Ø4.5 / Ø5.0	Ø4.5
	47	37	2nd MOLAR	Ø4.5 / Ø5.0	Ø4.5	Ø4.5 / Ø5.0	Ø4.5 / Ø5.0	Ø4.1 / Ø5.0	Ø4.5 / Ø5.0	Ø4.5
	48	38	3rd MOLAR	Ø4.5 / Ø5.0	Ø4.5	Ø4.5 / Ø5.0	Ø4.5 / Ø5.0	Ø4.1 / Ø5.0	Ø4.5 / Ø5.0	Ø4.5

STRONG SW MILLING SEQUENCE OF THE EXTERNAL HEXAGON IMPLANT

		1.500 RPM		800 RPM					25 RPM				
	Instrument Codes	FRLD 2020	FHD 2015	FRWD 35	FRWD 38	FCWD 41	FRWD 45	FRWD 50	CMRIW 35	CMRIW 37	CMRIW 38	CMRIW 45	CMRIW 50
 Strong SW External Hexagon	Ø 3.5	•	•	•					•				
	Ø 3.75	•	•	•	•	•				•			
	Ø 4.5	•	•	•	•		•					•	
	Ø 5.0	•	•	•	•		•	•					•

• The use of a male drill is optional in type I and II bone because it is a compressive implant, but the maximum torque must always be respected.

Male drill: Tightening should not exceed 60N.cm.

STRONG SW MILLING SEQUENCE OF THE INTERNAL HEXAGON IMPLANT

		1.500 RPM		800 RPM					25 RPM				
	Instrument Codes	FRLD 2020	FHD 2015	FRWD 35	FRWD 38	FCWD 41	FRWD 45	FRWD 50	CMRIW 35	CMRIW 37	CMRIW 38	CMRIW 45	CMRIW 50
 Strong SW Internal Hexagon	Ø 3.8	•	•	•	•						•		
	Ø 4.5	•	•	•	•		•					•	
	Ø 5.0	•	•	•	•		•	•					•

• The use of a male drill is optional in type I and II bone because it is a compressive implant, but the maximum torque must always be respected.

Male drill: Tightening should not exceed 60N.cm.

STRONG SW MILLING SEQUENCE OF THE CONE MORSE IMPLANT

		1.500 RPM		800 RPM					25 RPM				
	Instrument Codes	FRLD 2020	FHD 2015	FRWD 35	FRWD 38	FCWD 41	FRWD 45	FRWD 50	CMRIW 35	CMRIW 37	CMRIW 38	CMRIW 45	CMRIW 50
 Strong SW Cone Morse 16º e 11,5º	Ø 3.5	•	•	•					•				
	Ø 3.8	•	•	•	•						•		
	Ø 4.5	•	•	•	•		•					•	
	Ø 5.0	•	•	•	•		•	•					•

• The use of a male drill is optional in type I and II bone because it is a compressive implant, but the maximum torque must always be respected.

Male drill: Tightening should not exceed 60N.cm.

STRONG SW MILLING SEQUENCE WITH GUIDED SURGERY KIT EXTERNAL HEXAGON, INTERNAL HEXAGON AND MORSE TAPER IMPLANT

	20 RPM		400 RPM		1.500 RPM	800 RPM				25 RPM				
Instrument Codes	EM 35	EM 45	FPG 35	FPG 45	FHDG 20	FRWDG 35	FRWDG 38	FRWDG 41	FRWDG 45	CMRIWG 35	CMRIWG 35E	CMRIWG 37	CMRIWG 38	CMRIWG 45
Ø 3.5	•		•*		•	•				•	•**			
Ø 3.75		•		•*	•	•	•	•				•		
Ø 3.8		•		•*	•	•	•						•	
Ø 4.5		•		•*	•	•	•		•					•

• The use of a male drill is optional in type I and II bone because it is a compressive implant, but the maximum torque must always be respected.

•* The use of a flat drill is optional, this instrument is used for planing the alveolar ridge, creating a stable face for drilling with the other drills in the system.

•** The use of the male drill will only be in surgical planning with narrow washers.

Male drill: Tightening should not exceed 60N.cm.

STERILE R	PRODUTO ESTERILIZADO POR RADIAÇÃO GAMA	PRODUCT STERILIZED THROUGH GAMMA RAYS	GAMMA RADIATION STERILIZED PRODUCT
	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	CE MARK
	MANTENHA SECO	KEEP DRY	DRY MANTÉNGALO
	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 ENVOLVORIO ESTÁ DAÑADO
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO RE-STERILIZE
	ATENÇÃO	CAUTION	CAUTION
EU REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	TEMPERATURE LIMIT
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.	PRECAUTION: LAS LEYES FEDERALES (USA) RESTRICTEN LA VENTA DE ESTE DISPOSITIVO POR O EN EL ORDEN DE UN PROFESIONAL DE LA SALUD LICENCIADO.
	FABRICANTE	MANUFACTURER	MANUFACTURER
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDITY
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	REFERENCE CODE
MD	DISPOSITIVO MÉDICO	MEDICAL DEVICE	MEDICAL DEVICE
UDI	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	UNIQUE DEVICE IDENTIFIER
	SISTEMA DE BARREIRA DUPLO ESTÉRIL	DOUBLE STERILE BARRIER SYSTEM	STERILE DOUBLE BARRERA SYSTEM
	IMPORTADOR	IMPORTER	IMPORTER
	DISTRIBUIDOR	DETRIBUTOR	DISTRIBUTOR

	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	COUNTRY OF MANUFACTURE
	LOTE	BATCH CODE	LOT
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	RECYCLABLE PACKAGING
	MR CONDICIONAL	MR CONDITIONAL	MR CONDITIONAL
	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	PATIENT INFORMATION WEBSITE

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

ANVISA REGISTRATION
80108910009 and 80108910012