Strong sw PLUS

IMPLANTS

STERILE R	NÃO ESTÉRIL	NON-ESTERILE	NO ESTERIL
	NÃO REUTILIZAR	DO NOT REUSE	NO LO REUTILICE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
CE	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
PROIBIDO REPROCESSAR	PROIBIDO REPROCESSAR	PROHIBITED REPROCESS	PROHIBIDO REPROCESAR
35°C	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.

DEVELOPED AND MANUFACTURED BY:

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PRODUCT:

Strong SW Plus Implant with SINactive Surface
ANVISA Registration: 80108910052

CE 2460

S.I.N. Implant System

S.I.N. Osseointegrated Implants are intended for expert procedures, which must be performed by qualified professionals in Implant Dentistry. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRODUCT DESCRIPTION

Strong SW Plus Implants are produced in commercially pure Titanium (Grade 4). The macro geometry of the implant is hybrid, with cervical micro threads and external hexagon prosthetic coupling, internal hexagon and cone morse. The surface of the implant is nano and porous obtained by acid- etched process.

INDICATIONS OF USE

S.I.N. implants are indicated for surgical procedures in maxillary or mandibular bones generating a support platform for the installation of prosthetic components such as artificial teeth, restoring the patient's masticatory function. They can be used in conventional procedures (1 and 2 surgical stages) and immediate loading (activation in up to 48 hours) when there is acceptable primary stability (above 45 N.cm) and proper occlusal load. They can be used in single or multiple restorations.

APPLICATIONS

Strong SW Plus Implants are indicated for surgical installation in all bone densities, maxilla or mandible, as long as the maximum insertion torque (80 N.cm) is not surpassed. If the installation reaches a torque that exceeds the limit, it is recommended to use a specific ground thread for each model before the installation is finished.

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.

RECOMMENDATIONS

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.

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.
- In rehabilitations of a surgical stage (immediate loading), the primary stability should reach at least 45 N.cm.
- The maximum angulation allowed for S.I.N. is up to 30 degrees.
- 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. Millings and other instruments with low cutting power can generate heating during use, which hinders the osseointegrated 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.
- 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 Prosthetic Screws.
- 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.

EH, IH and CONE MORSE STRONG SW PLUS IMPLANT INSTALLATION

- Remove the blister from the outer cartridge.
- Keep the traceability labels that came with the product.
- In sterile surgical field and after breaking the sterile sealing of the blister, grasp the primary package (tube) with the non-dominant hand and open the lid.
- The implant will be exposed inside the tube to capture the wrench;
- For motor installation, use the contra-angle wrench.
- Grab the Implant by holding the wrench still and rotating the internal support slightly, looking for the perfect fit between the connection and the Implant. Press the wrench to the implant to get better fixation.
- Transport the implant to the bony site.
- In 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 Wrench or a ratchet wrench.
- The recommended maximum installation torque is 80 N.cm.
- The choice between installing the implant cap, healing or prosthetic component is at the professional's discretion.

- Select the intermediaries between the Implant and the prosthesis, observing its indications and limitations, according to the applicable literature.

INSTALLATION OF THE EXTERNAL HEXAGON GUIDE (EH) and CONE MORSE STRONG SW PLUS IMPLANT

- Remove the blister from the outer cartridge.
- Keep the traceability labels that came with the product.
- In sterile surgical field and after breaking the sterile sealing of the blister, grasp the primary package (tube) with the non-dominant hand and open the lid.
- The implant will be exposed inside the tube to capture the wrench.
- For motor installation, use the key for counter angle according to the choice EH or CONE MORSE implant system and observing the diameter of the chosen implant.
- Grab the Implant by holding the wrench still and rotating the internal support slightly, looking for the perfect fit between the connection and the Implant. Press the wrench to the implant to get better fixation.
- Fit one of the implant guides according to the selected implant diameter into the washer of the prototype surgical guide.
- Transport the Implant to the already attached implant guide.
- In 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 Wrench or a ratchet
- adjusting key length (short, medium or long) according to adjacent dental crown and available mouth opening. Remember that the diameter of this key must be the same as the pre-used key for counter-angle.
- The recommended maximum installation torque is 80 N.cm.
- The choice between installing the implant cap, healing or prosthetic component is at the professional's discretion.
- Select the intermediaries between the Implant and the prosthesis, observing its indications and limitations, according to the applicable literature.

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.

FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and for single use (sterilization method: gamma radiation), individually packaged with triple protection: tertiary package (cardboard), blister package (pet film and surgical grade paper) and primary package (transparent pipe).

Implant Diameters (mm)	**Length (mm)**
3.5, 3.8, 3.75, 4.5, 5.0	7, 8.5, 10, 11.5,13, 15.

SIDE EFFECTS

Because it is a surgical procedure, the implant installation can cause a slight discomfort and localized edema. More persistent symptoms may arise such as: chronic pain related to the dental implant, permanent paraesthesia, dysesthesia, loss of maxillary/mandibular bone border, localized or systemic infection, oro-antral or oro-nasal fistula, adjacent teeth adversely affected, irreversible damage to adjacent teeth, implant, maxillary, bone or prosthesis fractures, aesthetic problems, nerve damage, exfoliation, hyperplasia, loss of implant and/or prosthesis.

TRANSPORTATION

Strong SW Plus implants must be transported in an appropriate manner to avoid falling and storage under a maximum temperature of 35° C, away from heat and humidity. Transportation must be carried out in its original packaging.

STORAGE

SW should be stored in a cool, dry place at a maximum temperature of 35° C and protected from direct sunlight in the original closed package and from damage.

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.

HANDLING

The alveolus should be made according to the necessary care for the reduction of surgical trauma, including millings in a good cutting state with rotation from 800 to 1500 RPM and under abundant irrigation. Select the drill sequence according to the type and diameter of the intended implant (see table 2). For the infra-osseous positioning of the cervical portion of the implant, it is recommended to add 1 or 2 mm to the implant length during surgical instrumentation.

WARNING

Implants should receive components with compatible geometry, or specific components for the switching platform technique and installation indication.

S.I.N. - Sistema de Implante 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 80 N.cm. Torques above this value can cause irreversible damage, as well as surgical complications. The Product is for single use and cannot be resterilized. The torque for fixation of the intermediates (cemented abutment, conical or mini-abutment on the implant) is 20 N.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 not to 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.

DISPOSAL OF MATERIAL

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

TABLE 1: INDICATION OF IMPLANT APPLICATION PER REGION.

ARCH	POSITION		TOOTH	IMPLANT			COMPONENT		
				CM	EH	IH	CM	EH	IH
UPPER	11	21	CENTRAL INCISOR	Ø3,8 / Ø4,5	Ø4,1 / Ø4,5	Ø3,8 / Ø4,5	Ø4,0	Ø3,6/Ø4,1	Ø3,8 / Ø4,5
	12	22	LATERAL INCISOR	Ø3,5	Ø4,1 / *	Ø3,8 / *	Ø3,3 / Ø3,5	Ø4,1	Ø3,8/ *
	13	23	CANINE	Ø3,8 / Ø4,5	Ø4,1 / Ø4,5	Ø3,8 / Ø4,5	Ø4,0 / Ø4,5	Ø3,6/Ø4,1	Ø3,8 / Ø4,
	14	24	1st PREMOLAR	Ø3,8 / Ø4,5	Ø4,1	Ø3,8 / Ø4,5	Ø4,0 / Ø4,5	Ø4,1	Ø4,5
	15	25	2nd PREMOLAR	Ø3,8 / Ø4,5	Ø4,1	Ø3,8 / Ø4,5	Ø4,0 / Ø4,5	Ø4,1	Ø3,8 / Ø4,5
	16	26	1st MOLAR	Ø4,5 / Ø5,0	Ø5,0	Ø4,5 / Ø5,0	Ø4,5 / Ø5,0	Ø5,0	Ø3,8 / Ø4,5
	17	27	2nd MOLAR	Ø5,0	Ø5,0	Ø5,0	Ø5,0	Ø5,0	Ø5,0
	18	28	3rd MOLAR	Ø5,0	Ø5,0	Ø5,0	Ø5,0	Ø5,0	Ø5,0
LOWER	41	31	CENTRAL INCISOR	Ø3,5	*	Ø3,8/ *	Ø3,3 / Ø3,5	*	Ø3,8/ *
	42	32	LATERAL INCISOR	Ø3,5	*	Ø3,8/ *	Ø3,3 / Ø3,5	*	Ø3,8/ *
	43	33	CANINE	Ø3,8 / Ø4,5	Ø4,1	Ø3,8 / Ø4,5	Ø4,0 / Ø4,5	Ø3,6/Ø4,1	Ø3,8 / Ø4,5
	44	34	1st PREMOLAR	Ø3,8 / Ø4,5	Ø4,1	Ø3,8 / Ø4,5	Ø4,0 / Ø4,5	Ø4,1	Ø4,5 / Ø5,0
	45	35	2nd PREMOLAR	Ø3,8 / Ø4,5	Ø5,0	Ø3,8 / Ø4,5	Ø4,0 / Ø4,5	Ø5,0	Ø4,5
	46	36	1st MOLAR	Ø4,5 / Ø5,0	Ø5,0	Ø4,5 / Ø5,0	Ø4,5 / Ø5,0	Ø5,0	Ø4,5 / Ø5,0
	47	37	2nd MOLAR	Ø5,0	Ø5,0	Ø5,0	Ø5,0	Ø5,0	Ø5,0
	48	38	3rd MOLAR	Ø5,0	Ø5,0	Ø5,0	Ø5,0	Ø5,0	Ø5,0

***** *Indicated for cases where the mesio-distal prosthetic space is higher than 6mm;*

****** *It is recommended to use implants with 3.5 mm diameter from the Strong SW Morse (SWCM 35XX) family and their corresponding components, or Unitite Slim 2.9 (UCMS 29XX) for better aesthetic contour.*

FIT: *Components with prosthetic closure Ø3.6 mm and anatomical transmucosal profile.*

HE: *Components with prosthetic closure Ø4.1mm / Ø5.0mm and divergent profile.*

TABLE 2: SW IH, EH, CONE MORSE IMPLANT MILLING SEQUENCE

		1500 RPM							800 RPM				25 RPM
													
PLAT. (mm)	**DIAM. (mm)**	FRLD 2020	FHD 2020	FRWD 35	FRWD 38	FCWD 41	FRWD 45	FRWD 50	CMRIW 35	CMRIW 37	CMRIW 38	CMRIW 45	CMRIW 50
3.5	**3.5**	•	•	•					•				
3.8	**3.8**	•	•	•	•						•		
4.1	**3.75**	•	•	•	•	•				•			
4.5	**4.5**	•	•	•	•		•					•	
5	**5**	•	•	•	•		•	•					•

• *In type I and II bones it is necessary to use the male thread to guarantee the healing process.*

TABLE 3: SW GUIDE IMPLANT MILLING SEQUENCE

			Fixação da Guia	Confecção do Alveolo												
CÓDIGO	**PLAT. (mm)**	**DIÂM. (mm)**	FHG 1615	EMC 50	EMM 50	FICG 50	FRLG 2015	FHG 2015	FPG 2030	FRWG 35	FRWG 45	FCWG 41	FCWG 45	MRIWG 35	MRIWG 37	MRIWG 45
SWCM 35XX	**3,5**	**3,5**	•	•	•	•	•	•	•	•				•		
SCW 37XX	**4,1**	**3,75**	•	•	•	•	•	•	•	•		•			•	
SWCM 45XX	**4,5**	**4,5**	•	•	•	•	•	•	•	•	•		•			•
SCWE 45XX	**4,5**	**4,5**	•	•	•	•	•	•	•	•	•		•			•

● Opcional