

From synergy between unique macro geometry and the most advanced surface nano activation, we created Unitite®, a line of implants that has revolutionized the world market for its originality, innovation, and very high performance.



PRODUCT DESCRIPTION

Unitite implants are produced in commercially pure Titanium (Grade 4). The cylindrical (Unitite Compact) and hybrid (Unitite Slim and Prime) macrogeometry, with cervical microthreads and prosthetic coupling of Morse Taper type. The implant surface is composed of an ultrathin layer of hydroxyapatite and has moderate roughness obtained by an acid etching process. It comes with a cover screw as an accessory. The Unitite line has three models: Prime, Slim, and Compact.

Line Implant	Implant Diameters (mm)	Length (mm)
PRIME	3.5, 4.3, 5.0	8.5, 10, 11.5, 13, 15
SLIM:	2.9, 3.3	10, 11.5, 13
COMPACT	4.0, 5.0, 6.0	5, 6, 7

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 that will receive artificial teeth, restoring the masticatory function of edentulous patients. 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 45N.cm) and proper occlusal load. They can be used in single or multiple prosthesis.

The Unitite implant line was developed to suit the bone availability in the surgical alveolus:

Prime: Recommended for all maxilla and mandible regions.

Slim: Recommended for rehabilitation in narrow areas and limited interdental spaces, as well as regions of maxillary lateral incisors and mandibular incisors.

Compact: Recommended for situations of reduced bone availability in the maxilla and mandible.

HOW TO USE

Unitite implants are indicated for surgical installation in all bone densities, in maxilla or mandible, as long as the maximum insertion torque (60N.cm for Prime and Compact Implants and 45N.cm for Slim Implants) is observed. 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.

UNITITE IMPLANT INSTALLATION

- Remove the blister from the outer cartridge.
- Keep the traceability labels that came with the product.
- In sterile surgical drape 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 handpiece.

- Hold the Unitite implant by keeping the handpiece still and rotating the internal support slightly, looking for the perfect fit between the connection and the implant. Press the handpiece against the implant for better mounting.
- Transport the implant to the bony site.
- In the surgical motor, use a 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 60N.cm for Prime and Compact implants and 45N.cm for Slim implants.
- The choice between installing the cover screw, healing cap 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.
- Preferably, complete the implant installation with a Surgical Torque Wrench or a ratchet wrench matching wrench length (short or long) according to adjacent dental crown and available mouth opening. Remember that the connection of this wrench must be the same as the pre-used key for counter-angle.
- The maximum recommended installation torque is 60N.cm for Prime and Compact implants and 45N.cm for Slim implants.
- The choice between installing a cover screw, healing cap, 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.
- 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.

UNITITE IMPLANT INSTALLATION WITH GUIDED SURGERY KIT

- Remove the blister from the outer cartridge.
- Keep the traceability labels that came with the product.
- In sterile surgical drape and after breaking the sterile sealing of the blister, hold the primary package (tube) with the non-dominant hand and open the lid.
- The implant will be exposed inside the tube to hold the wrench.
- For motor installation, use the contra-angle handpiece, observing the chosen implant diameter.
- Hold the implant by keeping the wrench still and rotating the internal support slightly, looking for the perfect fit between the connection and the Implant. Press the wrench against the implant for better mounting.
- Fit one of the implant guides according to the selected implant diameter inside 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 35N.cm and rotation between 20-40 RPM.



ATTENTION

Unitite implants are intended for expert procedures, which must be performed by qualified professionals in implant Dentistry. The product must be used 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. 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 45N.cm.
- The maximum allowable angle for S.I.N. implants 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. Drills 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.
- 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 Unitite Prime, Slim, and Compact 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 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 indicate implant installation in patients with: acute inflammatory or infectious processes of living tissue, inadequate bone volume or quality, site root remnants, serious medical problems such as bone metabolism disorders, blood coagulation disorders, low healing capacity, incomplete jaw growth, allergy or hypersensitivity to titanium, patients with history of head and neck irradiation, bone situation anatomically unfavorable to implant stability, acute periodontitis, treatable pathological maxillary diseases, and oral mucosal changes.

SIDE EFFECTS

Because it is a surgical procedure, the installation of implants can cause side effects such as irritation at the implantation site, mild bleeding, mild inflammation, localized pain, tenderness, edema and ecchymosis. In case of failure in planning or executing the surgical procedure, adverse effects such as chronic pain, paraesthesia, paralysis, infection, hemorrhage, oroantral oronasal fistula, affected adjacent teeth, bone necrosis, fractures of the implant or prosthesis, bone loss around the implant or loss of the implant (not osseointegration).

WARNING

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

S.I.N. suggests a table of application of implants and components according to the region to be applied, but it is up to the dentist, trained with the specialty, the choice and choice regarding the diameter and length of the implant in relation to the region and anatomy to be installed.

Unitite Prime and Compact implants are designed to withstand a maximum torque of 60N.cm and Slim implants designed to torque a maximum of 45N.cm. Torques above these values can cause irreversible damage as well as surgical complications. The torque for fixation of the intermediates (cemented, tapered abutment or miniabutment over the implant) is 20N.cm.

The torque for clamping components above the intermediates is 10N.cm. Do not install the cap screw (ratchet) with ratchet wrench or torque wrench, as this will damage the implant; tightening must be performed manually using a digital driver. During the maintenance of the prosthesis the recommended torque value for each component must be respected. Exceeding values may damage/fracture the implant, reducing its life.

TRACEABILITY

All S.I.N. - Implant 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 Unitite 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.

DISPOSAL OF MATERIALS

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

TRANSPORTATION

Unitite 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.

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 Unitite Surgical Kit and Unitite Guided Surgery Kit.

STERILE 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).

SUPPLEMENTARY 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 S.I.N. 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.











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: INDICATION OF IMPLANT APPLICATION PER REGION






ARCH	POSITION		TOOTH	CM	
				Diameter	Component
UPPER	11	21	CENTRAL INCISOR	Ø3,5 / Ø4,3	Ø3,3 / Ø4,0
	12	22	LATERAL INCISOR	Ø2,9 / Ø3,5	Ø3,3 / Ø3,5
	13	23	CANINE	Ø3,5 / Ø4,3	Ø4,0 / Ø4,5
	14	24	1 st PREMOLAR	Ø4,3	Ø4,0 / Ø4,5
	15	25	2 nd PREMOLAR	Ø4,3	Ø4,0 / Ø4,5
	16	26	1 st MOLAR	Ø4,0 / Ø4,3 / Ø5,0 / Ø6,0	Ø4,5 / Ø5,0
	17	27	2 nd MOLAR	Ø5,0 / Ø6,0	Ø5,0
	18	28	3 rd MOLAR	Ø5,0 / Ø6,0	Ø5,0
LOWER	41	31	CENTRAL INCISOR	Ø2,9 / Ø3,5	Ø3,3 / Ø3,5
	42	32	LATERAL INCISOR	Ø2,9 / Ø3,5	Ø3,3 / Ø3,5
	43	33	CANINE	Ø3,5 / Ø4,3	Ø4,0 / Ø4,5
	44	34	1 st PREMOLAR	Ø4,3	Ø4,0 / Ø4,5
	45	35	2 nd PREMOLAR	Ø4,3	Ø4,0 / Ø4,5
	46	36	1 st MOLAR	Ø4,0 / Ø4,3 / Ø5,0 / Ø6,0	Ø4,5 / Ø5,0
	47	37	2 nd MOLAR	Ø5,0 / Ø6,0	Ø5,0
	48	38	3 rd MOLAR	Ø5,0 / Ø6,0	Ø5,0

TABLE 2: UNITITE PRIME IMPLANT DRILLING SEQUENCE

	1.200 RPM		800 RPM				20 RPM		
									
PLAT. (mm)	FRLD 2005 Ø2.0	FHCD 2015 Ø2.0	FUM 2915 Ø2.7	FUM 3515 Ø3.3	FUM 4315 Ø4.1	FUM 5015 Ø4.8	CMRU 35 Ø3.5	CMRU 43 Ø4.3	CMRU 50 Ø5.0
 3.5	•	•	•	•			•		
4.3	•	•	•	•	•			•	
5.0	•	•	•	•	•	•			•




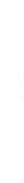







- In type I and II bones it is necessary to use the male thread to guarantee the healing process.

TABLE 3: UNITITE SLIM IMPLANT DRILLING SEQUENCE

	1.200 RPM		800 RPM		20 RPM	
						
PLAT. (mm)	FRLD 2005 Ø2.0	FHCD 2015 Ø2.0	FUM 2915 Ø2.7	CMRU 29 Ø2.9		
	2.9	•	•	•	•	



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

TABLE 4: UNITITE COMPACT IMPLANT DRILLING SEQUENCE

	1.200 RPM		800 RPM					20 RPM		
										
PLAT. (mm)	FRLD 2005 Ø2.0	FHCD 2015 Ø2.0	FUM 2915 Ø2.7	FUM 3515 Ø3.3	FHCD 3215 Ø3.8	FHCD 4215 Ø4.8	FHCD 5215 Ø5.8	CMRUC 40 Ø4.0	CMRUC 50 Ø5.0	CMRUC 60 Ø6.0
 4.0	•	•	•	•	•			•		
5.0	•	•	•	•	•	•			•	
6.0	•	•	•	•	•	•	•			•

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












TABLE 5: UNITITE IMPLANT DRILLING SEQUENCE WITH GUIDE SURGICAL KIT

PLAT. (mm)	20 RPM			400 RPM			1.500 RPM	800 RPM			25 RPM					
	EM 29	EM 35U	EM 45	FPG 29	FPG 35U	FPG 43	FHCDG 20	FUMG 29	FUMG 35	FUMG 43	FHCDG 40	CMRUG 29	CMRUG 35	CMRUG 35E	CMRUG 40	CMRUG 43
 2.9 (Slim)	•			•*			•	•				•				
 3.5 (Prime)		•			•*		•	•	•				•	•**		
4.0 (Compact)			•			•*	•	•	•		•				•	
4.3 (Prime)			•			•*	•	•	•	•						•

- The use of the screw tap is optional on bone types I and II because it is a compressive implant, however the maximum torque must always be respected.

- *The use of the flat cutter is optional, this tool is used for planning the alveolar ridge, creating a stable face for drilling with the other cutters of the system.

- ** The screw tap will only be used in surgical planning for narrow drill limiters

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
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
	LIMITE SUPERIOR DE TEMPERATURA 35°C	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	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDEZ
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA

DEVELOPED AND MANUFACTURED BY:
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RESPONSIBLE TECHNICIAN:

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 CREA-SP (register): 5061207169

PRODUCT:

Unitite Nano Implant with SINActive Surface

ANVISA REGISTRATION 80108910069