The Epikut Plus implant line arrives on the market to optimize daily clinical practice, providing a more cutting macrogeometry, facilitating installation in the bone and with high primary stability combined with the HAnano surface that helps in better osseointegration.

PRODUCT DESCRIPTION

Epikut Plus 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) and Morse taper (CM) type, platform diameter from 3.5 to 5.0mm and length from 7.0 to 24.0mm. Implants with a length of 18.0 to 24.0 mm are considered long implants. The implant surface is composed of an ultra-thin layer of hydroxyapatite and has moderate roughness obtained through an acid etching process. It comes with an implant cover as an accessory.

Diameters of the Implants (mm)	Length (mm)
3.5, 3.8, 4.0, 4.5, 5.0	7, 8.5, 10, 11.5, 13, 15, 18, 20, 22, 24.

Implant Chemical Composition according F67:

Chemical Element	Composition % (mass/mass)
Nitrogen	≤ 0.05
Carbon	≤ 0.08
Hydrogen	≤ 0.015
Iron	≤ 0.50
Oxygen	≤ 0.40
Titanium	Balance
Hydroxyapatite Coating	< 1.0

The coating is Hydroxyapatite (HAnano), composed of $Ca_5(PO_4)_3OH$, also known as Calcium Phosphate. It has a Ca/P ratio of 1.67.

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

INDICATION FOR USE

The Epikut Plus are indicated for human adults and elderly with good general health, surgical procedure in maxilla or mandible bones, generating a support platform for the installation of prosthetic components that will receive the artificial teeth, restoring the masticatory function of the edentulous patient. They can be used in conventional processes (1 or 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 units.

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 EPIKUT PLUS IMPLANT EXTERNAL HEXAGON AND MORSE TAPER

Epikut Plus implants are indicated for surgical installation in all bone densities, in maxilla or mandible, as long as the maximum insertion torque (80N.cm) is respected. For external hexagon implants, the installation must be performed at the bone level and for morse taper implants, the installation must be performed intraosseous of 1.5mm.

- 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 packaging (tube) with the non-dominant hand and open the lid;
- The implant will be exposed inside the tube to capture 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 THE EPIKUT PLUS IMPLANT EXTERNAL HEXAGON AND MORSE TAPER WITH GUIDED SURGERY KIT

- 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 packaging (tube) with the non-dominant hand and open the lid;
- The implant will be exposed inside the tube to capture the key.
- For motorized installation, use the contra-angle wrench according to the choice of the external hexagon or morse taper implant system and observing the implant diameter chosen.
- 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.
- Fit one of the implantation guides according to the selected implant diameter inside the prototyped surgical guide washer.
- Transport the implant to the implantation tab that is already docked.
- In the surgical motor, use maximum torque of 35N.cm and rotation between 20-40 RPM.
- Preferably, complete the implant installation with a surgical torque wrench or a ratchet wrench adjusting the length of the wrench (short or long) according to the adjacent dental crown and available mouth opening. Remembering that the connection of this switch must be the same as the pre-used contra-angle switch;
- 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.

⚠ ATTENTION

Epikut Plus 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, the bone quality and quantity of the implant recipient bed, by means of radiographic and/or tomographic examinations. Failure to perform the pre-surgical evaluation may result in the impossibility of verifying pre-existing diseases. Consider the patient's general health condition, he must be submitted to a thorough clinical and radiological analysis before surgery, evaluating his physical and psychological state. Patients who have local or systemic factors that may interfere with the healing processes of bone or soft tissues, or in the process of integration, should receive special attention. Perform material handling only in sterile field. All material used in the procedure must be sterile. Sterilization is only guaranteed if the secondary packaging (blister) is not damaged. Do not use the product if the packaging is tampered with. Open the package only at the time of surgery and use the product immediately. Implants not used after opening the package should be discarded. Products with expired expiration date should not be used. In one-stage surgical rehabilitations (immediate loading), primary stability should reach at least 45N.cm. The maximum angle allowed for S.I.N. implants is up to 30° degrees. Insertion torque higher than the recommended maximum may damage the product, losing its primary function. Observe the conditions of use of surgical instruments. Milling

cutters and other instruments with low cutting power can generate heat during use, hindering the osseointegration process. Replace instruments in case of damage, erased markings, compromised sharpening, deformations 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 the condition of your motor and contraangle before surgery. If necessary, perform preventive/corrective maintenance with the manufacturer. Unregulated equipment can directly interfere with the product's performance. During the surgical and prosthetic procedure, use only components and instruments specified by S.I.N., they have specific dimensions and tolerances for each implant system, ensuring the longevity of the product. Components from other brands or adapted to implant models can reduce the useful life of the system, causing irreversible damage. The professional must ensure that the patient does not aspirate the product. It is the responsibility of the practitioner to use the S.I.N. products in accordance with the instructions for use, as well as to determine if it is suitable for the individual situation of each patient. The patient should be informed of all possible surgical complications, contraindications, warnings, precautions, and adverse reactions. All documentation that accompanies 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 specialized in Surgery/Implantology.

RECOMMENDATIONS

S.I.N. recommends prior planning of the surgery for the installation of Epikut Plus implants. Inadequate planning and/or lack of occlusal adjustment can compromise the performance of the implant/prosthesis assembly, resulting in system failures, such as loss or fracture of the implant, loosening or fracture of the prosthetic screws. S.I.N. does not recommend the implant placement in patients with inadequate oral hygiene, uncooperative and unmotivated patients, with medication or alcohol abuse, psychoses, chemical dependence, prolonged functional disorders that resist any drug treatment, xerostomia, low immune system, diseases that require the use of steroids regularly, endocrinological diseases, drug allergy, diabetes mellitus, anticoagulant/bleeding diathesis medications, bruxism, other habits for functional, tobacco abuse, installation in children and pregnant women and during the breastfeeding period.

CONTRAINDICATION

The S.I.N. does not indicate the installation of implants in patients who have: acute inflammatory or infectious processes of living tissues, inadequate bone volume or quality, remains of roots at the site, serious medical problems such as: bone metabolism disorders, blood coagulation disorders, poor healing capacity, incomplete jaw growth, allergy or hypersensitivity to titanium, patients with a history of head and neck irradiation, anatomically unfavorable bone situation, implant stability, acute periodontitis, treatable spathological maxillary diseases, and oral mucosal alterations.

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, oro-antral or oro-nasal 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 must receive components with compatible geometry, or specific components for the switching platform technique and indication of installation. The S.I.N. suggests a table for the application of implants and components according to the region to be applied, but it is up to the dental surgeon trained with the specialty, the choice and discretion regarding the diameter and length of the implant in relation to the region and anatomy to be installed. S.I.N. implants are designed to withstand maximum torque of the order of 80N.cm. Torques above these values can cause irreversible damage, as well as surgical complications. The product is single-use and cannot be reprocessed and/or reused. The torque for fixing the intermediates (cemented, conical or mini abutment on the implant) is 20N.cm and for the external hexagon cemented abutment use 32Ncm. The torque for fixing components above the intermediates is 10N.cm. Do not install the protective screw (implant cover) with a ratchet wrench or torque wrench, so as not to damage the implant; Tightening must be performed manually using a digital key. During the maintenance of the prosthesis, the recommended torque value for each component must be respected. Values outside the stipulated 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 drape and should be handled only with the specific instruments available in the Surgical Kits.

DISPOSAL OF MATERIALS

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

TRANSPORTATION

Epikut Plus implants must be transported appropriately, 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	2.4 W/kg (15 minutes scanning, normal operation mode)
Specific Absorption (SAR) Rate Maximum Coil Type Head	2.0 W/kg (15 minutes scanning, normal operation mode)
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. 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.

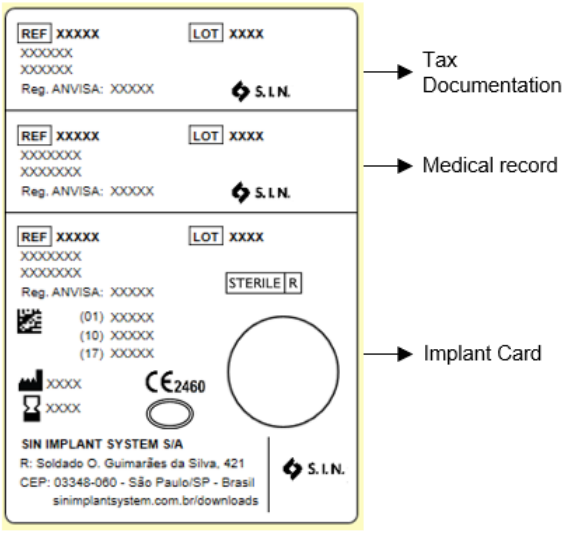
TRACEABILITY LABELS

The implants of the Epikut Plus line are made 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.

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

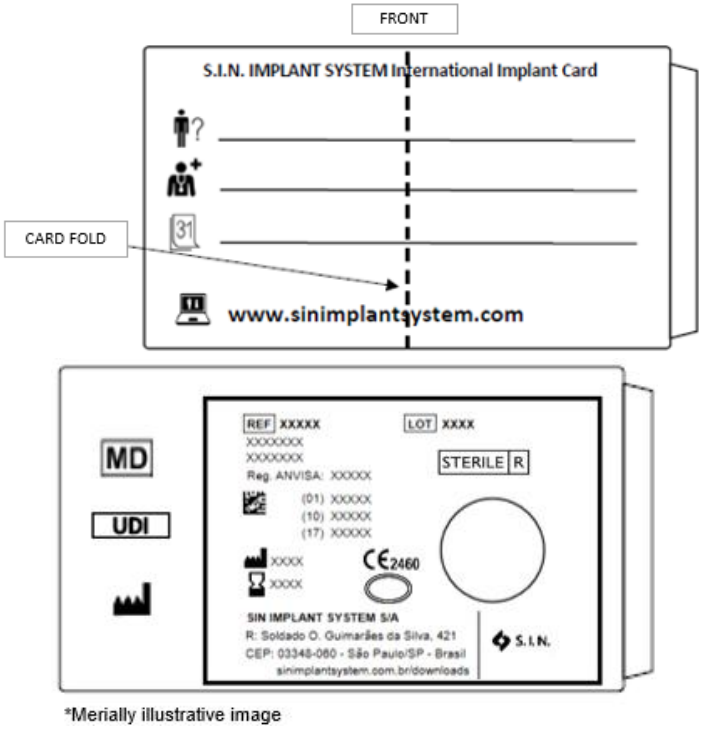
Implant card label: The dentist should stick a label on the implant card in order to inform about which products were used.



*Merially illustrative image

IMPLANT CARD

The implants of the Epikut Plus line are made available 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 unitarily in packaging that offers triple protection: tertiary packaging (cardboard), secondary blister packaging (pet film, 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.

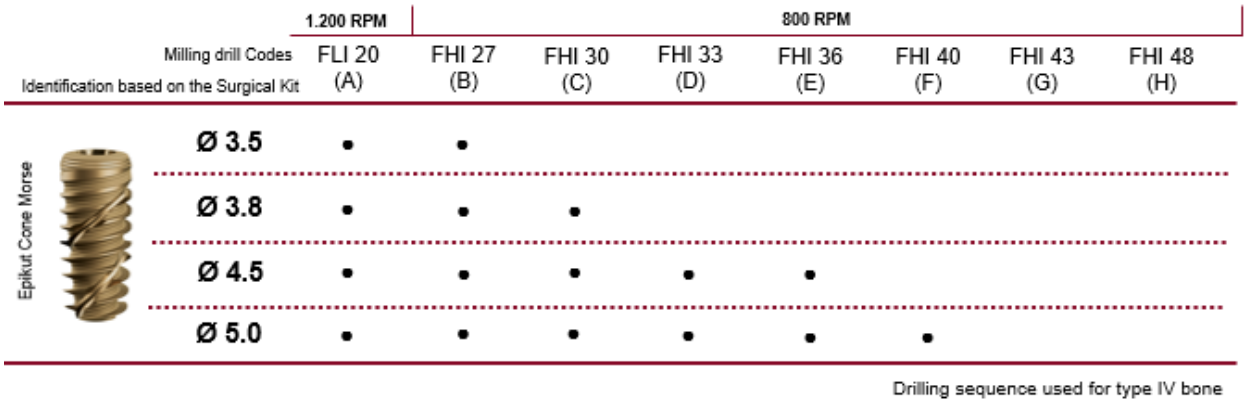
INDICATION OF IMPLANT APPLICATION BY REGION

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

DRILLING SEQUENCE OF EPIKUT PLUS IMPLANT MORSE TAPER, LONG AND EXTERNAL HEXAGON SOFT[1]

[1]Soft: For soft bones

Epikut Plus Surgical Kit



Drilling sequence used for type IV bone

	1.200 RPM	800 RPM						
Milling drill Codes	FLI 2024	FHI 2724	FHI 3024	FHI 3324	FHI 3624	FHI 3824	FHI 4024	FHI 4324
Identification based on the Surgical Kit	(A)	(B)	(C)	(D)	(E)	(E+)	(F)	(G)
 Epikut Long Cone Morse								
Ø 3.8	•	•	•					
Ø 4.0	•	•	•	•				
Ø 4.5	•	•	•	•	•			

Drilling sequence used for type IV bone

	1.200 RPM	800 RPM						
Milling drill Codes	FLI 20	FHI 27	FHI 30	FHI 33	FHI 36	FHI 40	FHI 43	FHI 48
Identification based on the Surgical Kit	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
 Epikut External Hexagon								
Ø 3.5	•	•						
Ø 4.0	•	•	•					
Ø 4.5	•	•	•	•	•			
Ø 5.0	•	•	•	•	•	•		

Drilling sequence used for type IV bone

Epikut Plus Guided Surgery Kit

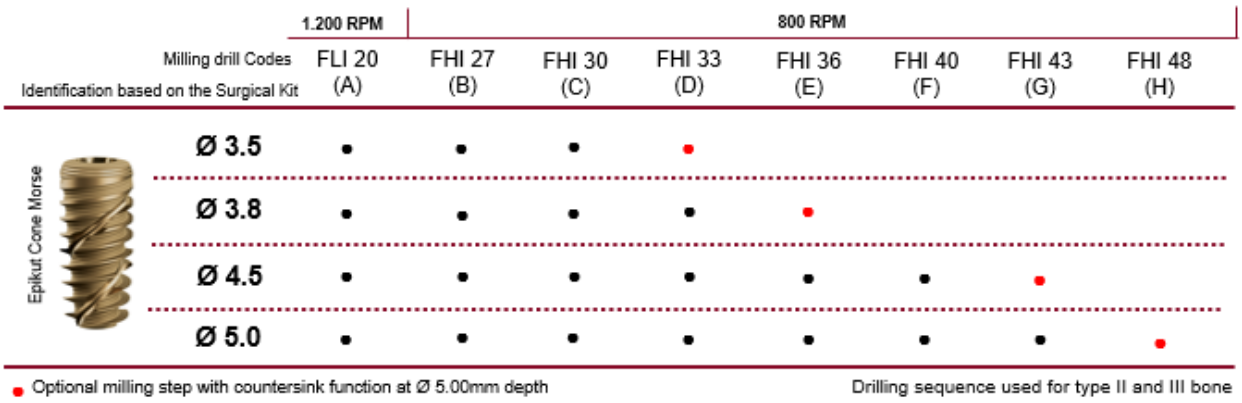
i. Long drill	FHG 20	FHIG 27	FHIG 30	FHIG 33	FHIG 36	FHIG 40	FHIG 43
ii. Long drill	FHG 20C	FHIG 27C	FHIG 30C	FHIG 33C	FHIG 36C	FHIG 40C	FHIG 43C
Identification based on the Surgical Kit	(A)	(B)	(C)	(D)	(E)	(F)	(G)
 Epikut Cone Morse  Epikut External Hexagon							
Ø 3.5	•	•					
Ø 3.8	•	•	•				
Ø 4.5	•	•	•	•	•		

Drilling sequence used for type IV bone

DRILLING SEQUENCE OF EPIKUT PLUS IMPLANT MORSE TAPER, LONG AND EXTERNAL HEXAGON MEDIUM²

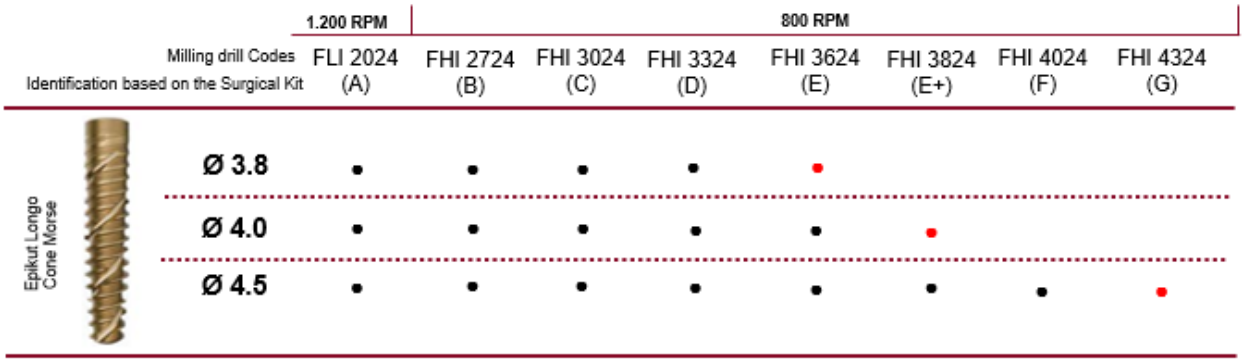
²Medium: For medium bones

Epikut Plus Surgical Kit



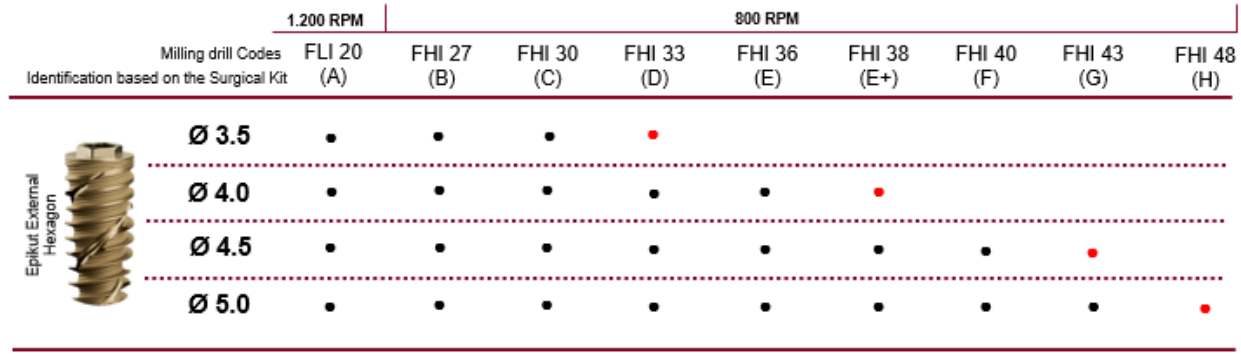
● Optional milling step with countersink function at Ø 5.00mm depth

Drilling sequence used for type II and III bone



● Optional milling step

Drilling sequence used for type II and III bone



● Optional milling step with countersink function at Ø 5.00mm depth

Drilling sequence used for type II and III bone

Epikut Plus Guided Surgery Kit

		1.200 RPM	800 RPM					
		FHG 20	FHIG 27	FHIG 30	FHIG 33	FHIG 36	FHIG 40	FHIG 43
		FHG 20C	FHIG 27C	FHIG 30C	FHIG 33C	FHIG 36C	FHIG 40C	FHIG 43C
		(A)	(B)	(C)	(D)	(E)	(F)	(G)
 Epikut Plus Cone Morse / Epikut Plus External Hexagon	Ø 3.5	•	•	•	•*			
	Ø 3.8	•	•	•	•	•*		
	Ø 4.5	•	•	•	•	•	•	•*

•* Optional milling step with countersink function at Ø 5.00mm depth

Drilling sequence used for type II and III bone

DRILLING SEQUENCE OF EPIKUT PLUS IMPLANT MORSE TAPER, LONG AND EXTERNAL HEXAGON HARD[3]

[3]Hard: For hard bones

Epikut Plus Surgical Kit

		1.200 RPM	800 RPM						
Milling drill Codes Identification based on the Surgical Kit		FLI 20 (A)	FHI 27 (B)	FHI 30 (C)	FHI 33 (D)	FHI 36 (E)	FHI 40 (F)	FHI 43 (G)	FHI 48 (H)
 Epikut Cone Morse	Ø 3.5	•	•	•	•				
	Ø 3.8	•	•	•	•	•			
	Ø 4.5	•	•	•	•	•	•	•	
	Ø 5.0	•	•	•	•	•	•	•	•

Drilling sequence used for type I bone

		1.200 RPM	800 RPM						
Milling drill Codes Identification based on the Surgical Kit		FLI 2024 (A)	FHI 2724 (B)	FHI 3024 (C)	FHI 3324 (D)	FHI 3624 (E)	FHI 3824 (E+)	FHI 4024 (F)	FHI 4324 (G)
 Epikut Long Cone Morse	Ø 3.8	•	•	•	•	•			
	Ø 4.0	•	•	•	•	•	•		
	Ø 4.5	•	•	•	•	•	•	•	•

Drilling sequence used for type I bone

	1.200 RPM	800 RPM							
Milling drill Codes	FLI 20	FHI 27	FHI 30	FHI 33	FHI 36	FHI 38	FHI 40	FHI 43	FHI 48
Identification based on the Surgical Kit	(A)	(B)	(C)	(D)	(E)	(E+)	(F)	(G)	(H)
 Epikut External Hexagon Ø 3.5	•	•	•	•					
Ø 4.0	•	•	•	•	•	•			
Ø 4.5	•	•	•	•	•	•	•	•	
Ø 5.0	•	•	•	•	•	•	•	•	•

Drilling sequence used for type I bone

Epikut Plus Guided Surgery Kit

	1.200 RPM	800 RPM					
i. Long drill	FHG 20	FHIG 27	FHIG 30	FHIG 33	FHIG 36	FHIG 40	FHIG 43
ii. Long drill	FHG 20C	FHIG 27C	FHIG 30C	FHIG 33C	FHIG 36C	FHIG 40C	FHIG 43C
Identification based on the Surgical Kit	(A)	(B)	(C)	(D)	(E)	(F)	(G)
 Epikut Cone Morse  Epikut External Hexagon Ø 3.5	•	•	•	•			
Ø 3.8	•	•	•	•	•		
Ø 4.5	•	•	•	•	•	•	•

Drilling sequence used for type I bone

	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
	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
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	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
Rua Soldado Ocimar Guimarães da Silva, 421 - Vila Rio Branco
CEP: 03348-060 - São Paulo - SP - Brazil

EU REP

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

CE 2460

PROFESSIONAL SERVICES
0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com
Email: sin@sinimplantsystem.com

TECHNICAL RESPONSIBLE
Alessio Di Risio
CREA-SP: 5061207169

PRODUCT
Epikut Plus Implant

ANVISA REGISTRATION
80108910097