Epikut

The line of Epikut implants reaches the market in order to optimize the clinical routine, bringing a more cutting macrogeometry, facilitating bone drilling and with a high primary stability.

PRODUCT DESCRIPTION

The Epikut Implants are produced in commercially pure titanium (Grade 4). The macrogeometry of the implant is hybrid, with cervical micro threads and prosthetic conection of external hexagon (HE) and cone morse (CM). The surface of the implant has moderate roughness obtained by acid etching process. Accompany the implant cover as an accessory.

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

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 an 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 45N.cm) and proper occlusal load. They can be used in single or multiple restorations.

HOW TO USE

Epikut implants are indicated for surgical installation in all bone densities, in the maxilla or mandible, as long as respected or maximum insertion torque (80N.cm).

EPIKUT IMPLANT INSTALLATION

- 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 blister seal, hold the primary packaging (tube) with your non-dominant hand and open the lid.
- The implant will be exposed inside the tube to capture the key.
- For motor installation, use the contra-angle drive.
- Capture the implant by holding 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.
- On the surgical motor, use a maximum torque of 35N.cm and rotation between 20-40 RPM.
- Preferably, complete the installation of the implant with the surgical torque wrench or ratchet wrench.
- The maximum recommended installation torque is 80N.cm.
- The choice between the installation of the implant cover, healing abutmente or prosthetic component is up to the professional.
- Select the intermediaries between the implant and the prosthesis, observing their indications and limitations, according to the applicable literature.

ATTENTION

Epikut 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 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 45N.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. Drills and other instruments with low cutting power can generate heating during use, which hinders the osseointegration 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 Epikut 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.

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 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.

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 receive components with compatible geometry, or specific components for the switching platform technique 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 (cemented abutment, conical or mini-abutment on the implant) is 20N.cm, for external hexagon cemented abutment use 32N.cm. The torque for fixation of components above intermediates is 10N.cm. Do not install the protective screw (implant cap) torque wrench in order to not 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.

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 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

The 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 tothe 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 surgical Kit.

STERILE R 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.

TABELA 1: INDICAÇÃO DE APLICAÇÃO DOS IMPLANTES POR REGIÃO

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

TABLE 2: EPIKUT IMPLANT DRILLING SEQUENCE HE AND CONE MORSE SOFT[1]

Ø	FLI 20 A	FHI 27 B	FHI 30 C	FHI 33 D	FHI 36 E	FHI 40 F	FHI 43 G	FHI 48 H
3,50	•	•						
3,80	•	•	•					
4,50	•	•	•	•	•			
5,00	•	•	•	•	•	•		

[1]Soft: drilling sequence used for bone type IV

TABLE 3: EPIKUT IMPLANT DRILLING SEQUENCE HE AND CONE MORSE MEDIUM[2]

Ø	FLI 20 A	FHI 27 B	FHI 30 C	FHI 33 D	FHI 36 E	FHI 40 F	FHI 43 G	FHI 48 H
3,50	•	•	•	•*				
3,80	•	•	•	•	•*			
4,50	•	•	•	•	•	•	•*	
5,00	•	•	•	•	•	•	•	•*

[2]Medium: drilling sequence used for bone type II and III

•* The use of the drill is optional in the COUNTERSINK function – Depth of 5mm

TABLE 4: EPIKUT IMPLANT DRILLING SEQUENCE HE AND CONE MORSE HARD[3]

Ø	FLI 20 A	FHI 27 B	FHI 30 C	FHI 33 D	FHI 36 E	FHI 40 F	FHI 43 G	FHI 48 H
3,50	•	•	•	•				
3,80	•	•	•	•	•			
4,50	•	•	•	•	•	•	•	
5,00	•	•	•	•	•	•	•	•

[3]Hard: drilling sequence used for bone type tipo I

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
	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
	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.
	FABRICANTE	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDEZ
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CODIGO DE REFERENCIA

DEVELOPED AND MANUFACTURED BY:
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PRODUCT:
Epikut Implant

ANVISA REGISTRATION 80108910096