COMPONENT

Peek Healing Cap

The Peek Healing Cap is designed to be customized and optimize the prosthetic emergence profile.

PRODUCT DESCRIPTION

Peek Healing Cap: Consists of a customizable cylindrical abutment, its body allows customization and has a conduit for access to the fixation screw. It consists of two parts, a PEEK cylinder and a titanium screw, its lower end adapts to the implant connection.

Peek Slim Healing Cap: Consists of a customizable cylindrical abutment, its body allows customization and has a conduit for access to the insertion and removal key. It is made of PEEK, and its lower end adapts to the implant connection.

		Diameter Profile (mm)		
		4.0	**5.0**	**8.0**
Height Profile (mm)	**4.0**	CM 3°	CM 4° CM 11,5° CM 16°	CM 4° CM 11,5° CM 16°
	5.0	-	HE HI	-
	8.0	CM 3°	CM 4° CM 11,5° CM 16°	CM 4° CM 11,5° CM 16 HE HI

INDICATIONS OF USE

Guiding proper healing of the peri-implant gum tissue, conditioning the space of the dental prosthesis in the patient's gingiva. It is also intended to leave the implant platform free for the next procedures. Indicated to be used for up to 30 days.

PURPOSE AND OPERATION PRINCIPLE

It has the finality of forming the emergency profile for correct seating of the prosthesis, in addition to protecting the interior of the implant from intra-oral contamination. They are based on the principle of stabilization and epithelialization of gingival tissue.

HOW TO USE THE COMPONENT

The healing cap is be used immediately after implant installation, when adequate primary stability for immediate loading has been achieved, or in the second surgical stage after osseointegration.

- The healing cap a component that should be used over the dental implant after the surgical installation procedure;
- Use imaging examinations such as tomography to make sure about the position of the dental implant;
- Check the label of the installed implant with respect to the implant model and diameter for the selection of the Peek Healing Cap. The available interocclusal and interdental space should also be considered for the selection of height and diameter. Check the distance from the implant platform to the gingival margin, so that the Peek Healer is 2 mm above the gingival margin ensuring adequate healing of the emergence profile;
- To install the Peek Healing Cap, remove it from its packaging and adapt it to the implant with the aid of digital wrenches. Use the transpassing screw in the internal conduit, fixing the healing cap to the implant.
- For the Unitite SLIM Implant, remove the Peek Slim Healing Cap from the packaging and adapt it to the implant head with the help of the insertion key exclusive for this model (CICS). Press it onto the implant until it is completely seated cone to cone through the imbrication;

- Perform customization of the customizable Healing Cap in the mouth as required for the interocclusal and interproximal spaces. Perform customization with high rotation pen, cooling and proper techniques;
- The Peek Healing Cap should be left for about 15 days in the oral cavity or up to a maximum of 30 days;
- After the healing period of the perimplant tissue remove the Peek Healing Cap and install the desired prosthetic component.
- For the Slim Peek Healing Cap, use the removal key exclusive of this model (CRCS), when inserting the key in the healer, rotate it clockwise until it is firm, make lateral movements pulling it slightly upwards, until it comes loose from the implant.

ATTENTION

The Peek Healing Cap is intended for specialized procedures, which must be performed by qualified professionals in Implant Dentistry. The use of the product must be performed in a surgical environment and under adequate conditions for the health and safety of the patient.

PRECAUTIONS

Considering the general health condition of the patient, he/she must be submitted to a thorough clinical analysis. Failure to perform a pre-surgical evaluation may result in the impossibility of detecting pre-existing diseases. Patients that present local or systemic factors that may interfere with the soft tissue healing processes must receive special attention. Handle the material only in a sterile field. All the material used in the procedure must be sterile. The sterility of the healer is only guaranteed if the primary packaging (blister) is not damaged. Do not use the product if the package is violated. Open the package only at the time of surgery and use the product immediately. Components not used after opening the package should be discarded. Products with expired validity should not be used. During the surgical and prosthetic procedure use only implants, components and instrumentals specified by S.I.N., they have specific dimensions and tolerances for each implant system ensuring the longevity of the product. Components of other brands or adapted to the implant models can reduce the life span of the system causing irreversible damage. The practitioner should ensure that the patient does not aspirate the product. It is the practitioner's responsibility to use the S.I.N. products in accordance with the instructions for use and to determine if it is suitable for each individual patient situation. If a correct diameter is not used, soft tissue irritation may occur. The patient should be informed of all possible surgical complications, contraindications, warnings, precautions, and adverse reactions. All documentation accompanying 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/implant dentistry.

RECOMMENDATIONS

For the placement of S.I.N. Components, it is recommended that the professional have a specialization course in the area and prepare a prosthetic execution plan. 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 diameter and the angulation of the implant, as well as the gingival height, must be taken into account when choosing the model of Components S.I.N. to be used. S.I.N. does not recommend implant installation in patients with inadequate oral hygiene, uncooperative and unmotivated patients, drug or alcohol abuse, psychoses, chemical dependence, prolonged functional disorders that resist any drug treatment, xerostomia, low immune system, diseases which require the use of steroids regularly, endocrinological diseases, drug allergy, diabetes mellitus, anticoagulants / bleeding diathesis, bruxism, other parafunctional habits, tobacco abuse, installation in children and pregnant women and during breastfeeding.

CONTRAINDICATIONS

S.I.N. does not indicate the installation of components in patients who have: acute inflammatory or infectious processes of living tissues, serious medical problems such as disorders of bone metabolism, disorders of blood coagulation, poor healing capacity, incomplete maxillary growth, inadequate parafunctional habits, ex. bruxism, allergy or hypersensitivity to titanium, acute periodontitis and oral mucosa alterations.

SIDE EFFECTS

If the technique is not adequate and the patient is not submitted to the indicated tests, the final result of the application of the components may not be successful, leading to loss or fracture of the product. The application of the product can cause some side effects in the

area where it was applied, such as pain, short-term sensitivity, tissue reaction, or infection.

WARNING

The implants must receive components with compatible geometry, or specific components for the switching platform technique and installation indication. The Product is single use only and cannot be resterilized and/or reused. Do not install the healer with a ratchet wrench or torque wrench, tightening must be performed manually using a digital wrench.

TRACEABILITY

All S.I.N. - Implant System products have sequential lots that allow for traceability, thus promoting greater safety for the professional who is qualified for the procedure. Through this lot number it is possible to know the entire history of the product from the manufacturing process to the moment of distribution. The components are available with three (3) way traceability labels.

STORAGE

Peek Healing Cap must 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 must not be damaged.

HANDLING

Peek Healing Cap are sterile products that should only be handled in a sterile field by trained professionals in appropriate uniforms at the time of the surgical procedure.

DISPOSAL OF MATERIALS

The disposal of materials must be done according to hospital standards and local legislation in force.

TRANSPORTATION

The Peek Healing Cap must be transported in a proper way, to avoid falling and stored under the maximum temperature of 35ºC, protected from heat and humidity. The transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATION

Magnetic Resonance Imaging (MRI): Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. Dental Implant System devices are MR Conditional.

CAUTION: Patient imaging can only be obtained by delimiting at least 30cm from the implant or ensuring that the implant is located outside the radiofrequency coil.

A patient with this device can be safely scanned on an MRI system under the following conditions:

Device Name	S.I.N. Dental Implant System
Static Magnetic Field Strength (B0)	≤ 3.0 T
Maximum Spatial Field Gradient	50 T/m (5,000 gauss/cm).
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head coil and body coil permitted. Extremity T/R coils permitted.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2.4 W/kg (15 minutes of scanning, Normal Operating Mode)
Maximum Head SAR	2.0 W/kg (15 minutes of scanning, Normal Operating Mode)
Scan Duration	15 minutes
Temperature Rise	Maximum temperature rise of 0.45 °C/(W/kg), after 15 minutes of continuous scanning in a static magnetic field of 3 T with either head type or body type coils
Artifact	When imaged using a gradient-echo sequence and a 3 T MR system, image artifact can extend up to approximately 12 mm with a body coil type, and up to approximately 32 mm with a head coil type

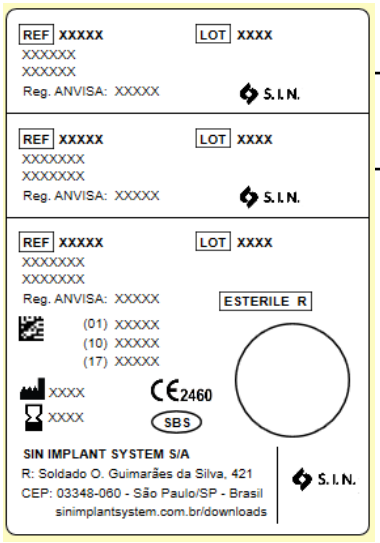
Product Exclusively for Odontological use. In case of any incident caused by the product, the professional must immediately inform the manufacturer. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplante.com.br or call to 0800 770 8290 will receive until 7 days calendar.

TRACEABILITY LABELS

The S.I.N. Sterile Components are available from S.I.N. with 3 (three) labels containing product information. The labels must be used as follows:

Tax label: The dental surgeon must stick a label on the implant's tax documentation.

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



*Merially illustrative image

STERILE R FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and single-use (sterilization method: gamma radiation) unitarily packed in a package that offers double protection: secondary packaging (cardboard) and primary blister packaging (pet film and surgical grade paper).

EXPIRATION DATE

Information about the expiration date can be found on the product labeling. After installation on the patient, the product must be monitored by the professional.

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
	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	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	MANUFACTURE	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDEZ
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA
MD	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
UDI	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	SISTEMA DE BARREIRA ESTÉRIL	SINGLE STERILE BARRIER SYSTEM	SISTEMA DE BARRERA ESTÉRIL SIMPLE
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
LOT	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE
	MR CONDICIONAL	MR CONDITIONAL	MR CONDICIONAL

DEVELOPED AND MANUFACTURED BY:
S.I.N. Sistema de Implante Nacional S/A
CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
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PRODUCT:
Peek Healing Cap

ANVISA REGISTRATION:
80108910091 and 80108910093