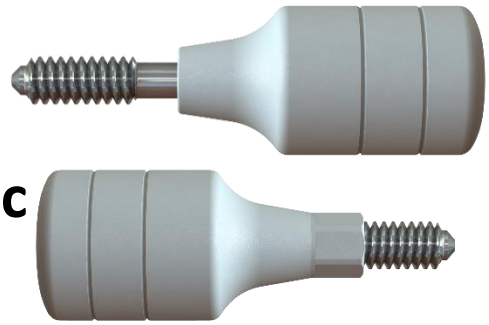
COMPONENT
PEEK HEALING CAP

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



PRODUCT DESCRIPTION

The Peek Healing Cap consists of a customizable cylindrical component, its body allows customization and has a conduit for access of the mounting screw. It comprises two parts, a PEEK cylinder and a titanium screw, its lower end adapts to the Implant connection.

Component Diameter (mm)	Length (mm)
4.0, 5.0, 8.0.	4.0, 6.0, 8.0.

INDICATIONS FOR USE

Indicated to etch to gingival tissue during the healing period, ensuring an appropriate emergence profile to make the implant prosthodontics, and must remain in the mouth for up to 30 days.

HOW TO USE

It can be used immediately after implant insertion, when appropriate stability for immediate loading is achieved or in the second surgical stage after osseointegration. The healing cap is customizable, providing emergency profile individualization for each case, helping in the dental prosthodontics construction.

PEEK HEALING CAP INSERTION

- The healing cap is a component that must be used after the surgical procedure for implant insertion.
- Before the procedure, the fibromucous tissue must be assessed for: thickness, profile, quality, and height of sulcus bottom.
- X-ray to know the correct implant location.
- Check the implant diameter through the implant label.
- Check the angulation that the implant was inserted into the bone;
- To select the height of the PEEK Healing Cap: check the distance from the implant platform to the gingival margin so the healing cap stays 2mm above the gingival margin, ensuring proper emergence profile healing.
- To select the diameter of the PEEK Healing Cap: check the size of the tooth to be rehabilitated as well as implant location, teeth span, implant diameter, ridge thickness, or space between implants to preserve gingival papilla formation.
- Customize the Customizable Healing Cap in the mouth according to the interocclusal and interproximal spaces requirements. Customize with high-speed pen, cooling, and proper techniques.
- To insert the PEEK Healing Cap, remove it from its packaging and fit it into the implant with the aid of digital drivers or ratchet wrench. Thread over the implant until it fully fits a digital torque of approximately 10N.MT.
- The PEEK Healing Cap must remain about 15 days, or up to 30 days, in the oral cavity.
- After the peri-implant tissue healing period, remove the PEEK Healing Cap and insert the component.

ATTENTION

The PEEK Healing Cap is intended for specialized procedures, which must be performed by skilled Implantology professionals. The product must be used in a surgical environment and in proper conditions for patient health and safety.

CAUTION

- Consider the general health of the patient, who must be subjected to a thorough clinical analysis. Failure to perform a pre-surgical assessment may lead to a failure in finding pre-existing diseases.
- Patients with local or systemic factors that may interfere with soft tissue healing processes must be given special attention.
- Only handle the material in a sterile field.
- All materials used in the procedure must be sterile.
- Healing cap sterilization is only guaranteed if the primary packaging (blister) is undamaged. Do not use the product if its packaging is damaged. Only open the package during surgery and use the product immediately.
- Unused components after opening the package must be disposed of.
- Expired products must not be used.
- During the surgical and prosthetic procedure, only use implants, components and instruments specified by S.I.N., these have specific dimensions and tolerances for each implant system to ensure product durability. Other brand components or adapted to implant models may reduce the service life of the system and cause irreversible damage.
- The professional must ensure that the patient does not inhale the product.
- The professional is responsible for using S.I.N. products in accordance with the instructions for use, as well as determining if it suits the individual situation of each patient.
- Failure to use correct diameter may cause soft tissue irritation.
- Patients must be informed on all possible surgical complications, contraindications, warnings, precautions, and side effects. All documentation accompanying the product must also be made available to customers.
- The correct use is inherent to the training of the professional who will use the material. It may only be used and/or applied by dentists with dental surgery/Implantology.

RECOMMENDATIONS

- To place the PEEK Healing Cap, the practitioner must preferably have a specialist 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/prosthodontics set resulting in system failure, such as Implant loss or fracture, Prosthetic Screws loosening or fracture.
- Implant diameter and angle, as well as gingival height, must be taken into consideration when choosing the PEEK Healing Cap model to be used.
- S.I.N. does not recommend the insertion of an implant in patients with inadequate oral hygiene, uncooperative, and unmotivated, who abuse drug or alcohol, presents psychoses, chemical dependency, long-term functional disorders that resist any drug treatment, xerostomia, weakened immune system, diseases requiring the regular use of steroids, endocrine diseases, drug allergy, diabetes mellitus, anticoagulation medications/bleeding diathesis , bruxism, other parafunctional habits, tobacco abuse, insertion in children and pregnant or lactating women.

CONTRAINDICATIONS

S.I.N. does not indicate component insertion in patients with: living tissue acute inflammatory or infectious processes, severe medical problems such as: bone metabolism disorders, blood coagulation disorders, poor healing capacity, incomplete maxilla growth, inadequate parafunctional habits, e.g. bruxism, titanium allergy or hypersensitivity, acute periodontitis, and oral mucosa changes.

SIDE EFFECTS

If the technique is not appropriate and the patient is not submitted to the indicated testing, the final result of component application may not be successful, causing product loss or fracture. Product application may cause side effects in the application area, such as pain, short-term sensitivity, tissue reaction, or infection.

WARNING

Implants must receive components with compatible geometry or specific components for the switching platform technique and insertion indication.

The product is disposable and may not be reprocessed and/or reused.

Do not insert the healing cap with a ratchet wrench or a torque wrench, it must be tightened manually, using a digital driver.

TRACEABILITY

All S.I.N. - Sistema de Implante products have sequential batches allowing traceability to promote increased safety for the professional qualified to the procedure. This batch number can be used to access the entire history of the product from manufacturing to distribution.

STORAGE

PEEK Healing Caps must be stored in a cool and dry place, at a temperature not exceeding 35°C, and away from direct sunlight, inside its unopened and undamaged original packaging.

TRANSPORT

PEEK Healing Caps implants must be transported in such a way to avoid falls, and stored at a temperature not exceeding 35°C, away from heat and humidity. Transport must be carried out in its original packaging.

HANDLING

PEEK Healing Caps are sterile products that must be handled in a sterile field by properly trained professionals wearing appropriate uniforms during the surgical procedure.

STERILE R FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and disposable (sterilization method: gamma radiation), individually packaged with triple protection packaging: tertiary packaging (cardboard), blister-type secondary packaging (PET film and surgical grade paper) and primary packaging (clear tube).

SHELF-LIFE

Shelf-life information can be found on the product labeling.

DISPOSAL OF MATERIALS

The disposal of materials must comply with hospital standards and local laws in force.

COMPATIBILITY TABLE

		Connection	Profile Diameter		
			ø 4.0	ø 5.0	ø 8.0
Profile Height (mm)	4.0	MT SW	-	MT SW	MT SW
		MT UNITITE	Slim	Prime; Compact	Prime; Compact
	6.0	EH	-	Plat: ø3.4; ø3.5	Plat: ø3.4; ø3.5; ø4.1; ø5.0
		IH	-	Plat: ø3.8	Plat: ø3.8; ø4,5
	8.0	MT SW	-	MT SW	MT SW
		MT UNITITE	Slim	Prime; Compact	Prime; Compact

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
	ATTENTION	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	ATTENTION: 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
	SHELF-LIFE	USE-BY DATE	VIDA ÚTIL
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA

DEVELOPED AND MANUFACTURED BY:

S.I.N. Sistema de Implante Nacional S/A

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PRODUCT:

PEEK Healing Cap

ANVISA REGISTRATION 80108910093 /80108910091