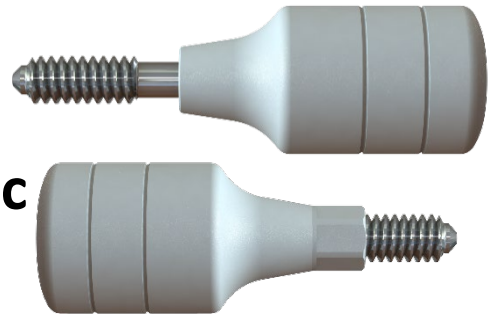
COMPONENT
PEEK HEALING ABUTMENT

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



PRODUCT DESCRIPTION

S.I.N. Dental Implant System Healing Caps are designed for the healing period between implant placement and abutment placement, and are used to contour trans gingival tissue during the healing period.

Healing Caps are manufactured from PEEK according to ASTM F2026. Compatible screws are manufactured from Ti-6Al-4V ASTM F136 Grade 5. Compatible screws have an anodized gold color for HI connection and an anodized pink color for CM connection.

Provided STERILE. Sterilized by irradiation

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

INDICATIONS FOR USE

S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

CONTRAINDICATIONS

S.I.N. Dental Implant System is contraindicated in the following conditions:

- the mandibular or maxillary bone quantity and quality is insufficient to provide initial stability to the implant
- when the site or systemic conditions show inadequate or poor oral hygiene
- acute or chronic periodontal infection
- chemical dependence
- occlusal parafunction
- radiation history to the implant site
- inappropriate patient for prolonged or complicated oral surgery
- inability to build a functional prosthesis
- rehabilitation with dental implants is also contraindicated for children, pregnant women and during breastfeeding
- In cases of immediate loading, inappropriate primary stability of the implant

WARNINGS

The surgical technique of dental implant installation is highly specialized and the surgical procedure complex, it is recommended that the professionals be technically qualified so that the application of the S.I.N. implants is safe and efficient.

Product is for professional use only.

Product is sterilized by gamma radiation. Sterility is ensured except in cases where the package has been violated or damaged. Do not use if the package is damaged package or after the expiration date.

Single use only. Do not resterilize.

The reuse or re-sterilization of this product can cause damage to health.

PRECAUTION

Before implant installation, to obtain a predictable long-term outcome, the professional must submit the patient to a detailed and careful medical history, examination, radiographs, laboratory tests, and study models for appropriate planning.

ADVERSE EFFECTS

Loss of the implant and prosthesis is possible due to a number of reasons, including implant contamination, inappropriate surgical technique, poor bone quality, inappropriate oral hygiene, and parafunctional habits (tooth-grinding).

SURGICAL COMPLICATIONS

The implant installation surgical procedure may bring risks during and after the surgery, such as: pain, edema, hemorrhage, dehiscence, paresthesia, and infection.

SHIPMENT AND HANDLING

The S.I.N. implants are sent to professionals duly packaged, sealed and sterilized. Therefore, the package must be opened using sterile technique, and must be handled only with sterilized titanium instruments.
ATTENTION
In order to obtain technical support or additional information material about the product, contact:
S.I.N. - Sistema de Implante Nacional S.A.
Contact details are provided at the end of these instructions.

INSTRUCTIONS FOR USE

After implant installation (1-stage procedure) or after a period of delayed healing (2-stage procedure):

1. Assess tissue fibrous mucosa: thickness, profile, quality and height of sulcus bottom.
2. Assess gum tissue thickness.
3. Take an x-ray to know the correct location of the implant with the professional's own technique.
4. Check the diameter of the implant through the note in the patient's chart on the day of implementation.
5. Check the angulation of the implant into the bone.
6. Select the height of the Healing Cap: check the distance from the implant platform to the gingival margin so the healing abutment stays 2 mm above the gingival margin, ensuring proper emergence profile healing.
7. Select the diameter of the 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.
8. Prepare the Healing Cap Abutment in the mouth according to the interocclusal and interproximal spaces requirements. Customize with high-speed pen, cooling, and proper techniques.
9. To insert the Healing Cap, remove it from its packaging and fit it into the implant with: digital drivers (CDQ 1220 or CDQ 1224) for implants with external hexagon (HE) or internal hexagon (HI) connection, and (CDH 1220 or CDH 1224) for implants with Morse taper (CM) connections; ratchet wrench (CQTM 20 or CQTM 24) for implants with external hexagon (HE) and internal hexagon (HI) connection, and (CDHC 20 or CDHC 24) for implants with Morse taper (CM) connections. Thread the Healing Cap over the implant until it fully seats, and apply a torque of approximately 10 N.cm.
10. The Healing Cap Slim and Healing Cap Slim Indexed models (CPUS 04xx / CPUS 04xxI) do not use an abutment screw. The , the Healing Cap Slim and Healing Cap Slim Indexed is press-fit into the implant.

MRI SAFETY INFORMATION

Non-clinical testing and in vitro electromagnetic simulations demonstrated that the S.I.N. Dental Implant System devices are MR Conditional.
A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	S.I.N. Dental Implant System
Static Magnetic Field Strength (B_0)	≤ 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

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10. The Healing Cap Slim and Healing Cap Slim Indexed models (CPUS 04xx / CPUS 04xxI) do not use an abutment screw. The , the Healing Cap Slim and Healing Cap Slim Indexed is press-fit into the implant.
11. It is recommended that the healing cap remains for approximately 15 days, or up to 30 days, in the oral cavity.
12. After the peri-implant tissue healing period, remove the healing cap insert the abutment component.

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 UNITITE	Slim	Prime; Compact	-

Symbols Glossary

ANSI/AAMI/ ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol6	Title of Symbol (References Number)	Meaning of Symbol
	Caution (5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Keep away from sunlight (5.3.2)	Indicates a medical device that needs protection from light sources.
	Upper limit of temperature (5.3.6)	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	Keep dry (5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Do not use if package Damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not re-use (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Date of manufacture (5.1.3)	Indicates the date when the medical device was manufactured
	Manufacturer (5.1.1)	Indicates the medical device manufacturer.
	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	MR Conditional (n/a)	Conditions under which a medical device can safely enter the MR environment

DEVELOPED AND MANUFACTURED BY:

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

CNPJ: 04.298.106/0001-74

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PRODUCT:

PEEK Healing Abutment

510(k) FDA Approval

K200992