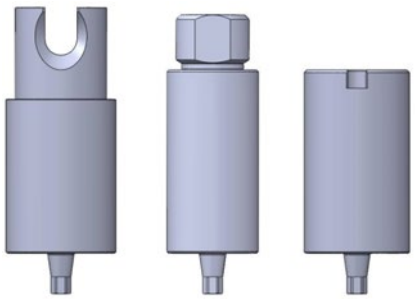
COMPONENT
Pre-Milled CAD-CAM abutments

Pre-Milled CAD-CAM abutments is used to design and fabricate a wax-up model, and the final abutment is cast using traditional techniques.



Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

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.

All digitally-designed custom abutments for use with Pre-Milled CAD-CAM Abutments are to be sent to a S.I.N.-validated milling center for manufacture.

PRODUCT DESCRIPTION

The Pre-Milled CAD-CAM Abutments are designed for screw-retained or cement-retained custom crown and bridge

restorations.

The Pre-Milled CAD-CAM Abutments are manufactured from Ti-6Al-4V alloy (ASTM F136).

The Pre-Milled CAD-CAM Abutments are provided with Morse taper connections (11.5° and 16°) for the milling holders

and S.I.N. implants summarized in the table below.

The Pre-Milled CAD-CAM Abutment is designed to facilitate the fabrication of a patient-specific abutment.

NOTE: The final abutment must be sterilized before clinical use – see Section 10, Sterilization.

CONTRAINDICATIONS

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

- When the implant is not osseointegrated and in case of immediate loading when the primary stability is not achieved.
- when the site showed inadequate or poor oral hygiene
- Acute or chronic periodontal infection
- 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

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 in order to perform surgeries and prosthetics rehabilitation with S.I.N. implants and components.

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

Product is for professional use only.

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

PRECAUTIONS

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 instabring risks during and after the surgery, such as: pain, edema, hemorrhagellation surgical procedure may, dehiscence, paresthesia, and infection.

SHIPIMENT AND HANDLING

The Interface CAD-CAM Abutments in Co-Cr alloy are provided non-sterile to the clinician.
NOTE: The final abutment must be sterilized before clinical use – see Section 10, Sterilization.

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

All milling of the Pre-Milled CAD-CAM Abutments into the final patient-specific abutment must be performed at S.I.N.-validated milling centers.

[Following is a placeholder for the website link to be updated]

Please see:
https://www.sinimplantsystem.com/USA/documents/VMC
for the current list of S.I.N.-validated milling centers.

Performed at the Validated Milling Center

After scanning the intraoral area, the S.I.N.-validated milling center will receive the STL file and design the final patient specific abutment using computer software (CAD) the according to the design parameters below and the space available.

Design parameters for all **Interface CAD-CAM Abutments** superstructure are:

- Minimum wall thickness – 0.55 mm
- Minimum post height for single-unit restoration – 4.0 mm
- Minimum gingival height – 0.55 mm
- Maximum gingival height – 3.5 mm
- Minimum prosthetic platform diameter – 3.5 mm
- Maximum allowable prosthetic post height – 6 mm
- Maximum angle – 0° to 30°

After the abutment is finalized by the milling center it needs to be steam sterilized before clinical use; see Section 10.

Performed by the Clinician

STERILIZATION INSTRUCTIONS FOR FINAL ABUTMENT AND SCREW

Standard autoclave sterilization is recommended, using a gravity cycle, with an exposure time of 30 minutes at 121 °C / 250 °F with a drying time of 30 minutes, using a sterilization wrap that is FDA cleared for the indicated cycle.

INSTALLATION AND RECOMMENDED ABUTMENT SCREW TORQUE

To install the Pre-Milled CAD-CAM abutments, use the abutment screw PTM18 (CM 11.5° abutments) or PT16 (CM 16° abutments), and the CTH 1220 or CTH 1224 contra-angle wrench, and the CDHC 20 or CDHC 24 ratchet driver. The recommended torque is 20 Ncm.

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

Types	Profile Ø, mm (before milling)	Abutment Holder	Compatible with S.I.N Implant Lines
Abutments for 11.5° CM* connection	12	Amann Girrbach	Unitite Strong SW Strong SW Plus Tryon CM Conical Tryon CM Cylindrical Body Conical Apex Tryon CM Cylindrical Epikut CM Epikut CM Plus
	10 14	DESS	
	11.5 15.8	Medentika	
Abutments for 16° CM connection	12	Amann Girrbach	Strong SW CM Strong SW CM Plus Epikut S Epikut S Plus
	10 14	DESS	
	11.5 15.8	Medentika	

*CM – Morse taper

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 [Corporate Taxpayer's Registry]: 04.298.106/0001-74
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CREA-SP: 5061207169

PRODUCT:

Pre-Milled CAD-CAM Abutments

510 (k) FDA-USA:

K230069