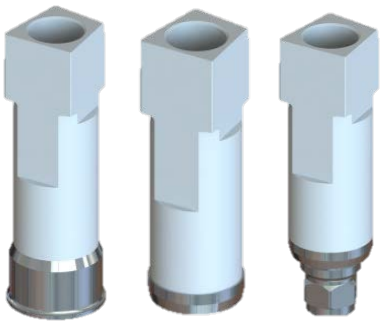
COMPONENT
Interface CAD-CAM Co-Cr-Mo Alloy

Co-Cr alloy 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 Interface CAD-CAM abutments are to be sent to a S.I.N.-validated milling center for manufacture.

PRODUCT DESCRIPTION

Interface CAD-CAM Abutments are two parts cast-on abutments consisting of a cobalt-chromium alloy base and the screw.

Interface CAD-CAM Abutments are designed for screw-retained or cement-retained custom crown and bridge restorations.

Interface CAD-CAM Abutments are provided in the connections and platforms summarize din the table below.

Interface CAD-CAM Abutments in Co-Cr-Mo alloy are manufactured from Co-Cr-Mo alloy conforming to ASTM F1537.

Each Interface CAD-CAM Abutment is provided with a Ti-6Al-4V alloy (ASTM F136) screw for attachment of the abutment to the dental implant.

The Interface CAD-CAM Abutments in Co-Cr-Mo Alloy are provided non-sterile to the clinician.

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

Interface CAD-CAM Abutments – Co-Cr-Mo Alloy are not to be placed on implants which are used for angulation correction or divergence correction, are not to be customized to create an angled abutment or to correct for angulation or divergence, and the final cast abutment is not to be fabricated with angulation or to correct for angulation or divergence.

The surgical technique of dental implant installation is highly specialized and the surgical procedure complex, it is recommended that the professionals are technically qualified in order to perform surgeries and prosthetics rehabilitation with S.I.N. implants and components. Product is for professional use only. The reuse of this product can cause damage to health.

MRI Safety Information

S.I.N. Dental Implant System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) Environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of

S.I.N. Dental Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 installation surgical procedure may bring risks during and after the surgery, such as: pain, edema, hemorrhage, 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

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

The coping/superstructure is milled (CAM) in wax and it is fixed to the Interface CAD-CAM Abutment base component.

After this procedure, add wax where needed to have the correct amount of material, including channels for the metal to flow during casting. After obtaining the desired shape the wax-up is coated (gypsum) for burn-out of the wax, to create the mold.

After the hardening of the coating, the mold is placed in an oven, where the wax will be melted, leaving the exact space for the future entrance of the metal.
The abutment may be cast in cobalt-chromium alloy or nickel-chromium alloy.
The molten metal is placed in the entrance of the mold and cast with the aid of a centrifuge. After cooling, the mold is removed from the metal part which then is prepared to be tried in the mouth. After checking the cast abutment in the mouth, proceed with the placement of the porcelain restoration.
After the abutment is finalized by the milling center it needs to be steam sterilized before clinical use; see Section 10.

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

- Minimum wall thickness – 0.5 mm
- Minimum post height for single-unit restoration – 4.0 mm
- Maximum angle – 0°. Straight only
- Maximum gingival height – 5.0 mm
- Minimum Gingival height – 0 mm
- Maximum allowable Post Height – 6 mm
- Total abutment height – 10 mm
- Abutment diameter- depends on available space (for the particular patient)

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

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

For the Interface CAD-CAM Abutments installation, the digital keys CDQ or CDH 1220 or 24, or contra-angle key CTQ or CTH1220 or 24 or CQTM ratchet wrenches or CDHC 20 or 24 should be used. The recommended torque are the following:

External Hexagon: 32N/cm

Internal Hexagon: 20N/cm

Morse Tapper: 20N/cm

Prosthetic Intermediary: 10N/cm

Types	Platform Ø, mm	Prosthetic Platform Ø, mm	Material	Compatible with*
Interface Conical Abutment	Matches Conical Abutment	5.5	Co-Cr alloy	Conical Abutments
Interface External Hex Abutment (HE, Strong, Tryon)	3.4 3.65 4.1	4.1 4.1 4.3	Co-Cr alloy	Implants: Strong SW HE Strong SW HE Plus Tryon
Interface Internal Hex Abutment (HI, Strong)	3.8	4.1	Co-Cr alloy	Implants: Strong SW HI Strong SW HI Plus
Interface Mini Abutments	Matches Mini Abutments	5.5	Co-Cr alloy	Mini Abutments
Interface Micro Mini Abutments	Matches Micro Mini Abutments	3.8	Co-Cr alloy	Micro Mini Abutments
Interface External Hex Abutment, non-indexed (HE, Strong, Tryon)	3.65 4.1	4.1 4.3	Co-Cr alloy	Implants: Strong SW HE Strong SW HE Plus Tryon

*HE – external hex; HI – internal hex

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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PRODUCT:

Interface CAD CAM CoCr Alloy

510 (k) FDA-USA:

K193096 / K221453