COMPONENT
UCLA Abutment - CoCr

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 implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.

PRODUCT DESCRIPTION

The UCLA Abutment is a two part cast-on abutment consisting of a cobalt-chromium alloy base and a polyoxymethylene (POM) burn-out sleeve. The UCLA Abutment is designed for screw retained or cement retained custom crown and bridge restorations.
The UCLA Abutment is provided for HE (platform diameters 3.65 and 4.1 mm), HI (platform diameters 3.8 and 4.5 mm) and CM connections.
The UCLA Abutment has two rotational options, without internal hexagon for multi-element prostheses and antirotational internal hexagon for single prostheses.
Each UCLA Abutment is provided with a Ti-6Al-4V alloy (ASTM F136) screw for attachment of the abutment to the dental implant.
The UCLA Abutment base is manufactured from cobalt-chromium alloy conforming to ASTM F1537.
Provided NON-STERILE. To be sterilized before use – see Section 10, Sterilization.

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.

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.

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.

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)
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
Scan Duration	15 minutes
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

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. UCLA Abutments are not intended for angulation correction.

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

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 receiving the plaster model, Prosthetics place the cobalt chrome UCLA abutment in the model and check its height. If necessary,

a cut will be made to adjust the height of the component to the height of the prosthesis that will be made.
After this procedure, add wax where needed to have the correct amount of material at the time of casting. After obtaining the desired shape is coating for burn-out of the wax and plastic.
After the hardening of the coating, this ring is placed in an oven, where the wax and plastic of the UCLA abutment will be melted, leaving the exact space for the future entrance of the metal.
The melted metal is placed in the entrance of the coating ring and casted with the aid of a centrifuge.
After cooling, the metal part is ready. After the proof of the metal in the mouth we can proceed with the placement of the porcelain.
Sterilize the abutment (after casting in the laboratory) and screw using the instructions in Section 10 below.

Attach to the implant using the screw provided.

For the UCLA Abutment installation, the digital keys (CDH 1220 or CDH 1224), or contra-angle keys (CTH 1220, CTH 1224, CDHC 20 or CDHC 24) should be used, applying the torque to 20 Ncm.
For the UCLA Abutment 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, applying the torque to 20 Ncm.

NOTE: Always check if the key is compatible with the screw type (square or hexagonal).
The recommended torque is 20 Ncm for attachment to implants with internal hexagon connection, and 32 Ncm for implants with external hexagon connection.

STERILIZATION INSTRUCTIONS FOR UCLA ABUTMENTAND 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.

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

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PRODUCT:

UCLA Abutment CoCr

510 (k) FDA-USA:

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