PROSTHETIC COMPONENTS

Angled Abutments

S.I.N. Sterile Components are intended for expert procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

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

PROUDCT DESCRITION

Abutments Cemented Morse Angled, Abutment Angled Morse, and **Abutment Mini Angled Morse** have a 16° CM / Morse Taper connection, and have an anodized gold color.

Abutments Cemented Morse Angled, Abutment Angled Morse, and **Abutment Mini Angled Morse** are provided for Strong SW CM implants (with the 16° CM connection).

Abutments Cemented Morse Angled have a post angle of 17° or 30°; **Abutment Angled Morse** have a post angle of 17°; and **Abutment Mini Angled Morse** have a post angle of 17° or 30°.

Abutments Cemented Angled SIT, Abutment Cemented Angled Indexed SIT, and **Abutment Mini Angled** have an 11.5° CM / Morse Taper connection, and have an anodized pink color.

Abutments Cemented Angled SIT, Abutment Cemented Angled Indexed SIT, and Abutment Mini Angled are provided for Tryon CM, Strong SW, and Strong SW Plus implant lines (all with the 11.5° CM connection), and all have a post angle of 17° or 30°.

All angled abutments are manufactured from Ti-6Al-4V alloy conforming to ASTM F136.
Provided STERILE. Sterilized by irradiation.

INDICATIONS OF 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.
Refer to Section 9 for instructions to maintain sterility of the product.
The reuse or re-sterilization of this product can cause damage to health.

The Abutment Cemented Angled Morse with a 4 mm prosthetic post height is not to be modified. The Abutment Cemented Angled Morse with a 6 mm prosthetic post height may be modified to a minimum height of 4 mm.
The Abutment Angled Morse has a 7 mm prosthetic post height and may be modified to a minimum height of 4 mm.

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

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.

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

Care must be taken to maintain the sterility of the abutment and abutment screw. The abutment and abutment screw are provided sterile and sealed within the blister pack.
The pack is opened by an assistant so that the clinician, using sterile gloves and sterile technique removes the abutment and abutment screw with sterile instruments and places them on a sterile field. The sterile abutment may be placed directly onto the implant.
If the abutment is prepped chairside, on a sterile field or within the patient's mouth, the clinician will use strict sterile technique including sterile instruments to prepare the abutment. After implant installation (1-stage procedure) or after a period of delayed healing (2-stage procedure):

Abutment Mini Angled Morse and Abutment Mini Angled, 17º and 30º:

1. Remove the abutment from its packaging and adapt it to the head of the implant.
2. Thread the abutment retaining screw onto the implant until the screw is fully seated onto the implant platform.
3. For implants with Morse taper connection CM 16°, use the 1.2 mm hexagonal ratchet wrench (CHTMA 24). For the abutments angled 17°, apply a torque of 20 N.cm. For the abutments angled 30°, use the 0.9 mm hex ratchet wrench (CCH 0920 or CCH 0924), and apply a torque of 15 N.cm. For implants with Morse taper connection CM 11.5°, use the 0.9mm hexagonal ratchet wrench (CCH 0920 or CCH 0924), and apply a torque of 15 N.cm.

Abutments Cemented Morse Angled, Abutment Angled Morse, Abutments Cemented Angled SIT, Abutment Cemented Angled Indexed SIT

1. Remove the abutment from its packaging and adapt it to the head of the implant.
2. Thread the abutment retaining screw onto the implant until the screw is fully seated onto the implant platform.
3. For implants with a Morse taper connection CM 16°, use the 1.2 mm hexagonal ratchet wrench (CHTMA 24). For Abutments Angled Morse (AIAM 350xxC-H–450xxC-H), apply a torque of 20N.cm. For Abutments Cemented Morse Angled (AAIM 33xxC–45xxC), use the 0.9 mm hexagonal ratchet wrench (CCH 0920 or CCH 0924), and apply a torque of 10N.cm. For implants with Morse taper connection CM 11.5°, use the 0.9 mm hexagonal ratchet wrench (CCH 0920 or CCH 0924). For Abutments Cemented Angled SIT and Abutment Cemented Angled Indexed SIT apply a torque of 10N.cm.

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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TECHNICAL RESPONSIBLE:

Alessio Di Risio
CREA-SP: 5061207169

PRODUCT:

Angled Abutments

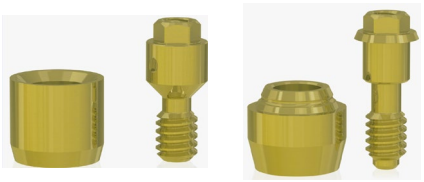
510 (k) FDA-USA:

K200992

PROSTHETIC COMPONENTS

Mini Abutments Zygomatic (HE connection)

Mini Abutment Zygomatic Standard and Mini Abutment Zygomatic Conical are straight, multi-unit, non-indexed abutments for the external hex connection of the Zygomatic implants.



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

PROUDCT DESCRITION

Mini Abutment Zygomatic Conical and **Mini Abutment Zygomatic Standard** and the corresponding abutment screws are prosthetic components to be used exclusively with Zygomatic implants with external hexagon (HE) connection. All abutments have a platform diameter of 4.1 mm. All Mini Abutments and abutment screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136.
Provided STERILE. Sterilized by irradiation.

Mini Abutments	Abutment Screw
Mini Abutment Zygomatic Conical, Ø 4.1, height 2.0 mm (ZC 4102)	PFZC 02
Mini Abutment Zygomatic Conical, Ø 4.1, height 3.0 mm (ZC 4103)	PFZC 03
Mini Abutment Zygomatic Conical, Ø 4.1, height 4.0 mm (ZC 4104)	PFZC 04
Mini Abutment Zygomatic Standard, Ø 4.1, height 3.0 mm (ZS 4103)	PFZS 03
Mini Abutment Zygomatic Standard, Ø 4.,1 height 4.0 mm (ZS 4104)	PFZS 04
Mini Abutment Zygomatic Standard, Ø 4.1, height 5.5 mm (ZS 4155)	PFZS 55

INDICATIONS OF USE

S.I.N. Dental Implant System Zygomatic implants are intended for placement in the maxillary arch to provide support for fixed or removable dental prostheses in patients with partially or fully edentulous maxillae. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System Zygomatic implants are 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.

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.

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.

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):

Mini Abutment Zygomatic Standard

1. Remove the Mini Abutment Standard from the packaging and adapt it to the implant prosthetic platform.
2. Thread the abutment retaining screw into the implant until the screw is fully seated on the implant platform.
   Use the 2.0mm hexagonal driver wrench (CDAC 20), applying a torque of 20 N.cm.
3. For the impression procedure, position the open tray transfer (TMAS) on the Mini Abutment Standard and screw it with the aid of the 1.2 mm digital key (CDH 1220 or CDH 1224) or with the 1.2 mm driver wrench (CDHC 20 or CDHC 24) with the aid of a torque wrench (TMEC), applying a torque of 10 N.cm. A periapical radiography can help to verify that the transfer is adapted in the correct position on the Mini Abutment Standard.
   Select the tray in the required dimensions and apply lightweight elastomeric impression material around the transfer. Add to the prepared tray with the heavy elastomeric impression material and place it directly in the patient's mouth for the position capture. When the impression material has taken hold, remove the screw and remove the impression tray together with the transferring, which must be attached to the impression material.
   Send the material to the laboratory with the specific analogue of the Mini Abutment Standard (ANS) to create the plaster model.
4. Still in the mouth, perform adequate cleaning to remove any residual molding material and install the Abutment Protector Standard (PAS) on the Mini Abutment Standard, fixing the screw with the aid of the 1.2 mm digital key (CDH 1220 or CDH 1224) or with the wrench driver screw (CDHC 20 or CDHC 24) with the aid of a torque wrench (TMEC), applying a torque of 10N.cm
5. After the plaster model is made, the final abutment and bar structure can be produced in the laboratory. Use the Co-Cr base (ECLAS) and burn-out cylinders (BDU) compatible with the Mini Abutment Standard. No modifications to the Co-Cr Base (ECLAS) are allowed, including no changes to the Co-Cr Base diameter, wall thickness, post height, or modification to create angulation.

Workflow for Casting
The Co-Cr Base (ECLAS) is used as a base for a cast-to straight abutment only, with no angulation, to make a bar structure for a multi-unit restoration.
The design of the final abutment is done using traditional wax-up technique. The final one-piece abutment is fabricated using standard lost wax casting techniques, including:

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

1. Add wax where needed, including channels for the metal to flow during casting.
2. After obtaining the desired shape, the wax-up is coated (gypsum) to create the mold.
3. After the hardening of the coating, the mold is placed in an oven for burn-out of the wax, leaving the exact space for the metal casting.
4. The abutment may be cast in cobalt-chromium alloy or nickel-chromium alloy.
5. The molten metal is placed in the entrance of the mold and cast with the aid of a centrifuge.
6. After cooling, the mold is removed from the metal part which then is prepared to be used to fabricate a bar structure.

6. A bar structure (incorporating multiple abutments to be placed on multiple implants) is fabricated and used to support the full arch restoration.
7. Prior to placement of the full arch restoration onto the implants in the patient, disinfect the construct according to the typical standard of care within the facility.
8. Install the prosthesis using the retaining screws (PRH 30) for fixation, with the aid of the 1.2 mm wrench driver (CDHC 20 or CDHC 24), applying torque of 10 N.cm.

Mini Abutment Zygomatic Conical

1. Remove the Mini Abutment Conical from the packaging and adapt it to the implant prosthetic platform.
2. Thread the abutment retaining screw into the implant until the screw is fully seated on the implant platform.
   Use the 2.0 mm hexagonal driver wrench (CDAC 20), applying a torque of 20 N.cm.
3. For the impression procedure, position the open tray transfer (TMAM 4800) on the Mini Abutment Conical and screw it with the aid of the 1.2 mm digital key (CDH 1220 or CDH 1224) or with the 1.2 mm driver wrench (CDHC 20 or CDHC 24) with the aid of a torque wrench (TMEC), applying a torque of 10 N.cm. A periapical radiograph can help to verify that the transfer is adapted in the correct position on the Mini Abutment Conical.
   Select the tray in the required dimensions and apply lightweight elastomeric impression material around the transfer. Add to the prepared tray with the heavy elastomeric impression material and place it directly in the patient's mouth for the position capture. When the impression material has taken hold, remove the screw and remove the impression tray together with the transferring, which must be attached to the impression material.

Send the material to the laboratory with the specific analogue of the Mini Abutment Conical (ANMA 4800) to create the plaster model.

4. Still in the mouth, perform adequate cleaning to remove any residual molding material and install the Abutment Protector Conical (PMA 4855) on the Mini Abutment Conical, fixing the screw with the aid of the 1.2 mm digital key (CDH 1220 or CDH 1224) or with the wrench driver screw (CDHC 20 or CDHC 24) with the aid of a torque wrench (TMEC), applying a torque of 10 N.cm.
5. After the plaster model is made, the final abutment and bar structure can be produced in the laboratory. Use the Co-Cr base (CLEM 4800-3) and burn-out cylinders (BDU) compatible with the Mini Abutment Conical.
   No modifications to the Co-Cr Base (CLEM 4800-3) are allowed, including no changes to the Co-Cr Base diameter, wall thickness, post height, or modification to create angulation.

Workflow for Casting

The Co-Cr Base (CLEM 4800-3) is used as a base for a cast-to straight abutment only, with no angulation, to make a bar structure for a multi-unit restoration.
The design of the final abutment is done using traditional wax-up technique. The final one-piece abutment is fabricated using standard lost wax casting techniques, including:

1. Add wax where needed, including channels for the metal to flow during casting.
2. After obtaining the desired shape, the wax-up is coated (gypsum) to create the mold.
3. After the hardening of the coating, the mold is placed in an oven for burn-out of the wax, leaving the exact space for the metal casting.
4. The abutment may be cast in cobalt-chromium alloy or nickel-chromium alloy.
5. The molten metal is placed in the entrance of the mold and cast with the aid of a centrifuge.
6. After cooling, the mold is removed from the metal part which then is prepared to be used to fabricate a bar structure.

6. A bar structure (incorporating multiple abutments to be placed on multiple implants) is fabricated and used to support the full arch restoration.
7. Prior to placement of the full arch restoration onto the implants in the patient, disinfect the construct according to the typical standard of care within the facility.
8. Install the prosthesis using the retaining screws (PRH 30) for fixation, with the aid of the 1.2 mm wrench driver (CDHC 20 or CDHC 24), applying torque of 10 N.cm.

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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TECHNICAL RESPONSIBLE:

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PRODUCT:

Mini Abutments Zygomatic

510 (k) FDA-USA:

K203725