COMPONENT

Conical Abut/ Mini Abutment/ Micro Mini Abut/ Cemented

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

Conical Abutment is a straight abutment having an indexed (anti-rotational) or non-indexed cone and is intended for a screw retained prosthesis. Two Conical/Prosthetic precision fit components (provisional and UCLA CoCr) are available for fabrication of the prosthesis. Conical Abutment is provided for HE (platform diameters 3.65 mm) and CM connection.

Mini Abutment is a straight multi-unit abutment. The Mini Abutment is provided for HE (platform diameters 3.65 and 4.1 mm), HI (platform diameters 3.8 and 4.5 mm) and CM connection.

Mini Micro Abutments are straight, non-indexed multi-unit abutments. Mini Micro Abutments are provided for the 11,5º CM connection.

Abutment Cemented are straight abutments designed for cement-retained prostheses. It is provided in two platform diameters (3.4 and 3.65 mm) for the HE connection and provided for the 11,5º CM connection.

The Abutment Cemented is gold anodized using standard electrolytic passivation processing.

Conical Abutments, Mini Abutments, Mini Micro Abutments and Cemented Abutment manufactured from Ti-6Al-4V alloy conforming to ASTM F136.

Mini Abutment, Conical Abutment, and Micro Mini Abutment for 11.5º implants are anodized to a pink color using standard electrolytic passivation processing.

Mini Abutment, Conical Abutment, and Micro Mini Abutment for CM implants are anodized to a gold color using standard electrolytic passivation processing.

Mini Abutment, Conical Abutment, and Micro Mini Abutment for CM implants are anodized to a gold color using standard electrolytic passivation processing.

Each abutment is provided with a Ti-6Al-4V alloy abutment screw for attachment to the dental implant.

Provided STERILE. Sterilized by irradiation.

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.

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. Abutments with a prosthetic post height less than 4.0 mm are intended for multi-unit restorations only.

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 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):

Conical Abutments HI and HE connections

1. Remove the Conical 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. With the aid of digital keys (CDA 20 or CDA 24), handpiece key (CTA1224) or ratchet wrench (CDAC 20), torque the abutment screw to 20 Ncm.

Conical Abutment CM connection

1. Remove the Conical 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. With the aid of digital keys (CDA 20 or CDA 24), handpiece keys (CTA1224) or ratchet wrenches (CDAC 20 or CDHC 24), torque the abutment screw to 20 Ncm.

Mini Abutments HI and HE connections

1. Remove the Mini 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.

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

With the aid of 2.0 torque connection wrench and the Prosthetic Torque Wrench (CHTMA 24), torque the abutment screw to 20 Ncm.

Mini Abutments CM connections

1. Remove the Mini 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. With the aid of digital keys (CDA 20 or CDA 24), handpiece key (CTA1224) or ratchet wrench (CDAC 20), torque the abutment screw to 20 Ncm.

Micro Mini Abutments

1. Remove the Micro Mini Abutment from its packing 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. With the aid of digital Keys (CDA 20 or CDA 24), handpiece key (CTA 1224) or ratchet wrench (CDAC 20), toque the abutment screw to 20 Ncm.

Prosthetics for Conical and Mini Abutments

1. Conical and Mini Abutment provisional and UCLA components are prosthetic components used to attach the prosthesis (restoration) to the abutment.
2. Upon completion of the prosthesis (restoration), attach the prosthesis to the abutment, and thread the prosthetic retaining screw onto the abutment until the screw is fully seated.
3. With the aid of 1.2 torque connection wrench and the Prosthetic Torque Wrench (CDHA 20, CDHC 24 or CHTMA 24), torque the retaining screw to 10 Ncm.

Cemented Abutment Retaining Screws – to attach prosthesis (restoration) to Cemented Abutment

1. Remove the abutment from its packaging and adapt it to the head of the implant with the aid of digital keys (CDH 1220 or CDH1224), handpiece keys (CTH1220 or CTH1224) or ratchet wrenches (CDHC 20 or CDHC 24).

Thread the component onto the implant until it is fully seated onto the implant platform.
Torque to 32 Ncm.

2. Upon completion of the prosthesis (restoration), fit the prosthesis on the Cemented Abutment, and thread the retaining screw onto the abutment until the screw is fully seated.
3. With the aid of 1.2 torque connection wrench and the Prosthetic Torque Wrench, torque the retaining screw to 20 Ncm.

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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TECHNICAL RESPONSIBLE:

Alessio Di Risio

CREA-SP: 5061207169

PRODUCTs:

Conical Abutment

Mini Abutment

Micro Mini Abutment

Cemented Abutment

510 (k) FDA-USA:

K170392/ K170398 / K051859 / K193096

COMPONENT
Provisional Abutment (HE/ CM/ Conical)

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 Provisional Abutment is designed to facilitate the fabrication of a custom restoration to be used between the time of abutment placement and final restoration placement. The Provisional Abutment is available in HE, CM and Conical Connection and is provided for Unitite Slim, Unitite, Unitite Compact, and Strong SW CM implants.

The Provisional Abutment is a straight abutment for screw-retained or cement-retained provisional restorations. The cylinder portion of the abutment can be reduced and is designed for adding material, such as acrylic or composite, when creating an esthetic provisional restoration.

The Provisional Abutment is provided in three platform diameters (3.65, 4.1, and 5.0 mm) for the HE connection, and provided in one multi-unit conical connection diameter (4.8 mm) for mini-conical abutments.

The Provisional Abutment is provided with screw for attachment of the abutment to the dental implant.

The Provisional Abutment is manufactured from Ti-6Al-4V alloy conforming to ASTM F136.

Each abutment is provided with a Ti-6Al-4V alloy abutment screw for attachment to the dental implant.

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.

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

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.

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 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

Sterilize the Provisional Abutment and screw using the instructions in Section 10 below.

1. Connect the Provisional Abutment to the implant and reduce if necessary.

   For the Provisional 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).
2. Fill the screw access hole with a suitable material (*).
3. Place a temporary restoration.
4. Remove the material from the screw access hole and loosen the screw using the appropriate key (*).
5. Make final adjustments.
6. Connect the temporary restoration.

(*) In the case of provisional cemented abutments, skip steps 2 and 4.

STERILIZATION INSTRUCTIONS FOR PROVISIONAL 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 20 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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TECHNICAL RESPONSIBLE:

Alessio Di Risio
CREA-SP: 5061207169

PRODUCT:

Provisional Abutment

510 (k) FDA-USA:

K170392/ K170398/ K221453/ K051859

COMPONENT
HEALING ABUT AND ABUTMENTS PROTECTORS

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

S.I.N. Dental Implant System Healing Abutments and Abutment Protectors are designed for the healing period between implant placement and abutment placement.

Healing Abutments are provided in three platform diameters (3.65, 4.1, and 5.0 mm) for the HE connection, two platform diameters (3.8 and 4.5 mm) for the HI connection, and three gingival heights (2.0, 4.0, and 6.0 mm). Healing Abutments are provided for Unitite Slim, Unitite, Unitite Compact, and Strong SW CM implants.

Healing abutments are used to contour trans gingival tissue during the healing period.

Abutment Protectors are provided with three interfaces for compatibility with the Conical Abutment and the Mini Abutment. They are designed to cover the screw hole of the abutment during healing to prevent foreign body impaction.

Healing Abutments and Abutment Protectors are manufactured from Ti-6Al-4V alloy conforming to ASTM F136.

Each abutment is provided with a Ti-6Al-4V alloy abutment screw for attachment to the dental implant. Provided STERILE. Sterilized by irradiation.

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.

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

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 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, type and height of the gum tissue.
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 in the bone.
6. Pre-calculate the height of the S.I.N. Component according to the thickness of the crest of the mucosa.

   Select a component that is approximately 2 mm higher.
7. Note that the diameter of the S.I.N. Component has variations according to the implanted tooth (higher or lower), implant location, spacing between teeth, implant diameter, edge thickness or spacing between the implants. The gingival papilla must be preserved.
8. Using a millimeter probe, measure the height between the head of the implant and gingival edge. This enables the choice of the ideal height of the S.I.N. Component, which should be approximately 2 mm supragingival.
9. Remove the S.I.N. Component from its packaging and adapt it to the head of the implant with the aid of digital keys (CDH 1220 or CDH1224), handpiece keys (CTH1220 or CTH1224) or ratchet wrenches (CDHC 20 or CDHC 24). Thread the component onto the implant until it is fully seated onto the implant platform. Hand tighten.
10. Following the healing period, remove the component and install the final prosthesis (abutment) to the implant.

Note: Healing abutments attach directly to the implant. Abutment Protectors attach to a multi-unit abutment placed on the implant.

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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TECHNICAL RESPONSIBLE:

Alessio Di Risio

CREA-SP: 5061207169

PRODUCT:

Healing Abutment and Abutment Protectors

510 (k) FDA-USA:

K170392/ K170398/ K193096 / K051859