COMPONENT

S.I.N. Sterile Component

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.

PROUDCT DESCRITION

Mini Abutment: It consists of a cylindrical abutment made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to the professional in sterile form. They may or may not accompany screw.

Angled Mini Abutment: It consists of a cylindrical abutment with an angulation variation of 17° or 30°, made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to the professional in sterile form. Supplied with grade V titanium screw.

Conical Abutment/Multifuncional: It consists of a conical abutment made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to the professional in sterile form. They may or may not accompany screw.

Cemented Abutment: It consists of a cylindrical abutment made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to the professional in sterile form. They may or may not accompany screw.

Angled Cemented Abutment: It consists of a cylindrical abutment with an angulation variation of 17° or 30°, made of titanium grade V with connection according to the implant platform to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to the professional in sterile form. Supplied with grade V titanium screw.

Interface: It consists of a cylindrical abutment made of titanium grade V with connection according to the implant platform or abutment to be used together, it has an internal perforation to access the prosthesis fixation screw, may or may not be anodized (yellow or pink). They are made available to the professional in STERILE form. Supplied with grade V titanium screw.

INDICATIONS OF USE

The S.I.N. Sterile Components are indicated for making dental prostheses on implants, they have the function of serving as an intermediary that makes the connection between the osseointegrated implant and the dental prosthesis.

OPERATION PRINCIPLE

Mini Abutment: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Mini Abutment is used for the manufacture of screwed, multiple, partial and total dental prostheses. In the case of the Micro Mini Abutment, it can also be used to make single prostheses. They enable passive rehabilitation in cases with divergent implants up to 25 ° for Mini Abutments and 20 ° for Micro Mini Abutments.. The recommended torque for installing the mini abutment is 20N.cm.

Angled Mini Abutment: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Angled Mini Abutment is used for making dental prostheses screwed, multiple, partial and total. It allows the correction of angled implants, with an angulation variation of 17º and 30º. The recommended torque for installing the mini abutment is 20N.cm, except for models in the cone morse line (CM 16°) 30° angle and cone morse (CM 11.5°) 17° and 30° angle where the recommended torque is 15N.cm.

Conical Abutment/ Multifuncional: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Conical Abutment is used for making dental prostheses screwed, multiple or unitary (rotational or anti-rotational). The recommended torque for the installation of the conical abutment is 20N.cm.

Cemented Abutment: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Cemented Abutment is used for making dental prostheses cemented, unitary, multiple e partial. Prosthetic Platform CM: The recommended torque for the installation of cemented abutment for cone morse (CM) implant is 20N.cm, except for the universal cemented abutment model of the Unitite Slim line that the recommended torque is 15N.cm and universal abutment model through bolt morse cone that the recommended torque is 10N.cm. Prosthetic Platform HE: The recommended torque for the installation of cemented abutment for external hexagon implant (HE) is 32N.cm except for the universal abutment model the recommended torque is 20N.cm. HI Prosthetic Platform: The recommended torque for the installation of cemented abutment for internal hexagon (HI) implant is 20N.cm.

Angled Cemented Abutment: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The Angled Cemented Abutment is used for making dental prostheses cemented, unitary, multiple and partial. It allows the correction of angled implants, with an angulation variation of 17º and 30º. Prosthetic Platform CM: The recommended torque for the installation of angled cemented abutment for cone morse (CM) implant is 20N.cm and add: except for the universal angled abutment model, the recommended torque is 10N.cm. Prosthetic Platform HE: The recommended torque for the installation of the angled cemented abutment for external hexagon (HE) implant is 32N.cm. HI Prosthetic Platform: The recommended torque for the installation of the angled cemented abutment for internal hexagon (HI) implant is 20N.cm.

Interface: Its purpose is to form a set with the implant and thus transmit the chewing forces to the bone board. They are based on the mechanical principles of assembling the load transmission system. The interface is used for making dental prostheses cemented oy screwed, multiple, unitary, partial and total by the CAD-CAM system. Prosthetic Platform CM: The recommended torque for the installation of the titanium interface for cone morse (CM) implant is 20N.cm. Prosthetic Platform HE: The recommended torque for the installation of titanium interface for external hexagon (HE) implant is 32N.cm. HI Prosthetic Platform: The recommended torque for the installation of the titanium interface for internal hexagon (HI) implant is 20N.cm. MiniAbutment: The recommended torque for the installation of the titanium interface for implant miniabutment is 10N.cm. Abutment Conical: The recommended torque for the installation of the titanium interface for conical abutment implant is 10N.cm.

HOW TO USE

1. Cementated Protheses: Cemented Abutment, Angled Cemented Abutment or Interface:

a. Selection of the component to be used in relation to height x diameter x multiple or unit.
b. Installation and component torque.
c. Registration of the three-dimensional position of the implant using impression technique with open or closed tray transfer or scanning by transfer to CAD-CAM system.
d. Finalization of the prosthesis on the analogue installed in the gypsum or drilling in the CAD-CAM system, using component of your choice.
e. Fixation of the prosthesis through the cement of your choice.

2. Prosthetic Screws: Mini Abutment, Angled Mini Abutment, Conical Abutment or Interface:

a. Selection of the component to be used in relation to height x diameter x multiple or unit.
b. Installation and component torque.

c. Registration of the three-dimensional position of the implant using impression technique with open or closed tray transfer or scanning by transfer to CAD-CAM system.
d. Finalization of the prosthesis on the analogue installed in the gypsum or drilling in the CAD-CAM system, using component of your choice.
e. Fixation of the prosthesis through a screw and suitable torque.

ATTENTION

The S.I.N. Sterile Components implants are intended for expert procedures, which must be performed by qualified professionals in implant Dentistry. The product must be used in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTIONS

Consider the general health of the patient, the same must undergo a thorough clinical analysis. Failure to perform the pre-surgical evaluation can lead to the impossibility of finding pre-existing diseases.
Patients with local or systemic factors that may interfere with the soft tissue healing process should receive special attention.
Sterilization of the S.I.N. Sterile Components is only guaranteed if the primary packaging (blister) is not damaged. Do not use the product if the packaging has been tampered with. Only open the package at the time of surgery and use the product immediately.
Handle the material only in a sterile field.
All material used in the procedure must be sterile.
Components not used after opening the carton should be discarded.
Products with expired validity should not be used.
During the surgical and prosthetic procedure only use implants, components and instruments specified by S.I.N., they have specific dimensions and tolerances for each implant system guaranteeing longevity of the product. Other brand components or adapted to the implant models can reduce the life of the system causing irreversible damage.
The platform of the S.I.N. Sterile Components that adapts to the implant must not be altered in any way.
The professional must ensure the patient does not aspirate the product.
It is the responsibility of the professional to use S.I.N. in accordance with the instructions for use, as well as to determine if it is appropriate to the individual situation of each patient.
If a correct diameter is not used, soft tissue irritation may occur.
The patient should be informed about all possible surgical complications, contraindications, warnings, precautions and adverse reactions. All documentation accompanying the product should also be made available to the customer.
The professional must inform the patient about the correct form of cleaning, the need for regular monitoring, avoiding physical and mechanical tensions and not subjecting the product to inappropriate efforts.

RECOMMENDATIONS

For the placement of components, it is recommended that the professional have a specialization course in the area and prepare a prosthetic execution plan.
Inadequate planning and/or lack of occlusal adjustment may compromise the performance of the implant / prosthesis combination resulting in system failure, such as implant loss or fracture, loosening or fracture of the Prosthetic Screws.
The diameter and the angulation of the implant, as well as the gingival height, must be taken into account when choosing the model of Components S.I.N. to be used.
The S.I.N. does not recommend implant installation in patients with inadequate oral hygiene, uncooperative and unmotivated patients, drug or alcohol abuse, psychoses, chemical dependence, prolonged functional disorders that resist any drug treatment, xerostomia, low immune system, diseases which require the use of steroids regularly, endocrinological diseases, drug allergy, diabetes mellitus, anticoagulants/bleeding diathesis, bruxism, other parafunctional habits, tobacco abuse, installation in children and pregnant women and during breastfeeding.

CONTRAINDICATIONS

The use of S.I.N. Sterile Components is contraindicated in cases of chronic periodontal inflammation, a patient not prepared to undergo oral rehabilitation, inappropriate parafunctional habits, for example bruxism, untreatable occlusion/joint problems, active intraoral infection and in the case of immediate loading, primary implant stability inadequate.

SIDE EFFECTS

The installation recommendations must be followed for the proper functioning of the product, if not, the final result can be compromised generating, loss or fracture of the part. The product can cause transient side effects due to compression of perimplant tissues such as, slight bleeding, edema, pain, discomfort or even infection in case of breaking aseptic barrier.

WARNING

The implants must receive components with compatible geometry, or specific components for the technique switching platform and installation indication.
Compatible only with S.I.N.
The Product is for single use and cannot be re-sterilized and/or reused.
The reuse or re sterilization of this product may cause contagious infectious disease, deformation and wear of the product.

TRACEABILITY

All S.I.N. – Implant System products have sequential lots that allow traceability, which promotes greater safety for the professional qualified to the procedure. Through this batch number, it is possible to know the entire history of the product from the manufacturing process to the distribution time.

STORAGE

The S.I.N. Sterile Components should be stored in a cool dry place at a maximum temperature of 35°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

The S.I.N. Sterile Components are sterile products that should be handled only in a sterile field by properly trained professionals and in appropriate scrubs at the time of the surgical procedure.

DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

TRANSPORTATION

The S.I.N. Sterile Components must be transported adequately to avoid falling and stored under a maximum temperature of 35°C, protected from heat and moisture. Carriage must be carried out in its original packaging.

STERILE R FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and single-use (sterilization method: gamma radiation) packaged in a unit that offers double protection: secondary packaging (cardboard) and primary blister packaging (PET film and surgical grade paper).

COMPLEMENTARY INFORMATIONS

Single use product. Reprocessing prohibited. Product for exclusive dental use. In the event of an incident caused by the product, the professional must immediately inform the manufacturer.

EXPIRATION DATE

The information regarding the expiration date can be found on the labeling of the product. After installation on the patient, the product must be monitored by the professional.

STERILE R	PRODUTO ESTERILIZADO POR RADIAÇÃO GAMA	PRODUCT STERILIZED THROUGH GAMMA RAYS	PRODUCTO ESTERILIZADO POR RADIACIÓN GAMA
	NÃO REUTILIZAR	DO NOT REUSE	NO LO REUTILICE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO LEJOS DE LA LUZ SOLAR
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NO LO UTILICE SI EL ENVOLTORIO ESTÁ DAÑADO
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO REESTERILIZAR
	ATENÇÃO	CAUTION	PRECAUCIÓN
EC REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
	LIMITE SUPERIOR DE TEMPERATURA	UPPER LIMIT OF TEMPERATURE	LÍMITE SUPERIOR DE TEMPERATURA
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTE DISPOSITIVO POR OU POR ORDEM DE UM PROFISSIONAL DE SAÚDE LICENCIADO.	CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER.	PRECAUCIÓN: LAS LEYES FEDERALES (USA) RESTRINGEN LA VENTA DE ESTE DISPOSITIVO POR O EN EL ORDEN DE UN PROFESIONAL DE LA SALUD LICENCIADO.
	FABRICANTE	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	VALIDADE	USE-BY DATE	VALIDEZ
REF	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA

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PRODUCT:
S.I.N. Sterile Component

ANVISA REGISTRATION 80108910028