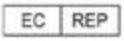
SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO 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
	ATENÇÃO	CAUTION	PRECAUCIÓN
	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.

DEVELOPED AND MANUFACTURED BY:

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PRODUCT:

Metalic Abutments – S.I.N.

Anvisa Registration: 80108910033

CE

S.I.N. Metalic Abutments 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.

PRODUCT DESCRIPTION

S.I.N. Metalic Abutment is a metal base used as a working template for the casting of the prostheses that will be rehabilitated over the implants or prosthetic sterile components.

The base of the S.I.N. Metalic Abutments is produced in Cr-Co (Chromium-Cobalt) alloy and its cylindrical body is made of Polyacetal. Its plastic structure allows the laboratory to cut the excesses and the desired shape of the future prosthesis to be waxed and the base, made with Cobalt Chrome, preserves the machined part of the abutments for a better adaptation between the Metalic Component on the implant or on the prosthetic sterile component in case of an infrastructure with the shape of the prepared tooth that will be made. It provides a standard for the creation of a screwed or cemented crown, thus supporting the prosthesis in a fixed position on the implant (Abutment EUCLA) or on the prosthetic sterile component (Cylindrical Abutment). It has two options of rotational fitting (without internal hexagon for multi-element prostheses) and anti-rotational (internal hexagon for single-piece prostheses). The finalization of the S.I.N. Metalic Abutement is through the implant/crown interface, as follows:

Screwed Prosthesis:

Stage 01: Definition of the implant characteristic;
Stage 02: Definition of the abutment to be used;
Stage 03: Definition of the type of "prosthesis" to be used;

Stage 04: Fixation of the prosthesis through screw.

The Cobalt Chrome Interface product comes in two pieces.

Metal base (Chromium-Cobalt); Plastic cylinder (polyacetal).

EUCLA Abutment: It consists of a cylindrical pillar with internal drilling to access the fixation screw of the prosthesis or without internal drilling for the cemented components. Used in external hexagon implants may have two options of rotational (without hexagon) or anti-rotational (with hexagon) fitting, following the seating platforms according to each implant model. They are made available to the professional in **NON-STERILE** form**.**

Cylindrical Abutment: It consists of a cylindrical pillar with internal drilling to access the fixation screw of the prosthesis. It has two options of docking, rotational (without hexagon) or anti rotational (with hexagon).

Chrome-cobalt Interface: It consists of a cylindrical pillar, straight, with varied heights, following the seating platform according to each implant model. They are available for prosthetic platforms external hexagon, internal hexagon and morse tapper, as they can be used on conical abutments, mini-abutments and micro-mini abutments. They are made available to the professional in **NON-STERILE** form.

INDICATIONS OF USE

The Metalic Aubutments are indicated for single or multiple prosthesis used as a working mold for the casting or production by the CAD CAM system of the prosthesis that will be rehabilitated on the implant or prosthetic sterile components..

EUCLA Abutment: It is recommended for the fixation of the unitary or multiple prosthesis in the implant, the recommended torque for fixing the Metalic Abutments directly on the implant is 20Ncm, as well for components with internal hexagon and morse tapper connection and 32Ncm for external hexagon components.

Cylindrical Abutment: Indicated for the fixation of single or multiple prosthesis in the prosthetic sterile components. Because it is a versatile component, it is widely used in many different clinical situations.

Chrome-cobalt interface: It is recommended for the preparation and fixation of the unitary or multiple prosthesis, the recommended torque for the direct fixation of the Metalic Abutments on the implant is 20Ncm as well for components with internal hexagon and morse tapper connection, 32Ncm for components external hexagon and 10Ncm for interfaces screwed on the intermediate prosthetic components.

OPERATION PRINCIPLE

Individual metal base: The metal base is an intermediate prosthetic component, to be installed between the implant and the prosthesis, manufactured in cobalt chromium. It has an interface for connection to the implant at one end. It presents different prosthetic interfaces in the rotational and anti-rotation version.

Individual metal base with the plastic cylinder: The metal base assembled with the plastic cylinder creates a component of the burnable type (EUCLA), used for the preparation of waxing and the overcasting of infrastructures of screwed prostheses installed on intermediaries. It is used in the laboratory phase to make the prosthesis on models in plaster and analogues of implants. After casting, it becomes part of the final prosthesis.

HOW TO USE

The manufacture of prostheses on dental implants or prosthetic sterile components requires a specific professional specialization. The use of the product without knowledge of the appropriate techniques and/or inadequate procedures and conditions may harm the patient leading to unsatisfactory results.
The dental surgeon or the prosthodontist is responsible for his/her previous qualification to use the S.I.N. Metalic Abutment.
Careful clinical and radiographic evaluations are necessary for proper treatment planning, which should take into consideration the most suitable prosthetic options for masticatory force balance, occlusal adjustment, aesthetics and other factors related to the good performance of the prosthesis. The exchange of information between the surgeon and the prosthodontist is of fundamental importance for the successful manufacture of the prosthesis.

For screws fixed to the implants (Ø 1,6mm, Ø 1,8mm) maximum torques of 20Ncm were established for internal connection / morse tapper and 32Ncm for external connection and for those fixed on the sterile components (Ø 1.4mm) was set maximum torque of 10Ncm.

Assembly procedure (Cobalt Chrome Interfaces)
1.Separate the metal base and plastic cylinder.
2.Position the plastic cylinder on the metal base.
3.Rub the plastic cylinder over the metal base until it snaps into place.

CONTRAINDICATIONS

The use of these components is contraindicated in the following cases:

- Chronic periodontal inflammation;
- Patient not prepared to undergo oral rehabilitation;
- Inaproppriate oral hygiene;
- Inappropriate parafunctional habits, for example, bruxism;
- Intractable occlusion/joint problems;
- Active intraoral infection;
- In cases of immediate loading, improper primary stability of the implant.

SIDE EFFECTS

If the technique is not adequate and the patient is not subjected to the indicated tests, the final result of application of the components may not succeed, generating product loss or fracture. The application of the product may cause effects in the area where it was applied, such as pain, tenderness of short duration, tissue reaction or infection.

PRECAUTIONS AND RECOMMENDATIONS

For the placement of S.I.N. Metalic Abutments, it is recommended that the professional has a specialization course in the area and prepare a prosthetic execution plan.

For the placement of S.I.N. Metalic Abutments, the professional should submit the patient to a thorough visual inspection to diagnose cases cited in the contraindications. The diameter should be taken into consideration. If a correct diameter is not used, it may occur irritation of the soft tissue. The settlement platform of the S.I.N. Metalic Abutments that adapt to the Implant shall not be changed at all.

The professional shall sterilize all surgical instruments before use, prepare the environment with sterile gowning and surgical field, carry out a good oral asepsis in the patient, check the packaging of the product and its identification and integrity, prevent the product to come into contact with any non-sterile object to minimize the risk of contamination. The professional should be aware of the force exerted when applying the product so as not to damage it.
The professional should inform the patient on the proper way of cleaning, the need for regular monitoring, avoiding physical and mechanical stresses and do not subject the product to improper efforts.

WARNING

Because it is the surgical technique for the installation of highly specialized and complex dental prosthesis components, it is highly recommended that professionals carry out specialized training so that the application of the Provisional Abutments is safe and effective. If the technique used is not adequate and the patient is not indicated for this type of surgery, the Provisional Abutment may not be successful and will be lost.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches 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 until the moment of distribution

STORAGE

S.I.N. Metalic Abutments must be stored in a cool and dry place, keep away from sunlight.

TRANSPORTATION

S.I.N. Metalic Abutments must be transported in room temperature, away from direct sunlight, avoiding places with great temperature and humidity instability. The transportation must be carried out properly to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

Once sterilized, Metalic Abutments should only be handled in a sterile environment by properly trained professionals and in appropriate attire at the time of the surgical procedure.

COMPLEMENTARY INFORMATION

Single use product. Reprocessing is prohibited.

DISPOSAL OF MATERIAL

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

EXPIRATION DATE

Indicated on the label.

CONDITIONS FOR STERILIZATION

It is the procedure that aims at the total elimination of microorganisms (viruses, bacterias, microorganisms and fungi), either in vegetative or sporulated form.

Recommendations

a. Dry all instruments before the steam sterilization cycle.
b. Use mechanical and chemical indicators (place the internal chemical indicator between instruments or materials to be sterilized) for each sterilization cycle.
c. Allow instruments to dry and cool in the sterilizer before handling to prevent contamination and oxidation of materials.
d. The autoclavable case can be sterilized at 121˚ C at 1 ATM pressure for 30 minutes or at a temperature of 134˚ C at 2 ATM pressure for 20 minutes.
e. Always place the case in an autoclave on a flat surface and away from the walls of the unit.
f. Never overlap objects or even other cases.
g. Chemical sterilization is not recommended as some products may cause discoloration and damage to the case.