# PROVISIONAL ABUTMENT

| SYMBOLOGY | DESCRIÇÃO | DESCRIPTION | DESCRIPCIÓN |
|---|---|---|---|
|  | NÃO ESTÉRIL | NON ESTERILE | NO ESTÉRIL |
|  | CONSULTAR INSTRUÇÕES DE USO | CONSULT INSTRUCTIONS FOR USE | CONSULTE LAS INSTRUCCIONES DE USO |
| CE | 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 |
| EC REP | REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA | AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY | REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA |
| 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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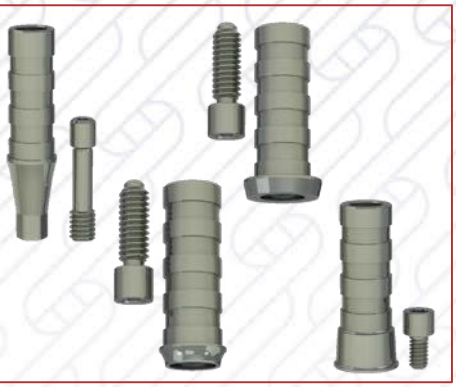
## PRODUCT:

Provisional Abutment

**Anvisa Registration:** 80108910027

CE 2460

**The Provisional Abutments are intended for specialized 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

**Provisional Abutment:** It consists of a cylindrical pillar, following the settlement platform according to each implant model. It is recommended for the fixation of the provisional prosthesis on the implant and is used as base for the preparation of the provisional restoration tooth.
**Screw:** It consists of a product with different thread options according to the characteristic of the implant with hexagonal fastening system. Its use is recommended for the fixation of the Provisional Abutments in the implants or working models.

## INDICATIONS OF USE

The Provisional Abutment is recommended for the fixation of the provisional prosthesis to the implant and or abutments, fastened through a screw. This product allows a temporary prosthetic solution, and should not exceed 06 months of use. After this period, the Provisional Abutment should be replaced by a definitive element according to the prosthetic solution chosen by the professional.
The prosthetic finalization takes place through the product/part of the product interface used in several stages, where the evolution of each stage depends exclusively on the success of the previous stage, 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 screw to be used;
- Stage 04: Definition of the type of "provisional tooth" to be used;
- Stage 05: "Provisional tooth" fixation.

## OPERATION PRINCIPLE

Provisional Abutments are based on mechanical principles of load-carrying system assembly. Since the Provisional Abutment is associated with the implant, the responsible for the transmission of the chewing force to the bone board, where they are surgically implanted..

## HOW TO USE

Provisional Abutments and screws should be sterilized as directed in this instruction manual.

1. Connect and modify the Provisional Abutment;
2. Close the screw access hole (*);
3. Perform a temporary restoration using a prefabricated mold with material suitable for crown and dental bridges;
4. Drill through the mold, loose the screw (s) using the appropriate wrench for the screw type and remove the restoration (*);
5. Make final adjustments;
6. Connect the provisional restoration.

(*) In the case of the provisional elements cemented to the abutments, disregard steps 01 and 04.

## CONTRAINDICATIONS

The use of these Provisional Abutments is contraindicated in the following cases:

- Chronic periodontal inflammation;
- Patient not prepared to undergo oral rehabilitation;
- Inappropriate parafunctional habits, for example, bruxism;
- Untreatable 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 can have effects in the region where it was applied as pain, swelling, short duration sensitivity, tissue reaction and infection.

## PRECAUTIONS AND RECOMMENDATIONS

For the placement of the Provisional Abutments, it is recommended that the professional has a specialization course in the area and that elaborates a prosthetic execution plan. The practitioner should sterilize all instruments prior to use, prepare the patient to minimize risk contamination risks and prevent the product from being in contact with any non-sterile objects. The professional should inform the patient the forms of hygiene to be made after application of the product.
For the placement of the Provisional Abutments and its screws, the surgeon must submit the patient to a full visual inspection to diagnose cases mentioned in contraindications. The diameter and angulation of the implant, as well as the gingival height should be taken into consideration. If a correct diameter is not used, it may occur irritation of the soft tissue. The Provisional Abutment sitting platform that adapts to the implant should not be altered in any way.
The dentist should sterilize all surgical instruments prior to use, prepare the environment with a sterile surgical field, submit the patient to a good oral asepsis, check the packaging of the product for its identification and integrity, be aware of the expiration date of the product, never use it with an expired validity and prevent the product from touching any non-sterile object at the time of application, in order to minimize contamination risks. Drills are recommended for the removal of material in restorative procedures (dental/ oral and maxillofacial / orthodontic). The dentist must be aware of the force exerted when applying the product so as not to damage it. The professional should inform the patient 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. products - 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 to the distribution time.

## STORAGE

Provisional Abutments should be stored in a dry, cool, ventilated place away from direct sunlight;

## TRANSPORTATION

Provisional Abutments should be transported at room temperature away from direct sunlight, avoiding locations where greater variations in temperature and humidity occur. The transportation must be carried out properly, to avoid falls and it must be carried out in its original package.

## HANDLING CONDITIONS

Once sterilized, Provisional 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 MATERIALS

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 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, once some products may cause discoloration and damage to the case.