IMPLANTABLE SCREW

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
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	REFER TO 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
	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
PROIBIDO REPROCESSAR	PROIBIDO REPROCESSAR	PROHIBITED REPROCESS	PROHIBIDO REPROCESAR
	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:

S.I.N. Sistema de Implante Nacional S/A

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RESPONSIBLE TECHNICIAN:

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PRODUCT:

Implantable Screw
Anvisa Registration: 80108910017

CE 2460

The IMPLANTABLE SCREW is 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

Implantable Screw (POT) High Utility model:
It consists of a self-drilling screw following external thread with several body diameters; the head has a perforation for attaching the steel ligature wire, spring and elastic and it is sold in yellow color. In the High Utility model, it is possible to use steel ligature wire, spring and elastic. They are available to professionals in STERILE form by gamma radiation. Indicated in orthodontic anchorage.

Implantable Screw (POTC) Wire Dynamic model: It consists of a self-drilling screw following external thread with several body diameters; the head has a perforation for attaching the orthodontic wire. In the Wire Dynamic model, only the wire. They are available to professionals in STERILE form by gamma radiation. Indicated in orthodontic anchorage.

INDICATIONS OF USE

The implantable screw is indicated in the direct or indirect intraoral orthodontic anchorage, simultaneous treatment between orthodontics and implant dentistry, for patients who have lost or not dental units and require orthodontic movements when reactive forces in the anchoring units are undesirable.

OPERATION PRINCIPLE

The Implantable Screw is based on the orthodontic treatment, whose purpose is to assist, supporting movement maneuvers made by the professional according to the needs of each patient.

HOW TO USE

Stage 1: Check if the package is in perfect conditions of use. If the package is damaged, do not use it.

Stage 2: Open the original package and remove the Implantable Screw.

Stage 3: After radiographic examinations, define the correct location for the implantable screw installation and anesthetize the region.

Stage 4: Start the drilling and install the screw.

CONTRAINDICATIONS

The preoperative assessment of the patient should be performed in order to determine the factors that may put the patient at risk due to the Implantable Screw placement procedure itself or factors that may affect the healing of the bone or adjacent tissues. The Implantable Screw should not be used in patients who are not medically fit to undergo a normal oral surgical intervention. For patients with localized or systemic factors that may interfere with the healing process of the bone or soft tissues (e.g. connective tissue disorder, steroid therapy, bone infections, smoking), the potential benefits and risks of the treatment should be carefully assessed.
The patient should also have an adequate volume of residual bone for the placement of the Implantable Screw of appropriate dimensions and number.

An insufficient size or number of the Implantable Screw to withstand biomechanical loads or an undesirable positioning may lead to mechanical failures of these elements, including fatigue ruptures.

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 Implantable Screw 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, swelling, tenderness of short duration, tissue reaction or infection.

PRECAUTIONS AND RECOMENDATIONS

Each patient should be carefully examined and assessed in order to determine the radiographic, psychological, and physical state, as well as dental, bone or adjacent soft tissue deficits that may influence the final results of the intervention. The patient should be instructed to maintain a perfect oral hygiene, especially in the immediate postoperative period. If the patient needs to undergo MRI, the responsible medical team should be informed of the presence of the Implantable Screw. Every effort should be made to minimize host tissue damage, with special focus on thermal or surgical trauma and on the elimination of contaminants and other sources of infection. The surgical procedure requires a high level of accuracy and care because the limits for acceptable tissue handling are much narrower than in the case of general oral surgery. Any divergence from the principle of the least possible injury during the installation of the Implantable Screw increases the risk of non-bone integration on part of the component. All drilling procedures should be performed at low speed (around 800 to 1200 rpm). All procedures should be performed with delicate and well-sharpened instruments under constant and abundant irrigation for adequate cooling. All instruments used in the intervention must be kept in good conditions. Due to the reduced dimensions of components and instruments, extreme care should be taken to prevent the patient from swallowing or aspirating them.

WARNING

SINGLE USE PRODUCT – STERILE
Sterilization Process: Gamma Radiation.
Non-ensured sterilization if the seal is broken.

TRACEABILITY

All S.I.N. - Sistema de Implante 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

The IMPLANTABLE SCREW must be stored in a cool and dry place and away from sunlight.

TRANSPORTATION

The IMPLANTABLE SCREW must be transported in room temperature, away from direct sunlight, avoiding places where large variations of 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

The IMPLANTABLE SCREW is a sterile product that should be handled only in a sterile field by properly trained professionals and in appropriate scrubs at the time of the surgical procedure.

ADDITIONAL INFORMATION

Single use product. Prohibited Reprocessing.
Exclusive dental use product.

DISPOSAL OF MATERIAL

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

EXPIRATION DATE

Indicated on the label.