# IMPLANTABLE SCREW

**The IMPLANTABLE SCREW is intended for specialized procedures, which must be performed by qualified professionals. The form of use of the product and surgical techniques are inherent to the formation of the professional. The use of the product must be performed in a surgical environment and under adequate conditions for the patient's health and safety.**

## PRODUCT DESCRITION

**Implantable Screw (POT) High Utility model:**
Consists of a self-perforating screw following external thread with varied body diameters, the head features perforation for fixing the mooring thread, spring and elastic is marketed in yellow color. In the High Utility model it is possible to use mooring thread, spring and elastic. They are available to the professional as STERILE by gamma radiation. Indicated for orthodontic anchorage.

**Implantable Screw (POTC) Wire Dynamic model:**
Consists of a self perforating screw following external thread with varied body diameters, the head has perforation for fixing the orthodontic wire. In the Wire Dynamic model only the wire is used. They are made available to the professional as STERILE by gamma radiation. Indicated for orthodontic anchorage.

## INDICATIONS OF USE

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

## OPERATION PRINCIPLE

The Implantable Screw bases its principle of operation on the orthodontic treatment whose objective is to assist, serving as support to the movement maneuvers made by the professional according to the needs of each patient.

## HOW TO USE

**Stage 1:** Check that the packaging is in perfect condition for use. If the package is damaged, do not use it.
**Stage 2:** Open the original package and remove the Implantable Screw.
**Stage 3:** Define, after radiographic exams, the correct site for the implantable screw installation and anesthetize the region.
**Stage 4:** Start drilling and install the screw.

## ATTENTION

The Implantable Screws are intended for specialized procedures, which must be performed by qualified professionals in Implant Dentistry. The use of the product must be performed in a surgical environment and under adequate conditions for the health and safety of the patient.

## PRECAUTIONS

Each patient must be carefully examined and evaluated in order to determine the radiographic, psychological and physical state, as well as any dental or bone or adjacent soft tissue deficits that might influence the final result of the intervention. The patient must be instructed to maintain perfect oral hygiene, especially in the immediate post-operative period. If there is the need for the patient to be submitted to a Magnetic Resonance exam, the medical team in charge must be informed about the presence of the Implantable Screw. Every effort should be made to minimize injury to the host tissue, with special attention to thermal or surgical trauma, and to eliminate contaminants and other sources of infection. The surgical procedure requires a high level

of precision and care, because the limits for acceptable tissue handling are much narrower than in general oral surgery.

## RECOMMENDATIONS

Any deviation from the principle of minimum possible injury during the installation of the Implantable Screw increases the risk of non-integration of the component into bone. All drilling procedures should be performed at low speed (about 800 to 1200 rpm). All procedures should be performed with delicate and sharp instruments, under constant and abundant irrigation for adequate cooling. All instruments used in the intervention should be kept in good condition. Due to the small size of the components and instruments, the utmost care should be taken to prevent swallowing or aspiration by the patient.

## CONTRAINDICATIONS

A preoperative evaluation of the patient should be performed in order to determine the factors that may put the patient at risk due to the 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 medically unfit to undergo normal oral surgical intervention. For patients who have localized or systemic factors that may interfere with the bone or soft tissue healing process (e.g. connective tissue disorder, steroid therapy, bone infections, smoking) the potential benefits and risks of treatment should be carefully evaluated. The patient must also have an adequate volume of residual bone for the placement of an implantable screw of adequate size and number. The insufficiency of the size or number of the Implantable Screw to support the biomechanical loads or the undesirable positioning of them can lead to mechanical failures of these elements, including ruptures by fatigue.

## SIDE EFFECTS

If the technique used is not adequate and the patient is not submitted to the indicated exams, the final result of the Implantable Screws application can be unsuccessful, generating a loss or fracture of the product. The application of the product can have effects in the region where it was applied, such as: pain, swelling, short term sensibility, tissue reaction, infection.

## WARNING

SINGLE USE PRODUCT - STERILE
Sterilization Process: Gamma Radiation.
Sterilization not guaranteed if the seal is violated.

## TRACEABILITY

All S.I.N. - Implant System products have sequential lots that allow for traceability, thus promoting greater safety for the professional who is qualified for the procedure. Through this lot number it is possible to know the entire history of the product from the manufacturing process to the moment of distribution. The implant card is sent in 3 copies, with one copy being given to the patient.

## STORAGE

The IMPLANTABLE Screwdriver should be stored in a dry, cool, well-ventilated place away from direct sunlight.

## HANDLING

The IMPLANTABLE SCREW is a sterile product and must be handled only in a sterile environment by professionals properly dressed and gowned at the time of the surgical procedure.

## DISPOSAL OF MATERIAL

The disposal of materials must be done according to hospital standards and local legislation in force.

## TRANSPORTATION

The IMPLANTABLE Screw must be transported at room temperature, away from direct sunlight, avoiding places where there are large variations in temperature and humidity. The transportation must be done in a proper way, to prevent it from falling and must be done in its original packaging.

## COMPLEMENTARY INFORMATIONS

Magnetic Resonance Imaging (MRI): The safety and compatibility of S.I.N. dental implants with the MRI environment have not been evaluated. No heating, displacement or distortion experienced by S.I.N. dental implants in the MRI environment have been tested. The safety of S.I.N. dental implants in the MRI environment is unknown. Performing an MRI scan on a patient with this device could result in harm to the patient. Product Exclusively for Dental Use. In case of any incident caused by the product, the practitioner must inform the manufacturer immediately. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplante.com.br or call to 0800 770 8290 will receive until 7 days calendar.

## STERILE R FORM OF PRESENTATION AND STERILIZATION

This product is supplied sterile and single-use (sterilization method: gamma radiation) unitarily packed in packaging that offers triple protection: tertiary packaging (cardboard), secondary blister packaging (pet film and surgical grade paper) and primary packaging (transparent tube).

## EXPIRATION DATE

Information regarding the expiration date can be found on the product labeling. After installation in the patient, the product must be monitored by a 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 | MANUFACTURE | FABRICANTE |
|  | DATA DE FABRICAÇÃO | DATE OF MANUFACTURE | FECHA DE FABRICACIÓN |
|  | VALIDADE | USE-BY DATE | VALIDEZ |
| REF | CÓDIGO DE REFERÊNCIA | REFERENCE CODE | CÓDIGO DE REFERENCIA |
| MD | DISPOSITIVO MÉDICO | MEDICAL DEVICE | DISPOSITIVO MEDICO |
| UDI | IDENTIFICADOR ÚNICO DO DISPOSITIVO | UNIQUE DEVICE IDENTIFIER | IDENTIFICADOR DE DISPOSITIVO ÚNICO |
|  | SISTEMA DE BARREIRA DOUPLO ESTÉRIL | DOUBLE STERILE BARRIER SYSTEM | SISTEMA DE DOBLE BARRERA ESTÉRIL |
|  | IMPORTADOR | IMPORTER | IMPORTADOR |
|  | DISTRIBUIDOR | DISTRIBUTOR | DISTRIBUIDOR |
|  | PAÍS DE FABRICAÇÃO | COUNTRY OF MANUFACTURE | PAÍS DE FABRICACIÓN |
| LOT | LOTE | BATCH CODE | LOTE |
|  | EMBALAGEM RECICLÁVEL | RECYCABLE PACKAGING | EMBALAJE RECICABLE |

**DEVELOPED AND MANUFACTURED BY:**
S.I.N. National Implant System S/A
CNPJ: 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 2445 - Vila Rio Branco CEP: 03348-060 - São Paulo - SP - Brazil

**SERVICES TO THE PROFESSIONAL**
0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com
e-mail: sin@sinimplante.com.br

EC REP

**OBELIS S.A.**
Bd. Général Wahis 53
1030 Brussels, Belgium

CE 2460

**RESPONSIBLE TECHNICIAN:**
Alessio Di Risio
CREA-SP: 5061207169

**PRODUCT :** Implantable Screw

**REGISTER ANVISA:** 80108910017