BONE GRAFT 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

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 2445 - Vila Rio Branco CEP: 03348-060 - São Paulo - SP - Brazil
Phone/Fax: +55 (11) 2169-3000

SERVICE TO PROFESSIONALS

0800 770 8290
+55 (11) 2169-3000
www.sinimplante.com.br
e-mail: sin@sinimplante.com.br

EC REP

OVER-REV-UNIPESSOAL LDA.

Rua General Ferreira Martins, nº10 8D1495-137 - Algés - Portugal

RESPONSIBLE TECHNICIAN:

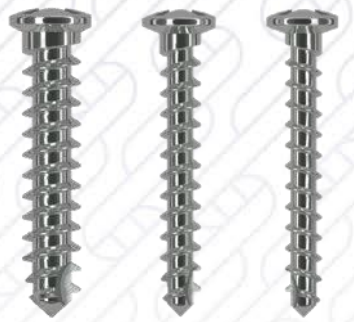
Alessio Di Risio
CREA-SP: 5061207169

PRODUCT:

Bone Graft Screw
Anvisa Registration: 80108910018

CE 2460

The BONE GRAFT 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

Bone Graft Screws have diameters of 1.4mm, 1.6mm, and 2.0mm and the screw length vary between 4.0 and 25.0mm with cross type insertion slot.

INDICATIONS OF USE

Bone Graft Screws are used in the maxillary autogenous bone graft surgery. These screws are called temporary, and only the healing period and bone repair remain, as their purpose is to keep the graft in position and not to osseointegrate.

OPERATION PRINCIPLE

The Bone Graft Screw is based on its working principle in the fixation of the bone graft, holding it in position during the period of healing and bone repair.

HOW TO USE

1. Select the length of the screw according to the thickness of the bone board and receiving region in order to stabilize it;
2. Select the necessary drills to obtain the proper drilling of the place taking into account the screw length, the thickness of the bone board, and receiving region;
3. Perform the desired drilling;
4. With the aid of the graft screwdriver, insert the screw by tightening until it is fully set, but do not force it after fixing, as the bone border may fracture and/or damage 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 screw placement procedure itself or factors that may affect the healing of the bone or adjacent tissues. Bone graft screws 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.

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 Bone Graft Screw may not succeed, generating 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 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 screws.
The treatment planning and placement of bone graft screws require special considerations in comparison to general dental techniques. It is recommended to the dental surgeon the frequency of practical courses, in order to learn appropriate techniques, including biomechanical and radiographic interpretation. The application of incorrect screw placement techniques can lead to failure of the screws and substantial loss of the adjacent bone.

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 Bone Graft Screw must be stored in a cool and dry place and away from sunlight.

TRANSPORTATION

The Bone Graft 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 Bone Graft 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.