BONE GRAFT SCREW

The Bone Graft 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 health and safety of the patient.

PRODUCT DESCRITION

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

INDICATIONS OF USE

The Bone Graft Screws are used in autogenous bone graft surgery in the maxilla. These screws are called temporary, remaining only during the healing and bone repair period, because their purpose is to keep the graft in position and not to osseointegrate.

OPERATION PRINCIPLE

The Bone Graft Screws are used in autogenous bone graft surgery in the maxilla. These screws are called temporary, remaining only during the healing and bone repair period, because their purpose is to keep the graft in position and not to osseointegrate.

HOW TO USE

1. Select the length of the screw according to the thickness of the bone block and receiving region, in order to stabilize it;
2. Select the necessary drills to obtain the adequate local perforation taking into account the screw length, the thickness of the osseous block and receptor region;
3. Perform the desired perforation;
4. With the graft screwdriver, introduce screw tightening until total fixation and should not be forced after fixation, as this can fracture the bone block and/or damage the screw.

ATTENTION

The Bone Graft Screw 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 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 undergo a magnetic resonance exam, the medical team in charge must be informed about the presence of the screws. Treatment planning and the placement of bone graft screws require special considerations comparable to general dental techniques.

RECOMMENDATIONS

It is recommended that the dental surgeon attend practical courses to learn the proper techniques, including biomechanical and radiographic interpretation. The use of incorrect techniques of screw placement can lead to screw failure and a substantial loss of adjacent bone.

CONTRAINDICATIONS

A preoperative evaluation of the patient should be done, in order to determine the factors that can put the patient at risk due to the placement procedure of the screws, or factors that can affect the healing of the bone or adjacent tissues. Bone graft screws should not be used in patients who are medically unfit to undergo 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.

SIDE EFFECTS

If the technique used is not adequate and the patient is not submitted to the indicated exams, the final result of the Bone Graft Screw application may not be successful, generating a loss or fracture. The application of the product may have effects in the region where it was applied, such as pain, swelling, short-term sensitivity, tissue reaction, and 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 Bone Graft Screw should be stored in a dry, cool, well-ventilated place away from direct sunlight.

HANDLING

The Bone Graft Screw is a sterile product and should be handled only in a sterile environment by properly dressed professionals in appropriate attire 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 Bone Graft Screw must be transported at room temperature, away from direct sunlight, avoiding places where there are great variations in temperature and humidity. The transportation must be done in an adequate manner, 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
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
35°C	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
BRA	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
LOT	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE

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