SURGICAL KIT

S.I.N. Graft Kit

The S.I.N. Graft Kit is 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 DESCRITION

The S.I.N. Graft Kit is composed of instruments used to fix screws during bone graft placement surgeries.

INDICATIONS OF USE

The S.I.N. Graft Kit is indicated for bone graft surgery.

Driver Hands: Quick coupling facilitates exchange, allows a 360° rotation, facilitates torque with perfect hand accommodation, better transmission of force, prevents oxidation and facilitates the visualization for attachment to hands.
Long and short Screw Drill: It facilitates the exchange, increase fixation of screws decreasing the risk of falls, an option and a solution for places of difficult access.
Cilindric Drill: Recommended for initiation of bone breakage and for screws with larger diameters, it facilitates cutting (perforation), ideal cutting format for perforation, allows visualization of drilling height, lower contamination index.

OPERATION PRINCIPLE

The operating principle applicable to the S.I.N. Graft Kit is rotating, that is, purely mechanical. The Torque exerted on the screw clockwise causes the bolt to penetrate the bone by fixing the graft in the position chosen by the professional.

HOW TO USE

Because it is an advanced surgical technique, S.I.N. Graft Kit must be used by professionals with deep technical knowledge acquired in a specialization course of Implant Dentistry or Oral and Maxillofacial Surgery. The dental surgeon should use the bone graft kit in procedures to increase horizontal or vertical alveolar bone tissue for block graft fixation. The professional should carry out a detailed anamnesis of the clinical case for diagnosis and surgical planning of the defect to be treated using three-dimensional imaging tests such as computed tomography. Once the treatment plan is defined, the professional should select the graft donor area, in cases of autogenous bone graft, or acquire a block biomaterial with dimensions that are compatible with the defect to be treated. The graft receiving area should be surgically exposed through a full thickness flap and must be clean and healthy to receive the graft. The chosen block graft should then be adjusted to the anatomy of the defect and secured in place using the S.I.N. bone graft screws with graft-compatible lengths and diameters. For fixation of the graft, it should be perforated using the drills available in the S.I.N. Graft Kit, and the selected screws must be manually installed by clockwise rotation to their final seating using the driver hands available in the S.I.N Bone Graft Surgical Kit. Excessive force should be avoided in the screw installation as it may lead to deformation or fracture of the screw.

ATTENTION

The S.I.N. Graft Kit is intended for specialized procedures, which must be performed by qualified professionals in 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

To use S.I.N. Graft Kit it is recommended that the professional have a specialization course in the area. The professional should submit the patient to a detailed anamnesis and definition of the treatment plan to diagnose the cases mentioned below, in the contraindications. Excessive use of Instruments, poor positioning, added to the leverage caused during use can compromise the active tip of the keys and the cutters. The professional should be aware of the force applied when using the product, in order not to cause harm to the patient and the product. The professional should inform the patient: the appropriate form of hygiene, the need for periodic monitoring and avoiding physical efforts after the application.

RECOMMENDATIONS

It is recommended to use up to 20 to 30 perforations, which are:

- 20 high-density bone perforations;
- 30 perforations in low density bones.

Do not stick labels, tapes, as well as write, or mark the surface of the product.
It is recommended to immediately wash and sterilize the kit and its components after use.

CONTRAINDICATIONS

Bone graft surgeries for increasing horizontal or vertical alveolar thickness are indicated only in cases where the patient presents local and systemic conditions adequate for this type of procedure. Changes in local and systemic health may temporarily or definitively contraindicate bone graft surgery and should be evaluated by the professional prior to surgery. S.I.N. Graft Kit does not present contraindications once that its recommendations are followed correctly and used by specialized professionals.

SIDE EFFECTS

O KIT ENXERTO S.I.N. é utilizado para estabilização de enxertos ósseos em bloco, dessa forma efeitos adversos ocorrerão apenas se a escolha do instrumental for inadequada.

WARNING

Não utilize o instrumental caso observe fissuras, desgaste ou pontos de oxidação/corrosão. Isso poderá ocasionar problemas no funcionamento das fresas odontológicas. Todos os itens podem apresentar desgaste natural gerado pelo uso e devem ser substituídos sempre que o profissional identificar perda de capacidade de encaixe ou precisão destes produtos, pois podem interferir no resultado final do trabalho.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches that allow for traceability, thus providing greater security to 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.

STORAGE

The S.I.N. Graft Kit should be stored in a cool, dry place, at a maximum temperature of 35°C and protected from direct sunlight.

HANDLING

Once sterilized, the instruments should be handled only in a sterile environment by properly dressed professionals in appropriate attire at the time of implant installation surgery.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

The S.I.N. Graft Kit must be transported in a proper way to avoid falls and stored at a maximum temperature of 35°C, protected from heat and humidity. The transport must be carried out in the original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for Odontological use. Passible of Reprocessing. See cleaning and sterilization conditions contained in this use instruction. In case of any incident caused by the product, the professional 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.

CLEANING INSTRUCTIONS

1. Remove manually all surgical instruments from the kit. Remove the kit box parts (lid, tray and bottom).
2. Prepare the enzymatic detergent, according to manufacturer's recommendation.
3. Immerse the trays into the prepared detergent solution and keep in contact for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove trays from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
5. Visual inspection of each part for cleaning process residue or organic waste from product use.
6. If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
7. Dry with a soft, clean, dry cloth or disposable paper.

RECOMMENDATIONS

a. Use the proper PPEs (gloves, masks, goggles, caps, etc.).
b. Start the cleaning right after the surgical use.
c. Never let the instruments dry with organic waste after the surgical use.
d. Never let the instrument dry naturally after cleaning.
e. Never use saline solutions, include sodium hypochlorite, disinfectant, hydrogen peroxide or alcohol to cleaning or rinsing the surgical instruments and kits.
f. Never use steel wool and abrasive products, so that the instruments are not damaged.
g. Do not stack the instruments in lots to avoid the deformation of smaller and delicate pieces.

STERILIZATION

Reusable product and provided non-sterile. It must be clean and sterilized in autoclave before use.

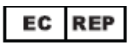
1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed in a steam sterilizable wrap.
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave over a plane surface and away of device walls.
5. Never stack objects or other cases.

RECOMMENDATIONS

a. Sterilize the products in the same day or one day earlier the procedure.
b. The chemical sterilization is not recommended, once some products may cause the discoloration and damages to the case.
c. Do not use temperature higher than 60°C to drying process.
d. Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N. - Implant System.

LIFE TIME

The S.I.N. Graft Kit can be reprocessed, depending on proper handling, cleaning, and sterilization, up to 250 times.

	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	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
	ATENÇÃO	CAUTION	PRECAUCIÓN
	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
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCLABLE PACKAGING	EMBALAJE RECICLABLE

DEVELOPED AND MANUFACTURED BY:
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