S.I.N. BONE GRAFT SURGICAL KIT

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTERIL
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE UTILIZACIÓN
	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
EC REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
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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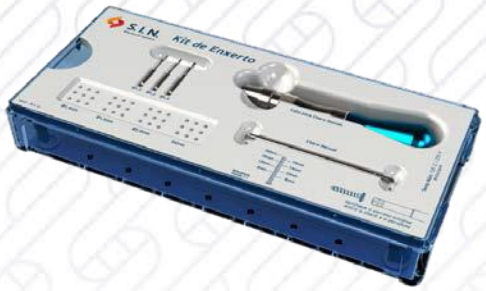
PRODUCT:

S.I.N. Graft Kit
Anvisa Registration: 80108910061

CE

The Bone Graft Surgical 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 DESCRIPTION

The Bone Graft Surgical Kit is composed of instruments used to fix screws during bone graft placement surgeries.

INDICATIONS OF USE

The Bone Graft Surgical 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. BONE GRAFT SURGICAL 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. Bone Graft Surgical 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. Bone Graft Surgical 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.

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. BONE GRAFT SURGICAL KIT does not present contraindications once that its recommendations are followed correctly and used by specialized professionals.

SIDE EFFECTS

S.I.N. BONE GRAFT SURGICAL KIT is used to stabilize bone block grafting, so adverse effects will occur only if the choice of instruments is inadequate.

PRECAUTIONS AND RECOMMENDATIONS

To use S.I.N. BONE GRAFT SURGICAL 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.

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.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of dental drilling.

All items may appear a natural wear due use and they should be replaced whenever the professional identifies loss of fitting capacity or accuracy of these products, as they may interfere with final work results.

TRACEABILITY

All S.I.N. products - Implant System 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

Bone Graft Surgical Kit Instruments should be stored in a dry, fresh, ventilated place away from direct sunlight;

TRANSPORTATION

The instruments of the Bone Graft Surgical Kit should be transported at room temperature, away from direct sunlight avoiding places where greater variations in temperature and humidity occur. The transportation must be carried out properly, in order to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

Once sterilized, instruments should be handled only in a sterile environment by properly trained professionals and in appropriate attire at the time of surgery to install dental implants.

COMPLEMENTARY INFORMATION

Multiple use product. Reprocessing Allowed. Check Cleaning and Sterilization Conditions included in these Use Instructions.

CLEANING INSTRUCTIONS

1. Pre-cleaning or De-embedding

a. Remove the organic matter from the instruments without manual contact.

b. Begin cleaning or de-embed quickly after surgical use.

Recommendations

a. Wear appropriate scrubs (gloves, masks, goggles, caps, etc.).

b. Use enzyme solutions at the concentration and time of exposure determined by the manufacturer of these chemical solutions

c. Perform a single rinse, directly under a stream of water, without handling the instruments.

2. Decontamination

a. The cleaning of microorganisms in vegetative form

b. This type of cleaning offers occupational hazards.

Recommendations

a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.

b. Never use saline solutions, especially sodium Hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

3. Washing

a. It is the removal of debris from surgical instruments through manual brushing or ultrasonic vibrations.

Recommendations

a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.

b. Use neutral soap at 1% or neutral detergent, both at pH 7.0.

c. Always use brushes with natural or Nylon bristles for cleaning racks, serrations and fittings.

d. Never use steel straws or sponges and abrasive products not to damage the instruments.

e. Do not accumulate instruments in large quantities on top of one another, to avoid deformation of minor and delicate parts.

f. Try to handle a few pieces at a time.

g. The ultrasonic cleaning, if used, should have the washing solution heated to a temperature of at least 45°C, as well as the instruments should be placed in open position for 3 to 5 minutes of immersion at a frequency of 35 KHz.

h. There may also be the need to brush the serrated parts and joints.

4. Rinse

a. It is the removal of chemical residues, detergents and foams still present in the instruments.

Recommendations

a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.

b. Never use saline solutions, especially sodium Hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

5. Drying

a. It is the removal of residual water and moisture, after the rinsing procedure.

Recommendations

a. Never let the instrument dry naturally.

b. Always use soft, absorbent fabric (e.g. Compressed material) or moisture-free compressed air.

c. Never use dry heaters to dry the S.I.N. Instruments.

STERILIZATION

It is the procedure that aims at the total elimination of microorganisms (viruses, bacterias, microorganisms, and fungi), either in vegetative or sporulated form.

Recommendations

a. Dry all instruments before the steam sterilization cycle.

b. Use mechanical and chemical indicators (place the internal chemical indicator between instruments or materials to be sterilized) for each sterilization cycle.
c. Allow instruments to dry and cool in the sterilizer before handling, to prevent contamination and oxidation of materials.
d. The autoclavable case can be sterilized at 121°C at 1 ATM pressure for 30 minutes or at a temperature of 134°C at 2 ATM pressure for 20 minutes.
e. Always place the case in an autoclave on a flat surface and away from the edges of the device.
f. Never overlap objects or even other cases.
g. The chemical sterilization is not recommended as some products may cause discoloration and damage to the case.

DISPOSAL OF MATERIALS

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

EXPIRATION DATE

Indicated on the label.