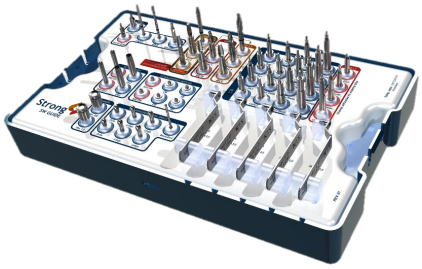
SURGICAL KIT

Strong SW Guide Surgical Kit - KCSWG

The Strong SW Guide Surgical Kit - KCSWG 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 Strong SW Guide Surgical Kit - KCSWG is a kit composed of the complete line of instruments necessary to install Strong SWHE: ø4.1mm and 4.5mm implants, SWCM: ø3.5mm and 4.5mm.

INDICATIONS OF USE

Recommended for installing Strong SW line implants in cases of total, partial or single rehabilitations, using the guided surgery technique.

OPERATION PRINCIPLE

The instruments contained in the Strong SW Guide Surgical Kit are based on mechanical action. All instruments are indicated for use in the placement of Strong SW implants and must be used following the appropriate dental techniques.

Fixators: Help in fixation or removal of components and implants;

Cutters: Used in drilling and bone abrasion;

Stem, Cylinders and Washers: Indicated to aid and guide correct drilling;

Forceps and Tweezers: Used to facilitate the handling of components and implants in the surgical procedure;

Stabilizers: Assist in fixing the surgical guides.

HOW TO USE

1. After planning the case and making the surgical guide, position the surgical guide over the region to be implanted, then drill the fixation area of the surgical guide with helical milling cutter Ø1.65mm (FHG 1620) - (1500RPM);
2. Position the surgical guide fixators (FGC 16) in order to stabilize the surgical guide;
3. Make the circular incision using the mucosa extractor (EMC 50) and counter-angle;
4. Complement the circular incision with the mucosa puller (EMM 50) manually if necessary;
5. Use initial guided cutter (FICG 50) to guide the next cutter and eliminate possible leftover soft tissue (mucosa); With the help of the 2.0 Milling Guide (HGF 20), break through the cortical bone with the guided lance cutter* (FRLG 2015) - (1500 RPM);
6. Using the same Cutter Guide as before, prepare the surgical alveolus with the Ø2.0mm guided helical cutter (FHG 2015) up to the height marking of the pre-selected implant - (1500RPM);
7. With the help of the 3.0 Milling Guide (HGF 30), prepare the surgical alveolus with the Ø2.0mm to Ø3.0mm pilot guided cutter (FPG 2030) up to the stop depth present in the cutter - (1500RPM);
8. Using the same Guide cutter as before, use guided conical cutter specific for the implants to be used up to the height marking of the pre-selected implant - (800 RPM);
9. In 7.0 implants (SCW 3707) disregard this step (countersink guided cutter with final profile of the 7.0mm implant);
10. Use countersink guided cutter for Strong Ø4.1mm (FCWG 41) up to height marking - (800 RPM). In dense bone (types I and II) use guided countersink for Strong implants Ø3.75 (MRIWG 37) - (25 RPM);

11. Position the Washer (AGCI35/AGCI41/AGCI45) guide for implant in the hole of the surgical guide;
12. After opening and capturing the implant to be installed, take the set to the prepared surgical socket and install the implant (20 RPM);
13. If necessary, complete the installation with the surgical torque wrench (TMECC) or the ratchet (CDC 100) coupled to the ratchet wrench
14. After implant seating, remove the implant installation key and the implant guide washer;
15. If necessary insert the vertical stabilizer (EVG 50) with the 1.2mm hex wrench (CDH 1220 or CDH 1224).

ATTENTION

The Strong SW Guide Surgical Kit - KCSWG 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

The Strong SW Guide Surgical Kit - KCSWG requires specialized surgical procedures, should only be used by qualified dental surgeons, including: diagnosis, preoperative planning and surgical protocol. The use of the product without knowledge of proper techniques and/or inadequate procedures and conditions, may harm the patient leading to unsatisfactory results.

RECOMMENDATIONS

For cutters, a maximum of 20 to 30 perforations is recommended, of which:

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

Do not stick labels, adhesive tape, write or demarcate the product's surface.

- During the preparation of the socket, avoid bending the cutters laterally and use abundant and uninterrupted irrigation. For a single operative time or immediate loading, the selected intermediate abutment must be installed.
- The threaded taps of the guided system have a standard depth of 8.5mm for cutting the cortical region, if the installed implant is shorter than 8.5mm in length, pay attention to the depth to be used by the threaded tap.
- The transport of the implant from the packaging to the insertion in the alveolus must be done through the keys with fitting for counter angle.

CONTRAINDICATIONS

The Strong SW Guide Surgical Kit - KCSWG has no contraindications as long as its recommendations are correctly followed and used by a specialized professional, who will be responsible for the adequate planning of the surgical procedure in which the Kit will be used.

SIDE EFFECTS

The Strong SW Guide Surgical Kit - KCSWG has no adverse effects.

WARNING

Do not use the instruments in case you notice cracks, wear or oxidation/corrosion points. This can cause problems in the functioning of the products, installation of the implants and in the post-operative period.

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 Strong SW Guide Surgical Kit - KCSWG should be stored in a dry, cool, well-ventilated place away from direct sunlight;

HANDLING

Once sterilized, the instruments must be handled only in a sterile environment by properly dressed professionals in appropriate attire at the time of surgery for installation of dental implants. Scratches, bends or notches of the surgical instruments must be avoided, since such factors can increase the possibility of corrosion of the products.

DISPOSSAL OF MATERIAL

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

TRANSPORTATION

The Strong SW Guide Surgical Kit – KCSWG must be transported at room temperature, protected from direct sunlight, avoiding places where there are wide variations in temperature and humidity. The transportation must be done in a proper way to avoid falling and must be done in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive of 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 INFORMATIONS

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 Strong SW Guide Surgical Kit - KCSWG can be used as follows depending on proper handling, cleaning and sterilization:

Cutters: 20 perforations in high density bone
30 perforations in low-density bone;

Washers: Single use;

Stem, Cylinders, Fixators, Stabilizers, Forceps and Clamps: 250 uses.

	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:
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

SERVICE TO PROFESSIONALS
0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com
email: sin@sinimplante.com.br

EC REP

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

CE

RESPONSIBLE TECHNICIAN:
Alessio Di Risio
CREA-SP (register): 5061207169

PRODUCT: Kit Cirúrgico Strong SW Guide - KCSWG

ANVISA REGISTRATION: 80108910042