SURGICAL KIT

Osteotome Kit - KOST

The Osteotome Kit - KOST 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

The Osteotome Kit - KOST is a Kit made up of four Summers Osteotomes with Stop. The instruments of the Kit are manufactured in:

Stainless steel
Osteotome.

Udel Polisulfone
Box.

Osteotome: Are used as surgical instruments during bone compaction or partial elevation of the maxillary sinus procedures and are not implantable. They allow the placement of osseointegrated implants, without or with little use of drills, to make better use of the patient's remaining bone tissue, often avoiding the need for bone grafting.

Box: Support for storing, transporting and sterilizing all kit items.

INDICATION OF USE

The Osteotome Kit consists of four Summers Osteotomes with Stops. These osteotomes are non-implantable surgical instruments intended for use during procedures involving bone compaction or partial elevation of the maxillary sinus. They facilitate the placement of bone-integrated dental implants with minimal or no use of drills, optimizing the utilization of the patient's remaining bone tissue and often eliminating the need for bone grafting. The kit is intended for professional use by trained dental surgeons in conjunction with S.I.N. dental implant systems.

PURPOSE AND OPERATION PRINCIPLE

The operating principle applicable to Osteotome Kit - KOST is that of the lever, that is, purely mechanical. The force exerted at the distal (wider) end is transferred throughout the body of the instrument, to the proximal end, which acts at the surgical site, compacting the bone in a vertical and/or horizontal direction.

HOW TO USE THE INSTRUMENT

The dentist must use the Osteotome Kit - KOST in bone compaction or partial elevation of the maxillary sinus procedures, following aseptic surgical techniques appropriate to each case. Described below is a suggested guide for the use of Osteotome Kit - KOST in cases of bone compaction and partial elevation of the maxillary sinus. After using the Osteotome Kit - KOST, separate it from other materials, wash and sterilize them following the instructions in the cleaning, disinfection and conditioning item described in this instruction for use.

Bone compaction:

1. Firstly, the bone is subjected to an initial drilling at the site of the implant to be installed with the lance drill, followed by the helical drill until the planned depth.
2. Before using the instruments, it is recommended to assemble the depth limiters, so as not to exceed the previously determined working depth.
3. Straight instruments allow easier access to the posterior area.
4. Larger diameter instruments are inserted manually, with slightly rotating movements or with light hammer blows, according to the length and diameter of the desired implant.
5. Careful insertion of the implant is recommended.

Partial elevation of the floor of the maxillary sinus:

1. Firstly, the bone is subjected to an initial drilling at the site of the implant to be installed with the lance drill, followed by the helical drill up to the limit of the floor of the maxillary sinus, with due care not to break this cortex with the drill. This process presupposes exact planning for the imaging exam.
2. Before using the instruments, it is recommended to mount the depth stop, so as not to exceed the previously determined working depth. Depth stops are mounted on the instruments manually. Straight instruments allow easier access to the posterior area.
3. After drilling, the floor of the maxillary sinus is fractured using a 2mm diameter Osteotome, which requires planning for the exact imaging examination. It is recommended to work with a depth limiter, so as not to exceed that previously defined in planning. The instrument is advanced with light hammer blows, according to the desired length of the implant.
4. During elevation, a filling material (autogenous bone or bone substitute) can be applied to the implant bed prior to its installation. The material introduced has the effect of a cushion that lifts the membrane of the maxillary sinus, according to the hydraulic principle.
5. Careful insertion of the implant is recommended.
6. Depending on bone availability and density at the site, it may be necessary to alternately use Osteotomes and drills with progressive diameters to obtain satisfactory clinical results.

⚠ ATTENTION

The Osteotome Kit - KOST intended for specialized procedures, which must be performed by qualified professionals in implantology. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTIONS

Excessive use of Osteotomes, poor positioning, and the lever effort caused during use can compromise the active tip of the Osteotomes. The professional must be aware of the force

exerted when using the product to avoid causing damage to the patient and the product. The professional must: prepare an environment with sterile clothing and surgical field, subject the patient to good oral asepsis, prevent the product from coming into contact with any non-sterile object at the time of application, to reduce the risk of contamination to a minimum. The professional must inform the patient: the appropriate form of hygiene, the need for periodic monitoring and avoiding physical exertion after surgery.

RECOMMENDATIONS

To use the Osteotome Kit - KOST, it is recommended that the professional has completed a specialization course in the area of Implantology or Oral and Maxillofacial Surgery. The professional must subject the instruments to a thorough visual inspection to diagnose cases mentioned in the warnings.

CONTRAINDICATION

The Osteotome Kit - KOST has no contraindications as long as its recommendations are followed correctly and used by a specialized professional, who will be responsible for the appropriate planning of the surgical procedure in which the Osteotome Kit - KOST will be used.

SIDE EFFECTS

The Osteotome Kit - KOST is used to assist in the installation of prosthetic components on dental implants, therefore adverse effects will only occur if the choice or use of the instrument is inadequate.

WARNING

Do not use the instrument if you notice cracks, wear or spots of oxidation/corrosion. This may cause problems with the functioning of the instruments. All items may show natural wear and tear caused by use and must be replaced whenever the professional identifies loss of fitting capacity or precision of these products, as they may interfere with the result of the work.

TRACEABILITY

All S.I.N. products have sequential batches that allow traceability, thus promoting greater safety for professionals skilled for the procedure. Through this lot number it is possible to know all product history from the manufacturing process to the time of distribution.

STORAGE

The Osteotome Kit - KOST should be stored in a cool dry place at a temperature of 15°C to 25°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

Once sterilized, the instruments should be handled in a sterile environment by properly attired professionals and in appropriate clothing at the time of surgery to install implants. Scratches or notches of the instruments should be avoided as such factors can increase the possibility of corrosion of the products.

DISPOSAL OF MATERIALS

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

TRANSPORTATION

The Osteotome Kit - KOST must be transported adequately to avoid falling and stored at a maximum temperature of 25ºC, protected from heat and moisture. Transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for dental use. Reprocessing is allowed. Refer to the cleaning and sterilization conditions contained in this instruction for use. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplantsystem.com or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Manually remove all surgical instruments from the kit. Wash the kit trays separately.
2. Prepare the enzymatic detergent according to the detergent manufacturer's instructions.
3. Immerse all parts of the product into the prepared detergent solution and leave for 5 minutes. Then, using a soft bristle brush, scrub the parts for at least 2 minutes until completely remove organic matter from the products.
4. Remove the parts from the detergent solution and rinse with tap water for 1 minute until the residue is completely removed. Repeat the rinse two more times.
5. Visually inspect each part to check for process residues or organic residues from the used of the product.
6. If residue in detect in the product, repeat the cleaning process until the residue is completely removed.
7. Dry with soft, clean, dry cloth or disposable paper.

RECOMMENDATIONS

a. Wear appropriate clothing (gloves, masks, glasses, hats, etc.).
b. Begin cleaning immediately after surgical use.
c. Never let the instrument dry containing organic residues after surgical use.
d. Never let the instrument dry naturally after cleaning.
e. Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide or alcohol to clean or rinse surgical instruments and Kit trays.

f. Never use steel wool or sponges or abrasive products, so that the instruments are not damaged.
g. Do not accumulate instruments in large quantities on top of each other to avoid 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 with a steam sterilizable wrap.
3. Steam sterilizes 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 on the same day or one day earlier the procedure.
b. Chemical sterilization is not recommended, since some products may cause discoloration and damage 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 Osteotome Kit - KOST can be reprocessed, depending on its correct handling, cleaning and sterilization, up to 250 times.

	NÃO ESTÉRIL	NON-ESTERILE	NON STÉRILE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTER LE MODE D'EMPLOI
	MARCAÇÃO CE	CE MARK	CE MARQUE
	MANTENHA SECO	KEEP DRY	GARDER AU SEC
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	TENIR À L'ABRI DE LA LUMIÈRE DU SOLEIL
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NE PAS UTILISER SI L'EMBALLAGE EST ENDOMMAGÉ
	ATENÇÃO	CAUTION	ATTENTION
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRÉSENTANT AUTORISÉ DANS LA COMMUNAUTÉ EUROPÉENNE
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LIMITE DE TEMPÉRATURE
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.	ATTENTION: LES LOIS FÉDÉRALES (AMÉRICAINES) LIMITENT LA VENTE DE CET APPAREIL PAR OU SUR ORDRE D'UN PROFESSIONNEL DE LA SANTÉ AGRÉÉ.
	FABRICANTE	MANUFACTURER	FABRICANT
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	DATE DE FABRICATION
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CODE DE RÉFÉRENCE
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIF MÉDICAL
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICATEUR UNIQUE DE L'APPAREIL
	IMPORTADOR	IMPORTER	IMPORTATEUR
	DISTRIBUIDOR	DESTRIBUTOR	DISTRIBUTEUR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAYS DE FABRICATION
	LOTE	BATCH CODE	CODE DE LOT
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALLAGE RECYCLABLE
DESCRIPTION ON THE LABEL	CONTÉM: 1 UNIDADE	CONTENT: 1 UNIT	CONTENU: 1 UNITÉ
DESCRIPTION ON THE LABEL	PRODUTO NÃO ESTÉRIL	NON STERILE PRODUCT	PRODUIT NON STÉRILE

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