SURGICAL INSTRUMENTS

Osteotomes and Expanders Family

Osteotomes and Expanders Family are intended for surgical procedures for installing dental implants, which must be performed by qualified professionals. The way of using the product is used and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in conditions suitable for the health and safety of the patient.

PRODUCT DESCRIPTION

Osteotomes and Expanders Family are made of high strength stainless steel, materials with recognized use in surgical instruments and with a lengthy history, both for instruments and implantable prostheses, resulting in excellent biocompatibility and without toxicity problems. Due to the design and fabrication characteristics of Osteotomes and Expanders Family, they have polished surfaces, in order to avoid the accumulation of residues, dirt or contaminants, facilitating their washing and pre-sterilization thereof. On the other hand, Osteotomes and Expanders Family are designed and manufactured in a way that allows the ergonomic use, with comfort and safety for the dental surgeon and for the patient. Osteotomes and Expanders Family allow the placement of osseointegrated implants, without or with little use of drills, since the anatomy often limits drilling with drills, making this procedure difficult.

INDICATIONS OF USE

The Osteotomes and Expanders Family is used as surgical instruments during bone compaction procedures and partial maxillary sinus elevation. They allow for implant placement with little or no use of drills, maximizing the use of the patient's remaining bone tissue, and are used for atraumatic sinus lifting.

PURPOSE AND OPERATION PRINCIPLE

Their purpose is to allow for bone compaction and atraumatic elevation of the maxillary sinus. The instrument has a conical shape and a convex active tip, which enables bone compaction and fracture of the sinus wall through the force applied to the opposite end of the instrument.

HOW TO USE THE INSTRUMENT

The dental surgeon should use the Osteotome and Expander Family in procedures of bone compaction or partial elevation of the maxillary sinus, following the aseptic and appropriate surgical techniques to each case. In the items described below, there is a suggested route for the use of Osteotomes and Expanders Family, in cases of bone compaction and partial elevation of the maxillary sinus. After using the Osteotome and Expander Family, separate them from other materials, wash and sterilize them following the instructions in the cleaning, disinfection and conditioning section described in this instruction manual.

Bone Compaction
First, the bone undergoes to pilot perforation, up to the planned depth. Before using the instruments, it is recommended to mount the depth Stop, in order not to exceed the previously determined working depth. Straight instruments allow easier access to the back area. 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. Careful insertion of the implant is recommended.

Partial Maxillary Sinus Elevation
Firstly, the bone is prepared with the help of helical drills, according to the desired diameter of the implant. It is approaching carefully to the cortex of the maxillary sinus (minimum distance 1 mm). This process assumes an exact planning in the radiological image. Before using the instruments, it is recommended to mount the depth stop in order not to exceed the pre-determined working depth. Depth stops are mounted on the instruments manually. Straight instruments allow easier access to the back area. In the first step, the floor of the maxillary sinus is fractured, which requires exact radiological planning. It is recommended to work with depth Stop, in order not to exceed the one previously defined in planning. The instrument is advanced with slight hammer strokes, according to the desired length of the implant. During elevation, a filling material or autologous and/or autologous bones is applied to the implant bed. The material introduced has the effect of a cushion that lifts the *Schneider Membrane*, according to the hydraulic principle. Careful insertion of the implant is recommended.

⚠ ATTENTION

Osteotomes and Expanders Family are 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

Do not introduce corroded instruments into the autoclave, in order to avoid contamination of the water with rust residues. Follow the surgical techniques appropriate to each case, in particular, carefully planning the procedure before starting it.

RECOMMENDATIONS

Use the product only as indicated in the use instructions. Always use aseptic techniques both in handling and using the device. If the Osteotome or Expander suffers severe mechanical shocks or falls and, as a consequence, fractures or changes in their original form, discontinue the use of the product.

CONTRAINDICATION

The Osteotomes and Expanders Family has no contraindications since its recommendations are followed correctly and used by a specialized professional, who will be responsible for the proper planning of the surgical procedure in which it will be used. None of the instruments are for permanent/implantable use, only for transient use during surgery.

SIDE EFFECTS

The Osteotomes and Expanders Family has no adverse effects, as long as the choice of instruments and technique are appropriate for the procedure.

WARNING

Do not use the instrument if you notice cracks, wear or spots of oxidation/corrosion. This may cause problems in the operation of the instruments. All items may exhibit natural wear and tear and should be replaced whenever the professional identifies loss of fit or accuracy of these products as they may interfere with the end 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 Osteotomes and Expanders Family should be stored in a cool dry place at a temperature of 15°C to 35°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 MATERIAL

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

TRANSPORTATION

The Osteotomes and Expanders Family must be transported adequately to avoid falling and stored at a maximum temperature of 35ºC, protected from heat and moisture. Transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for dental use. Reprocessing 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. Prepare the enzymatic detergent according to the detergent manufacturer's instructions.
2. 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 complete remove organic matter from the products.
3. 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.
4. Visually inspect each part to check for process residues or organic residues from the used of the product.
5. If residue in detect in the product, repeat the cleaning process until the residue is completely removed.
6. Dry with a soft, clean, dry cloth or disposable paper.
7. Proceed to the sterilization process.

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 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.

LIFE TIME

Osteotomes and Expanders Family can be used as below depending on the proper handling, cleaning and sterilization:

- 20 uses in high-density bones (types I and II)
- 30 uses in low-density bones (types III and IV).

	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 DE TEMPERATURA	TEMPERATURE LIMIT	LÍMITE 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	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DESTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE

MANUFACTURER
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PRODUCT
Osteotomes and Expanders Family