SURGICAL INSTRUMENTALS

Osteotomes and Expanders Family

The Osteotomes and Expanders family is intended for surgical procedures for installing dental implants, which must be performed by qualified professionals. The way of using 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 conditions suitable for the health and safety of the patient.

PRODUCT DESCRITION

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

INDICATIONS OF USE

Osteotomes and Expanders are used as surgical instruments during bone compaction procedures or partial elevation of the maxillary sinus, and are not implantable, allowing the placement of osseointegrated dental implants without or with little use of drills, since the anatomy often limits drilling to drills, making this procedure difficult.

OPERATION PRINCIPLE

The working principle applicable to Osteotomes and Expanders is that of 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 by compacting the material.

HOW TO USE

The Dental Surgeon should use the osteotome and expander 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 or expanders, in cases of bone compaction and partial elevation of the maxillary sinus.
After using the osteotome and expander, 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 pre-determined working depth.
Straight instruments allow easier access to the back area.

The larger diameter instruments are manually introduced, with slightly rotating movements or with slight hammer strokes, according to the length and diameter of the desired implant.
Careful insertion of the implant is recommended.

Partial Elevation of Maxillary Sinus

First, the bone is prepared with the help of the 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 manually mounted on the instruments. Straight instruments allow easier access in the back area;
In a 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 the 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 bone 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.

Benefits of the Osteotomes Family

- Used for implant placement, sinus lift, flap expansion and future site preparation;
- With a concave tip to load and push the bone in front of the osteotome;
- Lower probability of membrane rupture;
- Laterally compressed walls;
- Sharp perimeter edge to cut the bone on the walls of the site;
- Combined and progressive sizes;
- Laser markings combine with depth marks of implant millings cutters;
- It can be used with cylindrical or threaded implants

Osteotome Techniques

- Summers osteotome technique;
- Narrow-edge expansion technique;
- Beam expansion technique with modified osteotomes;
- Atraumatic elevation of sinus floor without graft;
- Atraumatic elevation of sinus floor with graft.

Notes

- Need to gain up to 5 or 6 mm in height;
- Bone type III or IV;
- Certify the absence of bone septa;
- Observe sinus membrane integrity;
- Minimum residual height of 5 mm;
- Do not exceed the cortical limit of the sinus floor with the osteotome.

Advantages of Osteotomes

- Less invasive and traumatic technique;
- Improves bone quality and quantity;
- Fewer surgical times;
- Shorter treatment time;
- Lower cost for the patient;
- Case resolution in the office;
- Immediate installation of the implant;
- Predictable techniques for optimal results.

ATTENTION

The Osteotomes and Expanders Family is 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;
Use the product only as indicated in the Use Instructions;

RECOMMENDATIONS

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.

CONTRAINDICATIONS

The Osteotomes and Expander 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 instrument and technique is appropriate to the procedure.

WARNING

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

The TI Instrumentals should be stored in a cool, dry place at a maximum temperature of 35°C and protected from direct sunlight.
Products of the Osteotomes and Expanders Family should be stored in a dry, cool, ventilated place away from direct sunlight;

HANDLING

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.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

Products of the Osteotomes and Expanders Family should be transported at room temperature away from direct sunlight, avoiding locations where large 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.

COMPLEMENTARY INFORMATIONS

Multiple use product. Reprocessing Allowed. Refer to the cleaning and sterilization conditions contained in these Use Instructions. 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 all internal organic material under running water, and proceed to the next step only when this has been done;
2. Prepare the enzymatic detergent according to the manufacturer's recommendation.
3. Immerse all parts of the product into the prepared detergent solution and keep in contact for at least 5 minutes, then using soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove parts 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.
8. Follow to sterilization process.

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

Assemblers and Washer Head: Use only once.

Driver: Use up to 50 times.

Expanders: 20 perforations in high density bones; 30 low density boné perforations.

Depth Rod, Direction Indicator, Guide Drill, Guide Fixer, Stabilizer and Surgical Tweezers: Use 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:
S.I.N. Sistema de Implante Nacional S/A
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