OSTEOTOMES AND EXPANDERS FAMILY

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON -ESTERILE	NO ESTÉRIL
	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:

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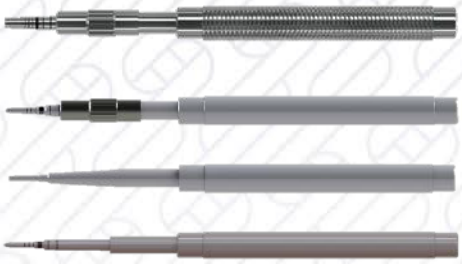
PRODUCT:

Osteotomes and Expanders Family
Anvisa Registration: 80108910014

CE

The Osteotomes and Expanders family is intended 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

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.

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.

PRECAUTIONS AND RECOMMENDATIONS

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;
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.

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

Products of the Osteotomes and Expanders Family should be stored in a dry, cool, ventilated place away from direct sunlight;

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.

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. Refer to the cleaning and sterilization conditions contained 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. Ultrasonic cleaning, if used, should have the washing solution heated to a temperature of at least 45°C and the instruments should be placed in the 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.