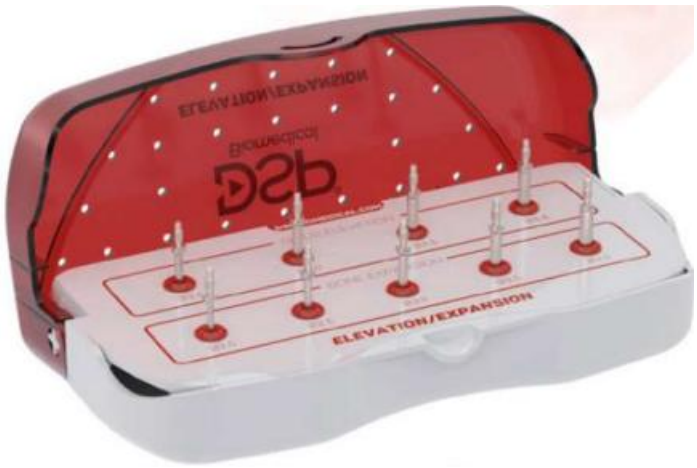
# INSTRUCTION FOR USE




WARNING: The figures are merely illustrative. They do not represent the actual dimensions and colors.

This device is indicated for specialized procedures, which must be performed by professionals qualified in Implant Dentistry. For best results, use the product with proper techniques. Always apply the product under appropriate conditions, in a surgical environment.

## INDICATION FOR USE

Elevators are used as surgical instruments during bone compaction or maxillary sinus elevation procedures. Expanders are used when the bone thickness is insufficient, requiring bone compression and expansion prior to implant placement.

## DESCRIPTION

DSP Elevators and Expanders are made from surgical stainless steel. One of its ends has a fitting for the assembly key. Its active end is available as indicated below:

- Elevator: It has a concave shape.
- Expander: It has a convex shape.

## NOTICE

Failure to recognize actual lengths in relation to radiographic measurements can result in permanent damage to nerves and other vital structures. Drilling beyond the intended depth for lower jaw surgery may result in permanent numbness in the lower lip and chin or lead to bleeding in the lower part of the mouth. Follow the mandatory procedures for any surgery, such as: asepsis during bone drilling, avoiding damage to blood vessels and nerves, using pre-operative anatomical and radiographic knowledge.

## CONTRAINDICATIONS

This product has no contraindications as long as it is used correctly for the indicated purposes.

## RISKS AND BENEFITS

Like any surgery, there is no total guarantee of full operation, as to obtain a good performance involves several factors, namely usability, clinical conditions of the patient and the product itself. Failure to observe the indicated usage limitations and work steps may result in failure.

## WARNING AND PRECAUTIONS

• Do not use descaling products.
• Avoid using enzymatic liquid in concentrations greater than 10% and drying parts that still contain cleaning solution residues, as these procedures favor oxidation.
• The use of steel brushes is also inadvisable.
• Drying the parts is extremely important before storage and sterilization, as the accumulation of moisture in the products is harmful and can cause oxidation.
• It is recommended to always use the instruments for removing implants parallel to the long axis of the implant to be removed.
• Excessive use of force can lead to fracture of the instrument, making the procedure unfeasible.
• The inclination of surgical instruments for removing implants during use can result in damage or even lead to fracture of the piece.
• Care must be taken in cases of patients who show signs of allergy or hypersensitivity to the chemical components of the material: stainless steel
• This product is for single use only.
• The reuse of this product may cause adverse biological effects resulting from residues of products, microorganisms and/or substances resulting from previous uses and/or reprocessing; changes to the original physical, mechanical and chemical, macro and microstructural characteristics of the product that may impair its intended functionality. Reuse of this product does not guarantee its safety and effectiveness and voids any warranty for related products.
• Do not use the product if the packaging is broken.
• Do not use the expired product.
• Before each procedure, make sure that the parts fit perfectly. • Ensure that parts are not swallowed or aspirated by the patient.

## IMPORTANCE OF THE NEED TO ADHERE TO A CARE REGIME

Products must be protected from aspiration when handled intraorally. Aspiration of products can lead to infection or unplanned physical injury. If you want to protect it, use rubber dam. In case an implant or an

instrument has been swallowed or aspirated, call a doctor immediately. In addition to the obligatory precautions for any surgery, such as asepsis, when drilling into the jaw bone, damage to the inferior alveolar nerve and facial, deep facial, upper labial and lower labial blood vessels must be avoided. Anatomical knowledge and preoperative medical imaging (e.g. radiography) should be consulted.
Improper use of products leads to poorly performed work and increased risk. In particular, users of hand tools should be careful to use them gently and with consideration. The user should always avoid touching instruments and unprotected parts (sterile protective gloves and aprons should be worn).
The Elevator and Expander is supplied in non-sterile condition and must be reprocessed and sterilized before first use. Improper cleaning and sterilization of instruments can result in infection of the patient with harmful bacteria. To avoid damaging the instruments, they must be removed from the blister pack individually. The shipping blister is not intended to be used as a container for steam sterilizing burs.
They must be unpacked before the first reprocessing. Do not use the device if the primary package has been previously damaged or opened. Instruments that are bent and/or non-functional must be discarded immediately. Damaged, corroded or worn devices must not come into contact with intact instruments to avoid fretting corrosion.

## OPERATING INSTRUCTIONS

The Elevator is a surgical instrument indicated for performing the traumatic maxillary sinus elevation technique, where the alveolus is prepared for the installation of the Implant in the region of the posterior maxilla with low bone height.

1. Select the bone elevator that matches the diameter of the hole drilled in the bone bed.
2. Screw the tip onto the desired hand wrench (straight or angled).
3. Use the assembly wrench to tighten the tension between the elevator and the cable.
4. With the concave tip, load a little autogenous bone.
5. Introduce the elevator into the bone cavity carefully, without breaking the sinus mucosa, until the desired length. 6. With the help of a surgical hammer, give small taps until the maxillary sinus is lifted.
7. The bone must be introduced little by little and compacted.

The Expander is a surgical instrument indicated for performing the bone expansion technique to shape the bone, in preparing the bed for the installation of dental implants, generally in situations where there are limitations in the thickness or quality of the bone to support the implant.
1. Select the bone expander that meets the diameter of the implant hole that will be installed.
2. Screw the tip onto the desired hand wrench (straight or angled).
3. Use the assembly wrench to tighten the tension between the elevator and the cable.

4. Insert the expander into the cavity you want to expand.

5. With the help of a surgical hammer, give small taps until the desired bone expansion occurs.

## CLEANING INSTRUCTION

## SANITATION

This product must be correctly sanitized after each use. Proceed as follows:

1. Disassemble the instruments (when applicable).

2. Immerse the instruments for at least 1 minute in the enzymatic detergent (CIDEZYME®) so that the instruments are sufficiently covered. Make sure there is no contact between the instruments.

3. Carefully use a soft brush to aid the cleaning process. Shake instruments several times during cleaning.

4. Immerse the instruments for 15 minutes in the cleaning solution (CIDEZYME®) using ultrasonic treatment, so that the instruments are sufficiently covered. Make sure there is no contact between the instruments.

5. Remove the instruments from the cleaning solution and wash them intensely for at least 3 times (for at least 1 minute) under running water.

## DISINFECTION

1. Immerse the instruments (disassembled, if applicable) for 10 minutes in the disinfectant solution (CIDEX® OPA Solution - undiluted) so that the instruments are sufficiently covered.

2. Remove instruments from the disinfectant solution and wash them according to the instructions below:

## WASHING INSTRUCTIONS

1. After removing the instruments from the CIDEX® OPA Solution, wash the medical device thoroughly by immersing it completely in a large volume of water. Use sterile water.

2. Keep the device fully immersed for at least 1 minute.

3. Remove the device and discard the wash water. Always use new volumes of water for each wash. 4. Repeat the procedure 2 more times, for a TOTAL OF 3 WASHES, with large volumes of clean water to remove residues of the CIDEX® OPA Solution (Residues can cause serious side effects). 5. Inspect and package instruments immediately after removal.

## AUTOMATIC CLEANING AND DISINFECTION

1. Use Neodisher® MediZym detergent.

2. Disassemble the instrumentation, if applicable.

3. Transfer the instruments to the Disinfectant Washer (make sure the instruments do not come into contact).

4. Start the program.

5. Remove the instruments from the Disinfectant Washer after the program has finished. 6. Check and pack instruments immediately after removal.

## PRESENTATION AND STERILIZATION

This instrument is for single use – NO REPROCESSING.

They are supplied NON-sterile and must be properly cleaned and sterilized before use.

Sterilize it the day before or on the day of the procedure.

ATTENTION: These products must not be autoclaved in their original packaging.

For sterilization, only use the steam sterilization method according to the parameters below:

| | Fractional Vacuum/Dynamic air Removal[1] | Gravitational[2] |
|---|---|---|
| **Sterilization Time** | 4 minutes | 15 minutes |
| **Sterilization Temperature[3]** | 132°C / 270°F | 132°C / 270°F |
| **Drying Time** | At least 20 minutes[4] | At least 20 minutes[4] |

1 At least three vacuum steps.
2 The less effective gravitational sterilization procedure should not be used if the fractional vacuum procedure is available.
3 Maximum sterilization temperature 134°C (273°F).
4 The required effectiveness in drying time depends directly on the parameters under the responsibility of the user (loading and density configuration, sterilization conditions, and these must be determined by the user. However, the drying time applied must not be less than 20 minutes).
NOTES:
1. After sterilization, package the instruments in a dry, dust-free environment.
2. Immediate/flash sterilization procedure should not be used.
3. Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

## MAINTENANCE DESCRIPTION

All products referred to in this instruction are supplied non-sterile. They must be sanitized and sterilized before each use. It is the responsibility of the professional to carry out this entire process.

## STORAGE INSTRUCTIONS

This product must be stored in its original packaging, in a clean and ventilated place, at a maximum temperature of 45°C and protected from direct sunlight.

## INSTRUCTIONS ON HOW TO SAFELY DISPOSE OF THE DEVICE

Every product and consumable used during surgery to install dental implants can endanger the health of those who handle them after use. Before discarding them in the environment, it is recommended to observe the current legislation and adhere to it.

## ADDITIONAL INFORMATION

Instruct the patient about the need for professional medical follow-up after surgery and follow the guidelines on precautions, hygiene and medication prescription. These guidelines are the responsibility of the professional responsible.

## LIFETIME

This product is for indefinite use. Regardless of the number of times the instrument is used, the professional must always evaluate its conditions after each use.

## EXPIRATION DATE

See packaging

## ADVERSE EVENTS

No adverse effects are expected provided the product is used according to the instructions for use.

## GUARANTEE

DSP Biomedical assures the owner of this product, guarantee against any material or manufacturing defect, the presence of any defect must be communicated immediately to the manufacturer, respecting the legal term. The guarantee of products manufactured by DSP Biomedical is linked to following the information described in the instructions for use. The inappropriate use of the product, ignoring the indications, exempts the manufacturer and/or distributor from any responsibility.

## SERVICE INFORMATION

If further information is needed, or if the product presents any adverse effect, with potential risk to the patient, which generates or has the potential to cause injury or threatens public health, or any customer dissatisfaction, DSP should be contacted through phone 0800 600 88 66, or send an email to qualidade@dspbiomedical.com.br.

## SÍMBOLOS

| SIMBOLOGIA | DESCRIÇÃO | SIMBOLOGIA | DESCRIÇÃO |
|---|---|---|---|
|  | Batch Number |  | See instructions for use |
|  | Date manufacturing |  | Attention |
|  | Manufacturing |  | Keep dry |
|  | Non Sterile |  | Keep away from sunlight |
|  | Product Code |  | Vality Date |
|  | Temperature limit |  | Unique device identifier |
|  | Umity limit |  | Do not use if the packaging is damaged and consult the instructions for use |
|  | European Representative |  | Country of manufacturer |
|  | Model Number |  | Medical Device |

| | | | |
|---|---|---|---|
|  | Fragile, handle with care |  | Importer |
|  | CE Mark |  | CE marking with number of Notified body; SIQ, number 1304 |
|  | Do not reuse |  | FDA-mandated prescription notification for the United States market |

## REF Produtos

| Descrição | Código |
|---|---|
| MEMBRANE ELEVATOR Ø2.6 | 28.5026E |
| MEMBRANE ELEVATOR Ø3.0 | 28.5030E |
| MEMBRANE ELEVATOR Ø3.5 | 28.5035E |
| MEMBRANE ELEVATOR Ø3.8 | 28.5038E |
| BONE EXPANDER Ø2.0 | 28.5120E |
| BONE EXPANDER Ø2.5 | 28.5125E |
| BONE EXPANDER Ø3.0 | 28.5130E |
| BONE EXPANDER Ø3.5 | 28.5135E |
| BONE EXPANDER Ø4.5 | 28.5145E |
| BONE CREST EXPANDER Ø3.5 | 28.5135B |
| BONE CREST EXPANDER Ø3.75 | 28.5137B |
| BONE CREST EXPANDER Ø4.0 | 28.5140B |
| BONE CREST EXPANDER Ø4.5 | 28.5145B |
| BONE CREST EXPANDER Ø5.0 | 28.5150B |
| CHISEL EXPANDER Ø2.6 | 28.5026C |
| CHISEL EXPANDER Ø3.0 | 28.5030C |
| CHISEL EXPANDER Ø3.5 | 28.5035C |
| CHISEL EXPANDER Ø3.8 | 28.5038C |

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