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

Rotary instrument indicated for controlled bone cuts. The intended use for this device is to create compacted bone osteotomy in the posterior region of the maxilla subantral to the sinus for placement of endosseous implants.

DESCRIPTION

DSP Osteotomes made of surgical stainless steel, used during bone compaction procedures or partial elevation of the maxillary sinus, are not implantable. They allow the placement of osseointegrated implants. These instruments are frequently used in sinus lift surgeries and in the placement of dental implants. Summers osteotomes have a cylindrical or conical shape and feature a sharp end to facilitate bone cutting and a rounded end to prevent injury to the surrounding soft tissues. The function is to manually form the osteotomy, compressing the bone to improve bone quality (bone condensation) and bone quantity (ridge expansion in horizontal and vertical dimensions) for sufficient primary stability of the implants. They consist of an ergonomic hand handle and a working part. They are limited to use in the maxillary arch and are intended for use in low density bone. Sinus lift: This technique is used to increase the height of the bone in the posterior region of the upper jaw, allowing the placement of dental implants. Osteotomes are used to make controlled bone cuts in the wall of the maxillary sinus in order to create an access window for elevation of the sinus membrane. There are two techniques used, namely: Alveolar bone expansion: They can also be used to expand the alveolar bone, which is the part of the maxillary or mandibular bone that supports the teeth. This technique is used when there is an insufficient amount of bone to place dental implants. And they are used to create controlled bone cuts, thus expanding the alveolar bone and creating space for implant insertion. It is important to highlight that the use of this product requires adequate skill and training on the part of the surgeon to avoid complications and guarantee satisfactory results.

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 Osteotomes 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

Follow the steps below for the drilling process.
1. Mark and drill the initial pilot hole with a 2mm twist drill to full depth.
2. Insert the tip of the 2.0 mm Osteotome into the pilot hole and push the instrument into the bone while rotating it, avoiding lateral or off-axis leverage. Leave the Osteotome in place for about 10 seconds to allow the bone to relax. Remove the Osteotome by simultaneously rotating the tool and removing it.
3. Use the same technique to progressively expand the implant site.

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]	132ºC / 270ºF	132ºC / 270ºF
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 responsible professional.

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
LOT	Batch Number		See instructions for use
	Date manufacturing		Attention
	Manufacturing		Keep dry
NON STERILE	Non Sterile		Keep away from sunlight
REF	Product Code		Vality Date
45°C	Temperature limit	UDI	Unique device identifier
	Umity limit		Do not use if the packaging is damaged and consult the instructions for use
EC REP	European Representative	CC	Country of manufacturer
#	Model Number	MD	Medical Device
	Fragile, handle with care		Importer
CE	CE Mark	CE 1304	CE marking with number of Notified body; SIQ, number 1304
	Do not reuse	Rx only	FDA-mandated prescription notification for the United States market

REF Produtos

Descrição	Código
OSTEOTOME Ø3.8	28.5038

FABRICADO POR

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