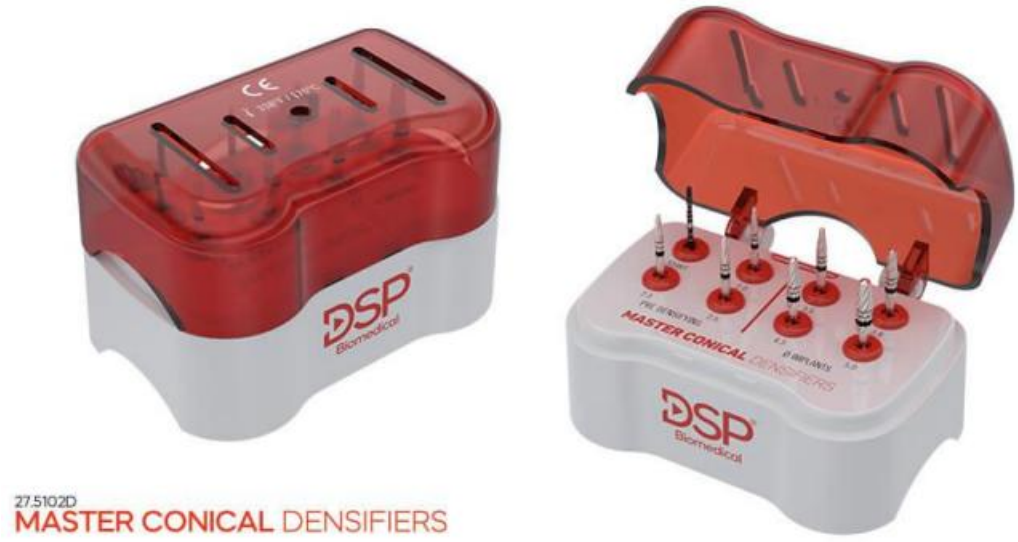
INSTRUCTION FOR USE

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

INDICATIONS FOR USE

Bone densification is a surgical technique that allows for bone compaction during instrumentation. The decrease in medullary spaces allows for an increase in bone density in the region and a consequent increase in primary stability of the implants to be installed. This Kit is recommended for implants with a conical design.

COMPOSITION



Descrição	Código
Cylindrical Drill ø1.6	28.8016C
Conical Densifier ø2.0	27.5120D
Conical Densifier ø2.3	27.5123D
Conical Densifier ø2.5	27.5125D
Conical Densifier ø3.5	27.5135D
Conical Densifier ø3.8	27.5138D
Conical Densifier ø4.3	27.5143D
Conical Densifier ø5.0	27.5150D
Autoclavable Case	27.5103D

DESCRIPTION

DSP Biomedical's bone densifier kits are rotary instruments for lateral bone densification. This technique is based on the biological characteristic of cancellous bone flexibility and predictability of horizontal propagation

provided by the instruments. The selection of the external geometry of the bone densifier is similar to the characteristic of the selected implant, which can be cylindrical or conical. Bone Densifier Kits are produced in surgical stainless steel. One of its ends has a counter-angle fitting.

APLICATION

The bone densification technique is based on the staggered instrumentation of bone densifiers which promote compaction instead of bone subtraction during instrumentation. Using the bone densification technique, controlled bone autotransplantation along the osteotomy wall is observed, reducing medullary spaces and creating a favorable environment for ideal primary stability of the dental implant. The drill design allows for an inversion between the cutting chisel and the tapered nail, performing bone compaction instead of subtraction. The bone densifier drills, when turned clockwise, have the property of bone densification. When bone densifiers are activated at high speeds in a counterclockwise direction, bone cutting and subtraction can be observed during instrumentation. Bone densification, clockwise, is indicated for low-quality bone tissue, promoting residual bone compaction and favoring increased primary stability. Scientific evidence shows that bone densification can accelerate the bone remodeling process.

NOTICE

Failure to recognize actual drill 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. How to follow the mandatory procedures for any surgery, such as: asepsis during bone drilling, avoiding damage to blood vessels and nerves, using anatomical knowledge and pre-operative radiographs.

CONTRAINDICATIONS

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

RISKS AND BENEFITS

Like any surgery, it cannot be guaranteed one hundred percent, as achieving good performance involves several factors, including usability, the patient's clinical conditions and the product itself. Failure to observe the indicated usage limitations and work steps may result in failure. Failure to recognize actual drill 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.

WARNINGS AND PRECAUTIONS

• Inadequate planning can compromise the performance of the implant/prosthesis set, resulting in system failures, such as loss or fracture of the implant, loosening or fracture of components and/or prosthetic screws.

• Due to its function, the drilling length must be a maximum of 0.5 mm greater than the implant insertion depth. This additional length must be considered during the planning phase.

• Drills must not be resharpened.

• Failure to replace the drills as recommended by the manufacturer may cause undue bone heating, compromising the success of the procedure.

• Care must be taken in cases of patients who show signs of allergy or hypersensitivity to the chemical components of the material: surgical stainless steel.

• Make sure to use the drill compatible with the sequence of drills indicated according to the dimensions and prosthetic interface of the planned implant.

• DSP Biomedical Drills are only compatible for preparation prior to the installation of DSP Biomedical implants.

• This product must be used sterile.

• To carry out the procedure, make sure that the patient has sufficient interocclusal space to handle the instruments in the desired region.

• Do not stop the motor rotation with the drill inside the surgical cavity, as this may make removal difficult or cause the drill to fracture.

• Do not use the product if its packaging is damaged.

• Do not use the product if its validity has expired.

• Before each procedure, check the perfect fit between the pieces.

• Ensure that the parts are not swallowed or aspirated by the patient.

• Make sure you have all the necessary instruments to perform the procedure according to the surgical plan.

• Before each procedure, check the condition of the instruments, always respecting their useful life. Replace instruments in case of damage, faded markings, compromised sharpening, deformation or wear.

• Always use the DSP Biomedical product sequence. The use of instruments and/or prosthetic components from other manufacturers does not guarantee the perfect function of the DSP Biomedical Implant System and exempts any product warranty.

• It is the dentist's responsibility to use DSP Biomedical products in accordance with the instructions for use.

IMPORTANCE OF THE NEED TO ADHERENCE TO A CARE REGIME

Products must be protected against aspiration when handled intraorally. Vacuuming products can lead to infection or unplanned physical injury. If you want to protect it, use rubber dam. If an implant or instrument has been swallowed or aspirated, call a doctor immediately. In addition to the mandatory precautions for any surgery, such as asepsis, during drilling into the jaw bone, damage to nerves and vessels must be avoided by referring to anatomical knowledge and pre-operative medical images (e.g. x-rays). Failure to recognize the actual duration of drills in relation to radiographic measurements can result in permanent damage to nerves and other vital structures. Drilling beyond the depth intended for lower jaw surgery can potentially result in permanent numbness in the lower lip and chin or lead to hemorrhage in the floor of the mouth. Inappropriate use of products leads to poorly executed work and increased risk. In particular, users of hand tools should be careful to use them gently and with consideration. The user must always avoid touching instruments and parts without protection (sterile protective gloves and aprons must be used). Thermal bone damage caused by rotating and oscillating tools must always be avoided (user training, work at low speed and with sufficient cooling (see section "Cooling"). During intraoral application, attention must be paid to the fact that the products are protected from being sucked in or dropped to the ground. Rotary instruments need to be secured as far as possible with their set speed before applying them to the object are used with the rotary instruments. bone or fracture of system components. Drills are supplied in non-sterile conditions and must be reprocessed and sterilized before first use on the patient and immediately after each use, all products must be disinfected and sterilized. Inadequate cleaning and sterilization of instruments may result in patient infection with harmful bacteria. To avoid damaging instruments, they must be removed from the blister packaging individually. The shipping blister is not intended to be used as a container for steam sterilization of drills. They must be unpacked before the first reprocessing. It is essential to only use turbines, as well as manual and angular parts that are technically and hygienically impeccable, maintained and clean. Do not use the device if the primary package has been previously damaged or opened. Do not use damaged or blunt instruments for drilling. Broken instrument cutting edges cause vibrations and large pressure forces, which in turn lead to broken preparation edges and rough surfaces. Instruments that are bent and/or do not work properly should be discarded immediately. Damaged, corroded or worn devices must not come into contact with intact instruments to avoid contact corrosion.

OPERATING INSTRUCTIONS

Start the instrumentation with the cylindrical drill 1.6mm at 800rpm, in the rotational direction to the indicated depth. After instrumentation, start bone densification, in the rotational direction with abundant irrigation. Use the densifier according to the model (conical or cylindrical) diameter and height of the chosen implant. After compaction and completion of the bone bed, the implant can be installed according to its instructions for use.

MANUAL CLEANING AND DISINFECTION SANITATION

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

1. Dismantle the instruments (when applicable).
2. Immerse the instruments for at least 1 minute in the enzymatic detergent (CIDEZYME ®, 1.6% v/v) so that the instruments are sufficiently covered. Be careful that there is no contact between the instruments.
3. Carefully use a soft brush to help with the cleaning process. Shake instruments several times during cleaning.
4. Immerse the instruments for 15 minutes in the cleaning solution (CIDEZYME ®, 1.6% v/v) under ultrasonic treatment, so that the instruments are sufficiently covered. Be careful that there is no contact between the instruments.
5. Remove the instruments from the cleaning solution and wash them well 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 - OPA Solution - undiluted) so that the instruments are sufficiently covered.
2. Remove the 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 - 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.
4. Always use new volumes of water for each wash.
5. 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 - OPA (Residues can cause serious side effects)
6. Inspect and package instruments immediately after removal.

AUTOMATIC CLEANING AND DISINFECTION

1. Use Neodisher® MediZym detergent.
2. Dismantle the instruments, if necessary;
3. Transfer the instruments to the Disinfectant Washer (be careful that the instruments do not come into contact);
4. Start the program;
5. Remove the instruments from the Disinfectant Washer after the end of the program;
6. Check and package instruments immediately after removal.

STERILIZATION

This product is reusable, supplied non-sterile and packaged individually.

This product must be properly sanitized 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). The required effectiveness in drying time depends directly on the parameters under the user's responsibility (configuration and load density, sterilization

conditions, and these must be determined by the user. However, the applied drying time must not be less than 20 minutes).

NOTES:
1. After sterilization, pack the instruments in a dry, dust-free environment.
2. The immediate/flash sterilization procedure should not be used.
3. Do not use thermal dry sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

PRECAUTIONS

The Surgical Instrument Kit is supplied in non-sterile packaging. It is up to the team to sterilize the product before use, following classic autoclaving and biosafety protocols.

ADVERSE EFFECTS

No adverse effects are expected, as long as the product is used in accordance with the instructions for use.

ADDITIONAL INFORMATION FOR THE PROFESSIONAL

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

USEFUL LIFE

This product is recommended for up to 20 uses, as long as the conditions of use recommended by DSP Biomedical are respected. Regardless of the number of times the instrument is used, the professional must always evaluate its conditions after each use.

STORAGE CONDITIONS

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

DISPOSAL OF MATERIAL

Any product and consumables used during surgery to install dental implants can compromise the health of those who handle them after use. Before disposing of them in the environment, it is recommended to observe current legislation and adhere to it.

GUARANTEE

DSP Biomedical guarantees the owner of this product a guarantee against any material or manufacturing defect. The presence of any defect must be communicated immediately to the manufacturer, respecting the legal deadline. The warranty for products manufactured by DSP Biomedical is linked to strict adherence to the information described in the instructions for use. Inappropriate use of the product, ignoring the instructions, exempts the manufacturer and/or distributor from any responsibility. Note: the warranty does not cover wear and tear of the product.

SUPPORT INFORMATION

If there is a need for further information, or if the product presents any adverse effect, with potential risk to the patient, which generates or has the potential for injury or threat to public health, or any customer dissatisfaction, you must contact DSP through telephone 0800 600 88 66, or send an email to sac@dspbiomedical.com.br.

VALIDITY

8 years in sealed packaging unused

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

FABRICADO POR

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