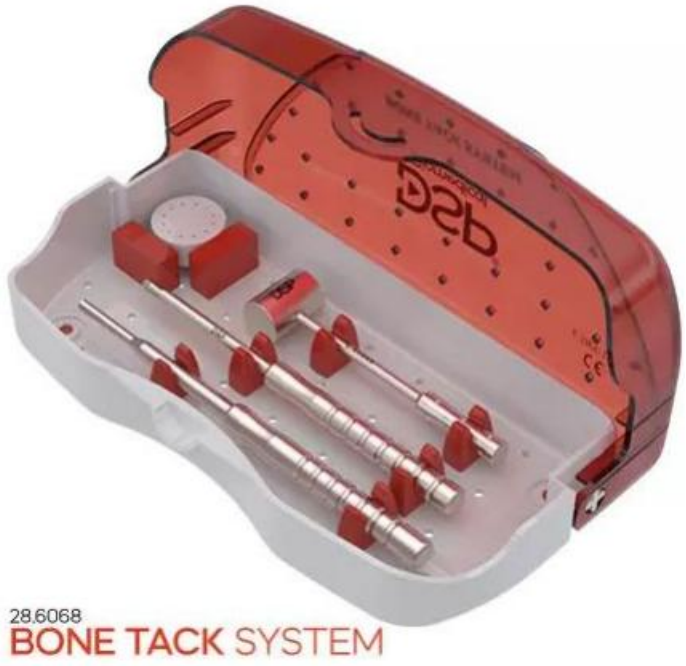
INSTRUCTION FOR USE

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

Used to fix the barrier, in order to form bone for implant installation.

COMPOSITION



Descrição	Código
BONE TACK DRIVER	28.6050
BONE TACK DISPENSER	28.6060
BONE TACK HAMMER	28.3000
OSTEOTOME ø 3.8 (stop	28.5038
AUTOCLAVABLE CASE	28.5031

DESCRIPTIONS

The Bone Tack System Kit are reusable instruments, made of stainless steel, supplied non-sterile.

INDICATIONS

Fix membranes or barriers over the bone graft, preventing displacement and mobility during guided bone regeneration.

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.

WARNINGS 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
• 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 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

1. Position the applicator in a perpendicular position (90º), press the applicator manually with moderate force until it clicks (when the applicator locks the tack).

2. Take the tack to the graft position and, with a light tap, insert the tack in order to fix the element to which it is aimed.

3. After inserting the tack into the bone, remove the applicator, moving in any direction.

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]	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). 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 responsible professional.

USEFUL LIFE

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.

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
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
	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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