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.

DESCRIPTIVE INFORMATION INDICATION FOR USE

Surgical instrument indicated to assist in the placement of Grafting screws.

DEVICE DESCRIPTION

The DSP Support Graft Kit Drills are produced in surgical stainless steel, which are used for the fixation and stabilization of bone grafting and membranes (barriers) through screws. They are available as indicated below:

1) Autoclavable case: used for safe storage and sterilization of the Kit instruments.
2) Spear Bur: Used to mark the place where the screw will be installed, causing the rupture of the cortical bone.
3) Surgical Bur: Used to deepen and direct drilling into bone tissue.
4) Trephine Bur: Used to remove grafting screws and/or bone tissue.
5) Wrench for contra angle: used to tighten/torque screws. It must be coupled in contra angle.
6) Digital Wrench: used to tighten/torque screws manually.
7) Tweezers: Used to capture screws.
8) Peek Cover Capture Wrench: used to capture/insert capsule.

NOTICE

The material should not be stored without complete drying, as the product is liable to oxidation. Failure to recognize the actual lengths of burs in relation to radiographic measurements can result in permanent damage to nerves and other vital structures. Drilling beyond the intended depth of 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. The mandatory procedures of any surgery must be followed, such as: asepsis during bone drilling, avoiding damage to blood vessels and nerves, using anatomical knowledge and preoperative radiographs. Product commercialized being NON sterile and must be sanitized and sterilized before and after use.

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 obtaining 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. Failure to recognize the actual lengths of burs in relation to radiographic measurements can result in permanent damage to nerves and other vital structures. Drilling beyond the intended depth of 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.

WARNING AND PRECAUTIONS

• Inadequate planning can compromise performance.
• Due to its function, the perforation length must be a maximum of 0.5 mm greater than the insertion depth. This additional length must be considered during the planning phase.
• Care must be taken in cases of patients who show signs of allergy or hypersensitivity to the chemical components of the material:
• Be sure to use the bur compatible with the sequence of burs indicated according to the dimensions and prosthetic interface.
• This product must be used sterile.
• Do not use the product if the package is damaged.
• Do not use the product if the expiration date has expired.
• Before each procedure, make sure that the parts fit perfectly.
• Ensure that 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 conditions of the instruments, always respecting their useful life. Replace

instruments in case of damage, erased 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.

• If the laser marks are illegible, the instrument must be replaced;

• The Kit of Instruments for grafting are reusable. However, before reuse, the user must inspect the kit components to verify that they are not damaged. If any failure is detected, DSP does not recommend reuse, and the component must be discarded.

• Never store the material without complete drying. Product subject to oxidation.

• Sold NON-sterile and must be cleaned and sterilized before and after use.

• Improper use, abuse or excessive force on the instruments may cause them to break.

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 (eg radiographs) should be consulted. Failure to recognize actual duration of burs 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 could potentially result in permanent numbness in the lower lip and chin or lead to bleeding in the floor of the mouth. 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). Thermal bone damage caused by rotating and oscillating tools must always be avoided (user training, work at low speed and with sufficient cooling). During intraoral application, care must be taken to ensure that the products are protected against being sucked in or dropped on the floor. Rotary instruments need to be fixed as far as possible with their set speed before applying them to the object are used with rotary instruments. Do not exceed recommended drilling speeds as this may cause bone necrosis or fracture of system components. The burs are supplied in non-sterile condition and must be reprocessed and sterilized before first use. Prior to their first use on the patient and immediately after each use, all products must be disinfected and sterilized. Improper cleaning and sterilization of instruments can

result in infection of the patient with harmful bacteria. It is essential to only use turbines, as well as hand and corner parts that are technically and hygienically impeccable, kept clean. Do not use damaged or blunt instruments for piercing. Broken instrument cutting edges cause vibrations and high pressure forces, which in turn leads to broken preparation corners and rough surfaces. 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 of the burs.

1. To prepare the receiving bed, start drilling with the spear bur.
2. Then use the 1.0 surgical bur (for bone types III and IV) or the 1.5 surgical bur (for bone types I and II).
3. Choose between the handpiece or the contra angle wrenches (short or long) and start screw insertion.
4. To place the capsule at the ends of the screw, use the capture wrench.
5. Start the engine and drill with continuous insertion and removal movements, with abundant irrigation.
6. This irrigation can be either manual or combined with engine irrigation.
7. During drilling, pressure should not be excessive.
8. Drilling must take place according to the length of the implant and the laser marking of the bur.
9. The indication of bur sequence and rotation speed for each implant must be respected, contributing to the success of osseointegration.
10. Do not stop the motor rotation with the bur inside the surgical cavity, as this may make removal difficult or cause the bur to fracture. During drilling, use lip balm.

CLEANING INSTRUCTIONS

SANITATION

This product must be properly 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 that 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®) under ultrasonic treatment, so that the instruments are sufficiently covered. Make sure that there is no contact between the instruments.
5. Remove the instruments from the cleaning solution and wash them intensively for at least 3 times (for at least 1 minute) in 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 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, 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 procedure 2 more times, for a TOTAL OF 3 WASHES, with large volumes of clean water to remove CIDEX® OPA Solution residue (Residue can cause serious side effects
5. Inspect and pack instruments immediately after removal.

AUTOMATIC CLEANING AND DISINFECTION

1. Use Neodisher® MediZym detergent.
2. Disassemble the instrument, 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 end of the program;
6. Check and pack instruments immediately after removal.

PRESENTATION AND STERILIZATION

This product is reusable, supplied non-sterile and individually packaged. This product must be properly sanitized and sterilized before use. Sterilize it the day before or on the day of the procedure.

WARNING:

These products should not be autoclaved in their original packaging. For sterilization, use only 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 gravitational sterilization procedure is less effective and should not be used if a fractional vacuum

procedure is available.
3. Maximum sterilization temperature 134°C (273°F).
4. The required efficiency in drying time directly depends 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 applied drying time should not be less than 20 minutes).

NOTES:
1. After sterilization, pack the instruments in a dry and dust-free environment.
2. Immediate use/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.

LIFESPAN

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 assess its conditions after each

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.

Note: the warranty does not cover wear and tear on the product

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 sac@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 it 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 bodies; SIQ, number 1304
	Do not reuse	Rx only	FDA-mandated prescription notification for the United States market

REF Produtos

Descrição	Código
ESTOJO AUTOCLAVAVEL	80.0006
BROCA BARBELL Ø1,3	28.8013B
BROCA BARBELL 1.1MM	28.8011B
BROCA LANÇA BARBELL 1.0	28.8210B
CHAVE C.A. LONGA BARBELL 0.9	28.2809B
CHAVE C.A. BARBELL 0.9	28.2309B
CHAVE DE CAPTURA PEEKLOCK	28.1500B
CHAVE DIGITAL BARBELL 0,9	28.1509B

BROCA TREFINA BARBELL 2,0	28.8120B
PINÇA PARA PARAFUSO BARBELL	28.4020B

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