

INSTRUCTIONS FOR USE OF DRILLS



ATTENTION: The figures are for illustrative purposes only. They do not represent actual dimensions or colors.

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

DESCRIPTIVE INFORMATION

INDICATION FOR USE

Rotary instrument indicated for drilling bone tissue.

DEVICE DESCRIPTION

DSP drills are made of surgical stainless steel, with one end fitted with a contra-angle fitting. The drills are unique for each implant length. They feature a DLC (diamond-like carbon) coating, which reduces drill-bone friction and, consequently, reduces the heat generated during the process, increasing resistance to wear and oxidation.

Its active end is available as indicated below:

- Initial Drill: used to mark the location where the implant will be installed, it has a spear-shaped tip, which facilitates cutting.
- Cylindrical Drill: Used to deepen and direct bone tissue drilling, preparing the bone bed for implant placement. Available with a stop attachment. The stop attachment is not included with the drills and must be purchased separately. The stop attachment helps limit the depth of bone drilling.
- Pilot Drill: Used in the surgical sequence after the screw cutter and before the conical drill to attenuate bone heating.
- Conical Drill: Drilling bone tissue during surgical socket preparation prior to placement in bone types I and II (bone quality classification according to Lekholm and Zarb , 1985¹). They are used to progressively widen the drilling diameter until the final dimension is adequate for placement of the conical implant. It comes with a stop attachment ; the stop attachment is not included with the drills and must be purchased separately. The stop attachment helps limit the depth of bone drilling.
- Countersink Drill : These are used as countersink drills at the end of the bone drilling sequence . Their purpose is to create a bevel for correct seating of the implant platform.
- Trephine Drill: used to create holes for removing dental implants and collecting autogenous bone blocks for later use .

- Pear Drill: These are multifaceted cutting instruments that allow for bone deburring . The drills are laser-marked to determine the drilling depth according to the surgical plan. They are used to prepare the maxillary alveolar ridge, enabling the transverse angular positioning of implants at the desired, surgically planned plateau level, thus facilitating load distribution in implant surgical protocols.

NOTICE

Failure to accurately match actual drill lengths to radiographic measurements can result in permanent damage to nerves and other vital structures. Drilling beyond the intended depth for lower jaw surgery can result in permanent numbness of the lower lip and chin or lead to bleeding in the lower mouth due to damage to important nerves such as the inferior alveolar or mental nerves.

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 preoperative radiographs.

CONTRAINDICATIONS

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

RISKS AND BENEFITS

As with any surgery, there is no guarantee of full functionality , as achieving good performance involves several factors, including usability, the patient's clinical condition, and the product itself. Failure to follow the indicated usage limitations and work steps may result in failure.

Failure to recognize the 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 can result in permanent numbness of the lower lip and chin or lead to bleeding in the lower mouth.

WARNINGS AND PRECAUTIONS

- Inadequate planning can compromise the performance of the implant/prosthesis assembly, resulting in system failures such as loss or fracture of the implant, loosening or fracture of the components and/or prosthetic screws.
- Due to its function, the perforation length should be no more than 0.5 mm greater than the implant insertion depth. This additional length should be considered during the planning phase.
- Drill bits should not be resharpened .
- Failure to replace the drills as recommended by the manufacturer may cause undue bone heating, compromising the success of the procedure.
- Caution should be exercised 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 drill sequence indicated according to the dimensions and prosthetic interface of the planned implant.
- Biomedical Drills are only compatible for preparation prior to the installation of DSP Biomedical implants .
- This product must be used sterile.
- To perform the procedure, ensure that the patient has sufficient interocclusal space to handle the instruments in the desired region.
- Do not interrupt 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 that the parts fit together perfectly.
- 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 if damaged, marked, compromised, deformed, or worn.
- 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 voids 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 FOR ADHERENCE TO A CARE REGIMEN

Products must be protected against aspiration when handled intraorally. Aspiration of products can lead to infection or unintended physical injury. If you want to protect yourself, use a rubber dam. If an implant or instrument is swallowed or aspirated, call a doctor immediately. In addition to mandatory precautions for any surgery, such as asepsis, when drilling the jawbone, damage to the inferior alveolar nerve and the facial, deep facial, upper and lower labial blood vessels must be avoided. Anatomical knowledge and preoperative medical imaging (e.g., X-rays) should be consulted.

Failure to recognize the actual length of drills 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 can potentially result in permanent numbness of the lower lip and chin or lead to bleeding in the floor of the mouth.

Improper use of products leads to poor workmanship and increased risk. In particular, users of hand tools should be careful to use them gently and with consideration. Users should always avoid touching instruments and parts without protection (sterile protective gloves and aprons should be worn). Thermal damage to bone caused by rotating and oscillating tools should always be avoided (by user training, working at low speeds, and with sufficient cooling (see "Cooling" section). During intraoral application, care must be taken to protect the products from aspiration or falling onto the floor. Rotary instruments must be fixed as far as possible at their set speed before applying them to the object used with the rotary instruments. Do not exceed the recommended drilling speeds, as this may cause bone necrosis or fracture of system components. Drills are supplied under non-sterile conditions and must be reprocessed and sterilized before first use. Before their first use on a 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. To avoid damaging the instruments, they must be removed from the blister packaging individually. The shipping blister is not intended to be used as a container for the Steam sterilization of burs. They must be unpacked before the first reprocessing. It is essential to use only turbines, as well as handpieces and angles that are technically and hygienically impeccable, maintained, and clean. Do not use the device if the primary packaging has been damaged or previously opened. Do not use damaged or blunt instruments for drilling. Broken instrument cutting edges cause vibrations and high pressure forces, which in turn lead to broken preparation corners and rough surfaces. Instruments that are bent and/or non-functional should be discarded immediately. Damaged, corroded, or worn devices should not come into contact with intact instruments to avoid contact corrosion.

OPERATING INSTRUCTIONS

Follow the steps below for the drill bit drilling process.

1. Attach the Drill to the Contra Angle and set the surgical motor to the drilling speed indicated by the selected implant.

2. As planned, take the drill to the surgical site of the mandibular alveolus.
3. Start the motor and drill with continuous insertion and removal movements, with abundant irrigation.
4. This irrigation can be either manual or combined with automatic irrigation associated with the motor.
5. During drilling, pressure should not be excessive.
6. Drilling must occur according to the length of the implant and the laser marking on the drill.
7. The indication of drill sequence and rotation speed for each implant must be respected, contributing to the success of the osseointegration of the implant.
8. Do not interrupt the motor's rotation while the drill is still in the surgical cavity, as this may make removal difficult or cause the drill to fracture. Use a lip protector while drilling.

CLEANING INSTRUCTIONS

HYGIENE

This product must be properly sanitized after each use.

Proceed as follows:

1. Disassemble the instruments (when applicable).
2. Soak the instruments for at least 1 minute in the enzymatic detergent (CIDEZYME®) so that they are sufficiently covered. Make sure there is no contact between the instruments.
3. Carefully use a soft brush to aid the cleaning process. Shake the instruments several times during cleaning.
4. Immerse the instruments for 15 minutes in the cleaning solution (CIDEZYME®) under ultrasonic treatment, ensuring that the instruments are sufficiently coated. Ensure that there is no contact between the instruments.
5. Remove the instruments from the cleaning solution and wash them intensively 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 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 rinse water. Always use fresh water for each rinse.
4. Repeat the procedure 2 more times, for a TOTAL OF 3 WASHES, with large volumes of clean water to remove CIDEX® OPA Solution residue (Residues can cause serious side effects).
5. Inspect and package instruments immediately after removal.

AUTOMATIC CLEANING AND DISINFECTION

1. 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 with each other).
4. Start the program.
5. Remove the instruments from the Disinfectant Washer after the program is complete.

6. Check and pack instruments immediately after removal.

PRESENTATION AND 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 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 temperature³	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 stages.
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 drying time efficiency depends directly on the parameters under the user's responsibility (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, pack the instruments in a dry, 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, or plasma sterilization.

MAINTENANCE DESCRIPTION

All products mentioned in these instructions are supplied non-sterile. They must be sanitized and sterilized before each use. It is the professional's responsibility 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

All products and consumables used during dental implant surgery can pose a health risk to those who handle them after use. Before disposing of them in the environment, it is recommended to observe and adhere to current legislation .

ADDITIONAL INFORMATION

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

USEFUL LIFE

This product is recommended for up to 20 uses, as long as the conditions of use recommended by DSP Biomedical are followed. Regardless of how many times the instrument is used, the professional should always evaluate its condition after each use.

EXPIRATION DATE

See packaging.

ADVERSE EVENTS

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

GUARANTEE















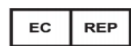









DSP Biomedical guarantees the owner of this product against any material or manufacturing defects. Any defect must be reported immediately to the manufacturer within the legal deadline. The warranty for products manufactured by DSP Biomedical is linked to compliance with the information described in the instructions for use. Improper use of the product, ignoring the instructions, exempts the manufacturer and/or distributor from any liability.

Note: The warranty does not cover wear and tear due to use of the product.

ASSISTANCE INFORMATION

If further information is required, or if the product presents any adverse effect, with potential risk to the patient, which generates or has the potential to cause injury or threaten public health, or if there is any customer dissatisfaction, contact DSP by calling 0800 600 88 66, or send an email to qualidade@dspbiomedical.com.br.

SYMBOLS

SYMBOLISM	DESCRIPTION	SYMBOLISM	DESCRIPTION
	Batch number		Consult the instructions for use or consult the electronic instructions for use
	Date of manufacture		Careful
	Produced put		Keep in a dry place
	No Sterile		Keep protected from sunlight
	Product code		Expiration date
	Temperature limit		Unique device identification number
	Upper and lower humidity limit		Do not use if packaging is broken and consult instructions for use.
	Authorized representative in the European community		Manufacturer Country
	Model number		Medical Device
	Fragile , handle with care		Importer
	CE Mark		CE marking with number of Notified body ; SIQ, number 1304
	No reuse		FDA-mandated prescription notification for the United States market

: Products

Device Name(s)	Code	Device Name(s)	Code
REGULAR CONICAL DRILL 3.5	27.3515	CYLINDRICAL DRILL TO STOP Ø2.5	28.8025CS
REGULAR CONICAL DRILL 3.8	27.3815	ZYGOMATIC DRILL Ø2.7	28.8027Z
REGULAR CONICAL DRILL 5.0	27.5015	Zygomatic Short Drill Ø2.7	28.8027ZS
REGULAR CONICAL DRILL 4.3	27.4315	Zygomatic Short Drill Ø3.3	28.8033ZS

Short Conical Drill 3.8	27.3807	Cylindrical Drill Ø3.5	28.8035
Short Conical Drill 4.3	27.4307	CYLINDRICAL DRILL TO STOP Ø3.5	28.8035CS
Short Conical Drill 5.0	27.5007	Cylindrical Drill Ø3.8	28.8038
Long Conical Drill 3.8	27.3821	CYLINDRICAL DRILL TO STOP Ø3.8	28.8038CS
SHORT CONICAL DRILL TO STOP Ø3.8	27.3807CS	Cylindrical Drill Ø4.3	28.8043
Conical Drill Ø3.8	27.3810	CYLINDRICAL DRILL TO STOP Ø4.3	28.8043CS
Medium Conical Drill Ø3.8	27.3811	Cylindrical Drill Ø4.5	28.8045
REGULAR CONICAL DRILL TO STOP Ø3.8	27.3815CS	Cylindrical Drill Ø4.8	28.8048
SHORT CONICAL DRILL TO STOP Ø4.3	27.4307CS	Cylindrical Drill Ø5.0	28.8050
Medium Conical Drill Ø4.3	27.4311	Cylindrical Drill Ø5.0	28.8050C
Conical Drill Ø4.3	27.4313	Cylindrical Drill Ø3.3	28.8033
REGULAR CONICAL DRILL TO STOP Ø4.3	27.4315CS	CYLINDRICAL DRILL TO STOP Ø3.3	28.8033CS
HIZ CONICAL DRILL Ø4.3	27.4315Z	CYLINDRICAL DRILL TO STOP Ø3.15	28.8031CS
ZYGOMATIC CONICAL DRILL Ø4.3	27.4315ZS	Angled Countersink Drill	27.8343C
SHORT CONICAL DRILL TO STOP Ø5.0	27.5007CS	Long Cylindrical Drill Ø1.2	28.8112C
Medium Conical Drill Ø5.0	27.5011	Long Cylindrical Drill Ø1.5	28.8115
REGULAR CONICAL DRILL TO STOP Ø5.0	27.5015CS	Long Cylindrical Drill Ø1.6	28.8116C
REGULAR CONICAL DRILL TO STOP Ø3.5	27.3515CS	INITIAL DRILL 2.0	28.8220C
Long Cylindrical Drill Ø1.0	28.9210C	INITIAL DRILL 2.5	28.8225C
Long Helical Drill 1.5	28.8115C	FITGUIDE INITIAL DRILL Ø2.0	27.8120
CYLINDRICAL DRILL 1.0	28.8010C	ANGLED THE INITIAL DRILL	27.8320C
CYLINDRICAL DRILL 1.5	28.8015C	Long Initial Drill Ø2.0	28.8221C
CYLINDRICAL DRILL 1.6	28.8016C	PILOT DRILL 2/3	28.8223C
CYLINDRICAL DRILL 2.0	28.8020C	PILOT DRILL 3.0/3.8	28.8234C
CYLINDRICAL DRILL 2.5	28.8025C	PILOT DRILL Ø2.0/2.5	28.8221
CYLINDRICAL DRILL 2.8	28.8028C	PILOT DRILL Ø2.0/2.8	28.8222
CYLINDRICAL DRILL 3.0	28.8030C	PILOT DRILL Ø2.0/2.8	28.8222C
Cylindrical Drill 3.15	28.8031C	PILOT DRILL Ø2.0/3.0	28.8223
CYLINDRICAL DRILL 3.3	28.8033C	PILOT DRILL Ø2.5/3.3	28.8233
CYLINDRICAL DRILL 3.5	28.8035C	COUNTERSINK DRILL 3.3	28.8333C
CYLINDRICAL DRILL 3.8	28.8038C	Countersink Drill 3.75	28.8337C
CYLINDRICAL DRILL 4.3	28.8043C	COUNTERSINK DRILL 4.0	28.8340C
Angled Hex Drill Ø2.8	27.8328C	COUNTERSINK DRILL 4.3	28.8343C
Angled He Drill Ø3.15	27.8331C	COUNTERSINK DRILL 5.0	28.8350C
Angled Hex Drill Ø3.3	27.8333C	Countersink Drill Ø3.3	28.8333
Angled Hex Drill Ø3.5	27.8335C	Countersink Drill Ø3.75	28.8337
Cylindrical Drill Ø1.0	28.8010	Countersink Drill Ø4.0	28.8340
Long Cylindrical Drill Ø1.0	28.8010V	Countersink Drill Ø4.3	28.8343
Short Cylindrical Drill Ø1.0	28.8010VS	Countersink Drill Ø5.0	28.8350
Cylindrical Drill Ø1.2	28.8012	Countersink Drill Ø3.3	28.8333
Cylindrical Drill Ø1.2	28.8012C	Countersink Drill Ø3.75	28.8337
Cylindrical Drill Ø1.5	28.8015	Trephine Drill 3.3	28.8133
Cylindrical Drill Ø1.6	28.8016	TREPINE DRILL 4.0	28.8140
CYLINDRICAL DRILL TO STOP Ø1.6	28.8016CS	Trephine Drill 4.3	28.8143
Cylindrical Drill Ø2.0	28.8020	TREPINE DRILL 5.0	28.8150
CYLINDRICAL DRILL TO STOP Ø2.0	28.8020CS	Trephine Drill 8.0	28.8180
CYLINDRICAL DRILL TO STOP Ø2.3	28.8023CS	TREPINE DRILL 10.0	28.8100
Cylindrical Drill Ø2.5	28.8025	HEZ PILOT DRILL Ø2.7/3.3	28.8233C
Cylindrical Drill Ø2.8	28.8028	HEZ SHORT PILOT DRILL Ø2.7/3.3	28.8233ZS
CYLINDRICAL DRILL TO STOP Ø2.8	28.8028CS	HEZ SHORT INITIAL DRILL Ø2.0	28.8220ZS
Cylindrical Drill Ø3.0	28.8030		
CYLINDRICAL DRILL TO STOP Ø3.0	28.8030CS		
Cylindrical Drill Ø3.15	28.8031		
ANVISA Registration : 80116980004			

MANUFACTURED BY

DSP INDUSTRIAL LTDA
Marechal Floriano Peixoto Street, 303 – Ouro Verde II
Campo Largo /PR – Brazil
CNPJ 03.960.018/0001-23
Phone: +55 41 3291-2200
www.dspbiomedical.com
Technical Manager: CREA- PR 25412/D

REPRESENTATIVE IN THE EUROPEAN COMMUNITY

DSP BIOMEDICAL EUROPA UNIP LDA
Ocean Avenue, 142 Lt . 4.24 0H
Nations Park – Lisbon - Portugal
1990-502
Phone: (351) 962833592

ANVISA Registration: 80116980004

Reference.

1 -Lekholm U, Zarb G. Patient selection and preparations. Branemark , PI, Zarb,G & Albrektsson, T, eds Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chigado : Quintessence; 1985. p. 233-40.