MANUAL DE INSTRUÇÕES
KIT CIRÚRGICO CÔNICO FITGUIDE

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EC REP DSP Bimedical Europa Unip Lda – Alameda dos Oceanos, 142 Lt 4.24 OH – Parque das Nações – Lisboa/Portugal

INSTRUCTIONS FOR USE

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 environment.

INDICATIONS FOR USE

The FITGUIDE CONICAL SURGICAL KIT consists of instruments used by qualified dental surgeons to perform specialized surgical procedures. Specifically, the FITGUIDE CONICAL SURGICAL KIT is used in guided surgery systems, a technique for installing dental implants with maximum precision through virtual planning and prototyped guides. This system provides greater predictability, safety, agility, and patient comfort during the surgical procedure.

COMPOSITION

Description	Code
FITGUIDE FIXING PIN	27.0031
SHORT GUIDE STABILIZER Ø 3.8	27.0037
LONG GUIDE STABILIZER Ø 3.8	27.0038
CONICAL STOP FOR DRILL Ø3.5X8.5	27.0835C
CONICAL STOP FOR DRILL Ø3.8X8.5	27.0838C
CONICAL STOP FOR DRILL Ø3.0X10.0	27.1030C
CONICAL STOP FOR DRILL Ø3.5X10.0	27.1035C
CONICAL STOP FOR DRILL Ø3.8X10.0	27.1038C

CONICAL STOP FOR DRILL Ø3.0X11.5	27.1130C
CONICAL STOP FOR DRILL Ø3.5X11.5	27.1135C
CONICAL STOP FOR DRILL Ø3.8X11.5	27.1138C
CONICAL STOP FOR DRILL Ø3.0X13.0	27.1330C
CONICAL STOP FOR DRILL Ø3.5X13.0	27.1335C
CONICAL STOP FOR DRILL Ø3.8X13.0	27.1338C
CONICAL STOP FOR DRILL Ø3.0X15.0	27.1530C
CONICAL STOP FOR DRILL Ø3.5X15.0	27.1535C
CONICAL STOP FOR DRILL Ø3.8X15.0	27.1538C
CMI LONG CA SCREWDRIVER Ø3.8X10.0	27.2010L
CMI SHORT CA KEY Ø3.8X10.0	27.2010S
CMI LONG CA SCREWDRIVER Ø3.8X11.5	27.2011L
CMI SHORT CA KEY Ø3.8X11.5	27.2011S
PERIODONTAL PROBE	27.4002
TITANIUM TWEEZERS	27.4040
FITGUIDE CYLINDRICAL DRILL Ø1.3	27.8013
CYLINDRICAL DRILL STOPPER Ø2.0X8.5	28.0820C
CYLINDRICAL DRILL STOPPER Ø2.0X10.0	28.1020C
CYLINDRICAL DRILL STOPPER Ø2.0X11.5	28.1120C
CYLINDRICAL DRILL STOPPER Ø2.0X13.0	28.1320C
CYLINDRICAL DRILL STOPPER Ø2.0X15.0	28.1520C
MEDIUM SCREWDRIVER 1.2	28.2512
AC RATCHET CONNECTOR	28.4009
SURGICAL TORQUE WRENCH	28.4103
Mucosal Punch Ø3.8	28.8006
INITIAL STOP OF THE DRILL Ø2.0	28.8120C
UPPER DRILL Ø3.8	28.8250
DENSE BONE DRILL Ø3.0	28.8430
DENSE BONE DRILL Ø3.5	28.8435
DENSE BONE DRILL Ø3.8	28.8438
FITGUIDE CONICAL KIT AUTOCLAVABLE CASE	27.0010/1

APPLICATION

The FITGUIDE CONICAL SURGICAL KIT consists of drills, installation keys and other accessories for the following purposes:

FITGUIDE FIXING PIN: used to fix the surgical guide in the planned position, avoiding unwanted movements and ensuring precision in the surgical procedure.

FITGUIDE 1.3: drills the channel that will receive the fixing pins according to the planned position and to the desired depth.

MUCOSAL PUNCH: used to remove gum tissue with an efficient and controlled cut, which preserves the mucosal region and facilitates healing, reducing trauma to the patient.

UPPER DRILL: Designed to level the bone at the surface, ensuring a uniform and prepared bone surface for subsequent procedures, which is crucial for the success of the procedure.

INITIAL DRILL: designed to drill the densest bone layer located on the surface, it has a sharper cutting tip that facilitates access to this region.

CYLINDRICAL DRILL STOP: Designed to deepen and direct bone drilling, ensuring better fit and predictability during implant placement, providing greater precision, stability, and efficiency. The drills have a stop that limits the drilling depth.

CONICAL DRILL STOP: Designed to drill the appropriate size for the implant to be installed, optimizing the implant and providing greater precision, stability, and adaptation to the shape of the implant bed, facilitating safe and efficient installation. The drills also feature a stop that limits the drilling depth.

DRILL FOR DENSE BONE: optionally used at the end of the drilling sequence, to drill dense bone and facilitate insertion of the implant into the bone bed.

PERIODONTAL PROBE: Aids in checking bone depth and evaluating surrounding tissues. It has a handle and angled tip, facilitating access to the prepared bed.

CMI CA DRIVER: assists in capturing, transporting, and inserting implants into the prepared bed. The drivers have a contra-angle connection.

TITANIUM FORCEPS: assists in capturing and transporting the implant when the insertion tool does not fit perfectly. The implant must be held with the forceps and pressed against the insertion tool until it is fully seated.

RATCHET AC CONNECTOR: it is attached to drivers with a contra-angle connection and has a ratchet type fitting for manual installation with a surgical torque wrench.

SURGICAL TORQUE KEY: used to apply controlled and precise torque when inserting the implant, providing stability and safety to the procedure.

STABILIZING GUIDE: Ensures the surgical guide remains firmly in place during the installation of two or more implants. Helps prevent unwanted movements that can compromise the accuracy of bone drilling and implant placement.

MANUAL SCREWDRIVER 1.2: with hexagonal fitting, used to fix the guide stabilizer to the implant.

AUTOCLAVABLE CASE: Safely stores the kit's instruments during the surgical procedure and subsequent autoclave sterilization. Visual markings facilitate sequential use of the instruments.

DRILLING SEQUENCE

Bone type I, II, III and IV										
Diameter	Mucosal Punch	Upper drill	Initial exercise	Cylindrical Drill Bit Ø2.0	Conical Drill Ø3.0	Conical Drill Bit Ø3.5	Conical Drill Bit Ø3.8	Dense Bone Drill Ø3.0	Drill for dense bone Ø3.5	Drill for dense bone Ø3.8
Ø3.0 mm	▲	●	●	●	●			▲		
Ø3.5 mm	▲	●	●	●	▲	●			▲	
Ø3.8 mm	▲	●	●	●	▲	▲	●			▲
●	RECOMMENDED SEQUENCE								IMPLANT HEIGHTS	
▲	OPTIONAL								8.5 – 10 – 11.5 – 13 – 15	

TO PERCEIVE

Failure to identify the actual drill length 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.

Mandatory procedures for any surgery must be followed, 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's no guarantee of 100% success, as successful performance depends on several factors, including usability, the patient's clinical condition, and the product itself. Failure to follow the recommended usage limitations and work steps may result in failure.

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WARNINGS AND PRECAUTIONS

• Inadequate planning may compromise the performance of the implant/prosthesis assembly, 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 should be a maximum of 0.5 mm greater than the implant insertion depth. This additional length should be considered during the planning phase.

• Drill bits 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.

• 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.

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

• This product must be used sterile.

• To perform the procedure, make sure 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 the packaging is damaged.

• Do not use the product if the expiration date has expired.

• Before each procedure, check that the parts fit 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, faded marks, compromised sharpness, deformation, or wear appear.

• Always use the DSP Biomedical product sequence. The use of instruments and/or prosthetic components from other manufacturers does not guarantee the perfect functioning of the DSP Biomedical Implant System and waives 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. Aspirating products can lead to infections or unintended physical injuries. 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, during jaw drilling, damage to nerves and vessels must be avoided by consulting anatomical knowledge and preoperative medical images (e.g., x-rays). Failure to recognize the actual length of the 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 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 increases risks. Users of hand tools must exercise caution and consideration. Users should always avoid touching instruments and parts without protection (sterile protective gloves and aprons should be worn). Thermal bone damage caused by rotating and oscillating tools should always be avoided (user training, working at low speeds, and with sufficient cooling). During intraoral application, care must be taken to protect products from suction or falling to the floor. Rotary instruments must be clamped as far as possible at the set speed before applying them to the object on which they will be used. This can cause bone fracture or fracture of system components. Drills are supplied under non-sterile conditions and must be reprocessed and sterilized before first use on a patient, and all products must be disinfected and sterilized immediately after each use. Improper cleaning and sterilization of instruments can result in patient infection with harmful bacteria. To avoid damage to instruments, they should be removed individually from the blister packaging. The shipping blister is not intended to be used as a container for steam sterilization of burs. They should 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, preserved, 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 breakage of preparation edges and rough surfaces. Bent and/or malfunctioning instruments should be discarded immediately. Damaged, corroded, or worn devices should not come into contact with intact instruments to avoid contact corrosion.

SAW OPERATING INSTRUCTIONS

Follow the steps below for the drill bit drilling process.

• Attach the drill to the contra-angle and set the surgical motor to the drilling speed as indicated by the selected implant.

• As planned, take the drill to the surgical alveolus site.

• Start the motor and drill with continuous insertion and removal movements, with abundant irrigation. This irrigation can be manual or combined with engine irrigation.
• During drilling, pressure should not be excessive.
• Drilling must be done according to the length of the implant and the laser marking on the drill.
• The indication of the drill sequence and rotation speed for each implant must be respected, contributing to the success of the osseointegration of the implant.
• 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.

MANUAL CLEANING AND DISINFECTION

SANITATION

This product must be properly sanitized after each use.
Proceed as follows:
1. Disassemble the instruments (where applicable).
2. Immerse the instruments for at least 1 minute in the enzymatic detergent (CIDEZYME®, 1.6% v/v) to ensure they are sufficiently covered. Ensure there is no contact between the instruments.
3. Carefully use a soft brush to aid cleaning. Shake the instruments several times during cleaning.
4. Immerse the instruments for 15 minutes in the cleaning solution (CIDEZYME®, 1.6% v/v) under ultrasonic treatment, ensuring that the instruments are sufficiently covered. Ensure that there is no contact between the instruments.
5. Remove the instruments from the cleaning solution and wash them thoroughly 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 plenty 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 fresh 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 any residue of the CIDEX® OPA SOLUTION - OPA (Residues can cause serious side effects).
6. Inspect and pack instruments immediately after removal.

AUTOMATIC CLEANING AND DISINFECTION

1. Use Neodisher ® MediZym detergent.
2. Disassemble the instruments if necessary.
3. Transfer the instruments to the Washer Disinfectant (be careful not to let the instruments come into contact with each other).
4. Start the program.
5. Remove the instruments from the Washer Disinfectant after the program ends.
6. Check and pack instruments immediately after removal.

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. CAUTION: 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]	134ºC / 273ºF	134ºC / 273ºF
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 fractionated vacuum procedure is available.

3. Maximum sterilization temperature: 134°C (273°F). The required drying time efficiency depends directly on the parameters under the user's responsibility (configuration and load density, sterilization conditions, which 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/rapid 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.

PRECAUTIONS

The Surgical Instrument Kit is supplied in non-sterile packaging. It is the team's responsibility to sterilize the product before use, following standard autoclave and biosafety protocols.

ADVERSE EFFECTS

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

ADDITIONAL INFORMATION FOR THE PROFESSIONAL

Inform the patient about the need for professional medical monitoring after surgery and follow instructions regarding precautions, hygiene, and medication prescriptions. These instructions are the responsibility of the professionals in charge.

USEFUL LIFE

This product is recommended for up to 20 uses, provided that 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.

STORAGE CONDITIONS

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

MATERIAL DISPOSAL

Any products and consumables used during dental implant surgery can jeopardize the health of those who handle them after use. Before disposing of them in the environment, it is recommended to observe and comply with current legislation.

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 strict adherence to the information described in the instructions for use. Improper use of the product, in disagreement with the instructions, exempts the manufacturer and/or distributor from any liability.

Note: The warranty does not cover product wear and tear.

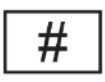
SUPPORT INFORMATION

If you need further information, or if the product presents any adverse effect, with potential risk to the patient, which causes or has the potential to cause injury or threat to public health, or if you experience any customer dissatisfaction, you should contact DSP by phone at 0800 600 88 66 or send an email to sac@dspbiomedical.com.br.

VALIDITY

8 years in sealed packaging without use

SYMBOLISM

SYMBOLISM	DESCRIPTION	SYMBOLISM	DESCRIPTION
	Batch number		Consult the instructions for use or consult the electronic instructions for use
	Date manufacturing		Made by
	Non-sterile		Keep dry
	Product code		Keep away from sunlight
	Model number		Single sterile barrier system
	Temperature limit		Used to date

EC REP	Authorized representative in the European Community	UDI	Unique Device Identifier
	Careful		Manufacturer's country
	Importer		Do not use if packaging is damaged and consult instructions for use.
	Fragile, handle with care		Moisture limitation
CE	CE Mark	MD	Medical device
CE 1304	CE marking with notified body number; SIQ, number 1304	Rx Only	FDA-mandated prescription notification for the United States States Market

MANUFACTURED BY

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