



## 703167 IFU Bone Profile Drill and Guide-Revision 02

### ITEMS

CODE	DESCRIPTION	CE MARK
ZD03.033	BONE PROFILE DRILL	CE 1984

### REGULATORY TABLE

***Non-sterile / Reusable / CE1984***

Symbology	Description	Symbology	Description	Symbology	Description
	Product size		Material used		Do not use if package is damaged
	Product code		Non-sterile		CE Mark for European Community market
	Batch Number		Refer to instructions for use		Notification required by FDA for United States market
	Date of manufacture		Upper limit of temperature		Representative in the European Community
	Shelf life		Keep dry		Manufacturer
	Quantity		Keep protected from sunlight		

### ADDRESSES

Manufactured by: ZINEDENT İMPLANT ÜRETİM A.Ş.  
Kızılırmak Mah. Ufuk Ün. Cd. 1445. Sok. 2/B 8 Çukurambar-Çankaya-Ankara/TÜRKİYE

European Representative: Intradent AG, Peter Merian-Weg 12 CH-4052, Basel, Switzerland

Batch and date of manufacture: see label

# BONE PROFILE DRILL AND GUIDE

This device is intended for a specialized procedure, which must be performed by professionals qualified in Dental Implants. For optimum results, use the product knowing the appropriate techniques and always apply them under appropriate conditions, including in an operation room.

## DESCRIPTION

The Bone Profile Drill is manufactured in surgical stainless steel. Its active end presents a cavity that fits the Bone Profile Drill Guide with a cutting profile. Its other end presents a fitting for contra-angle. The Bone Profile Drill Guide presents a fitting for Hand Screwdriver and a thread that adapts directly over the implant.

## INDICATIONS FOR USE

Rotary instrument indicated for drilling dentin or bone tissue.

## APPLICATIONS

This product is a surgical instrument used to prepare and level bone tissue around the implant platform. The Bone Profile Drill Guide has the function to protect the implant prosthetic interface and orient the Bone Profile Drill.

## CONTRAINDICATIONS

This product presents no contraindications as long as it is used according to its instructions for use.

## HANDLING

After removing the Cover Screw from the implant, install the Bone Profile Drill Guide, slightly tightening it, manually and using the Hand Screwdriver 1.2 mm. Fit the Bone Profile Drill in the contra-angle or in the Hand Implant Driver handpiece and set the surgical motor to a drilling speed between 200 to 300 rpm. Couple the Bone Profile Drill over the Bone Profile Drill Guide and advance it until it reaches the maximum proximity to the implant, leaning over the Guide. During drilling, the pressure cannot be excessive and there must be abundant irrigation.

## SANITATION

This product must be correctly cleaned after each use.

Proceed as follows:

### Manual cleaning and disinfection

#### Cleaning

1. Disassemble the instruments if possible (see specific disassemble instructions for each instrument, when applicable).
2. Soak the disassembled instruments for at least 1 min in the cleaning solution (CIDEZYME®, 1.6 % v/v) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by carefully brushing with a soft brush. Sway movable parts several times during cleaning.

If applicable, rinse all lumens of the instruments for, at least, five times using a single-use syringe (minimum volume of 10 mL).

3. Soak the disassembled instruments for 15 minutes in the cleaning solution (CIDEZYME®, 1.6 % v/v) with ultrasonic treatment so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments.

4. Remove the instruments from the cleaning solution and intensively post-rinse them for, at least, 3 times (for the minimum time of 1 minute) under running water.

If applicable, rinse all lumens of the instruments for, at least, five times at the beginning of the soaking time using a single-use syringe (minimum volume of 10 mL).

### **Disinfection**

1. Soak the disassembled instruments for 12 minutes in the disinfectant solution (CIDEX® OPA - OPA Solution -, undiluted) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments.

If applicable, rinse all lumens of the instruments for, at least, five times at the beginning of the soaking time using a single-use syringe (minimum volume of 10 mL).

2. Remove the instruments from the disinfectant solution and post-rinse them according to the instructions of the manufacturer of CIDEX® OPA - OPA Solution-:

### **Rinsing Instructions**

- Following removal of the instruments from CIDEX® OPA - OPA Solution - Solution, thoroughly rinse the medical device by immersing it completely in a large volume of water. Use sterile water unless potable water is acceptable (maximum of 10 germs/mL, maximum of 0.25 endotoxin/mL).

- Keep the device totally immersed for, at least, 1 minute.

- Manually flush all lumens with large volumes (not less than 100 mL) of rinse water.

- Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.

- Repeat the procedure for 2 additional times, concluding A TOTAL OF 3 RINSES, with large volumes of fresh water to remove CIDEX® OPA - OPA Solution - Solution residues. Residues may cause serious side effects.

3. Check and pack the instruments immediately after the removal.

### **Automated cleaning/disinfection (WD (Washer-Disinfector))**

Use neodisher® MediZym.

1. Disassemble the instruments if possible (see specific disassemble instructions for each instrument, when applicable).

2. Transfer the disassembled instruments to the WD (pay attention that the instruments are not in contact with each other).

3. Start the program.

4. Remove the instruments from the WD after the end of the program.

5. Check and pack the instruments immediately after the removal.

### **NOTE:**

1. Pay attention to the following points during the selection of the WD:

- approved efficiency of the WD (e.g. CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration);

- possibility of an approved program for thermal disinfection (A0 value > 3000 or - in case of older devices - at least 5 minutes at 90 °C/194 °F; in case of dangerous chemical disinfection of disinfectant remnants on the instruments);

- use appropriate program for instruments, as well as sufficient information on rinsing in the program;

- post-rinsing only with sterile or low contaminated water (e.g. maximum of 10 germs/mL, maximum of 0.25 endotoxin/mL);
  - use only filtered air (oil-free, low contamination with microorganisms and particles) for drying;
  - regular maintenance and check/calibration of the WD.
2. Please do not clean any instruments using metal brushes or steel wool.
  3. After cleaning and disinfection, check all instruments on corrosion, damaged surfaces, and impurities. Do not use damaged instruments. Instruments that are still contaminated must be cleaned and disinfected again.
  4. Packaging: insert the cleaned and disinfected instruments on the corresponding sterilization trays, in single-use sterilization packagings (single or double packaging) and/or sterilization containers, which fulfill the following requirements:
    - EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance);
    - suitable for steam sterilization ;
    - sufficient protection for instruments as well as for maintenance of sterilization packagings against mechanical damage;
  5. After using the instruments, it is recommended to remove coarse impurities, performing the pre-treatment, before cleaning and disinfection (within a maximum deadline of 2 hours). The pre-treatment step must be performed for both cases of cleaning and disinfection (automated and manual).
    - a. Disassemble the instruments if possible;
    - b. Rinse the instruments for, at least, 1 minute under running water (temperature < 35 °C);
    - c. If applicable, rinse all lumens of the instruments five times per application using a single-use syringe (minimum volume of 10 mL). Sway movable parts several times during pre-treatment;
    - d. Remove manually all visible impurities by using a clean and soft brush (or a clean, soft, and lint-free cloth). In no case use metal brushes or steel wool;
    - e. Rinse again for, at least, 1 minute under running water.
  6. If the cleaning/disinfection products mentioned cannot be found, make sure to use similar products to those indicated. This replacement is the owner's responsibility.
  7. The drying of the parts is of utmost importance before storage and sterilization, because the accumulation of moisture on the products is harmful and may cause oxidation.

NOTE: During sanitation, try to avoid contact between cutting tools and other tools so the cutting power is not harmed.

## PRESENTATION AND STERILIZATION

This product is reusable and supplied non-sterile, being unitarily packaged. This product must be correctly cleaned and sterilized before each use. Sterilize the products on the previous day or on the day of the procedure. ATTENTION: Do not autoclave this product in its original packaging.

Please use for sterilization only the steam sterilization according to the following parameters:

	Fractionated Vacuum / Dynamic Air Removal <sup>1</sup>	Gravity Displacement
<b>Sterilization Time</b>	4 minutes	15 minutes
<b>Sterilization Temperature</b>	132 °C / 270 °F	132 °C / 270 °F
<b>Drying Time</b>	At least 20 minutes <sup>2</sup>	At least 20 minutes <sup>2</sup>

<sup>1</sup> At least three vacuum steps.

<sup>2</sup> The effectiveness required in drying time depends directly on the parameters of sole responsibility of the user (density and load configuration, sterilizing conditions, which must be determined by the user). Nevertheless, a drying time shorter than 20 minutes cannot be applied.

**Note:**

1. After sterilization, package the instruments at a dry and dust-free place.
2. A flash/immediate use sterilization procedure cannot be used.
3. Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

## **PRECAUTIONS**

- Make sure to use the drill compatible with the indicated drilling sequence according to the prosthetic interface and dimensions of the planned implant.
- Do not interrupt the rotation of the motor while the drill is inside the surgical cavity, as this may impede its removal or cause it to break.
- The drills cannot be resharpened.
- Be aware in cases of patients that present signs of allergy or hypersensitivity to chemical elements of the material: surgical stainless steel.
- Failure to replace the drills as recommended by the manufacturer can cause improper bone heating, compromising the success of the procedure.
- This product must be used sterile.
- Inappropriate planning can compromise the performance of the implant/prosthesis unit leading to failures of the system, such as loss or fracture of the implant, loss or fracture of abutments and/or prosthetic screws.
- Do not use the product if its packaging is damaged.
- Do not use the product with its validity expired.
- Before each procedure, ensure the pieces fit perfectly.
- Ensure that the parts are not swallowed or aspirated by the patient.
- Make sure you have all the necessary instruments for the procedure according to surgical planning.
- Before each procedure, check the conditions of the Zinedent surgical instruments, always respecting their useful life. Replace the instruments if there is damage, deleted markings, compromised sharpening, deformation or wear.
- Always use the Zinedent product sequence. The use of prosthetic abutments and/or instruments from other manufacturers does not ensure the perfect function of the Zinedent Implant System and exempts any product warranty.
- It is the professional's responsibility to use the Zinedent products according to their instructions for use.

## **ADVERSE EFFECTS**

Adverse effects are not expected as long as the product is used in accordance with its instructions for use.

## **POST-OPERATIVE PRECAUTIONS AND MAINTENANCE**

Instruct the patient as to the need for a professional medical monitoring after the surgery and to obey the guidelines regarding precautions, hygiene and prescription of drugs. The professional in charge is responsible for providing these guidelines.

## **STORAGE CONDITIONS**

This product must be stored, in its original packaging, in a clean and dry location, at a maximum temperature of 40°C and protected from direct sunlight.

## **DISPOSAL OF MATERIAL**

All products and consumables used in the surgery for the installation of dental implants may endanger the health of anyone who handles them. Before discarding them into the environment, it is recommended to observe the current legislation and adhere to it.

## **DATE OF EXPIRATION**

Written on the label.

## **LIFE CYCLE**

This product is recommended for up to 30 uses, as long as the conditions of use indicated by Zinedent are respected.

Regardless of the amount of times that the instrument has been used, the professional must always evaluate its condition after each use.

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