703164 IFU Countersink Drill-Revision 03

ITEMS

CODE	DESCRIPTION	CE MARK
ZD03.006	COUNTERSINK DRILL 3.5	CE 1984
ZD03.007	COUNTERSINK DRILL 4.3	CE 1984
ZD03.008	COUNTERSINK DRILL 5.0	CE 1984

REGULATORY TABLE

Non-sterile / Reusable / CE1984

Symbology	Description
SIZE	Product size
REF	Product code
LOT	Batch Number
	Date of manufacture
	Shelf life
Qty	Quantity

Symbology	Description
MAT	Material used
NON-STERILE	Non-sterile
	Refer to instructions for use
	Upper limit of temperature
	Keep dry
	Keep protected from sunlight

Symbology	Description
	Do not use if package is damaged
CE 1984	CE Mark for European Community market
Rx only	Notification required by FDA for United States market
EC REP	Representative in the European Community
	Manufacturer

ADDRESSES

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

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

Batch and date of manufacture: see label

COUNTERSINK DRILL

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 Countersink Drill is manufactured in surgical stainless steel. Its active end presents a guide of reduced diameter for positioning during drilling and cutting facets in its nominal diameter. Its other end presents a fitting for contra-angle.
The laser markings determine the implant installation levels according to the table below:

Drill	Laser Markings
ZD03.006 – 2.8/3.5	**1st marking:** installation of implant in bone crest level; **2nd marking:** installation of implant 1 mm below the bone crest; **3rd marking:** installation of implant 2 mm below the bone crest; **4th marking:** reference level (3 mm).
ZD03.007 – 3.6/4.3	
ZD03.008 – 4.3/5.0	**1st marking:** installation of implant in bone crest level; **2nd marking:** installation of implant 1 mm below the bone crest; **3rd marking:** installation of implant 2 mm below the bone crest;

The Countersink Drills receive the application of a dark-colored carbon coating on the cutting surface. This coating has the main purposes of: reducing the heat generated during osteotomy; reducing the friction between drill and bone; increasing wear resistance; increasing the resistance to oxidation.

INDICATIONS FOR USE

Rotary instrument indicated for drilling dentin or bone tissue.

APPLICATIONS

This product is a surgical instrument used to drill bone tissue, with the purposes of final perforation, with the function to prepare the bone crest for seating the cervical third of the chosen implant.

CONTRAINDICATIONS

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

HANDLING

Fit the Countersink Drill in the contra-angle handpiece and set the surgical motor to drilling speed, as indicated for the selected implant. Activate the motor and perform the drilling, with abundant irrigation. This irrigation can be manual or combined with the irrigation from the motor. During drilling, the pressure cannot be excessive and must respect the bone quantity and quality, the implant selected, and the surgical planning. The drilling must be in accordance with the laser markings on the drill. The laser markings on the drill represent the implant installation levels.
Note 1: The correct sequence of drills and the rotation speed indicated for each implant must be respected, contributing to the success of the osseointegration of the implant. Note 2: Do not interrupt the rotation of the motor with the drill inside the surgical cavity, as this may make it difficult to remove it or may cause the drill to break.

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[1]	**Gravity Displacement**
Sterilization Time	4 minutes	15 minutes
Sterilization Temperature	132°C / 270°F	132°C / 270°F
Drying Time	At least 20 minutes[2]	At least 20 minutes[2]

[1] At least three vacuum steps.

[2] 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.

Not all products are available in all countries. Please, contact the authorized distributor.