

Coated Drills Family

Coated Drills Family are intended for specialized procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.



PRODUCT DESCRIPTION

The Coated Drills Family are produced in stainless steel, at one end it has a fitting for contra-angle (active device) and at the other end an active tip with cut and geometry compatible with the implant to be installed. The drills are laser marked to determine the depth of the drilling according to the surgical planning. The drills have DLC surface (Diamond-Like Carbon).

INDICATIONS OF USE

The Coated Drills Family are surgical instruments indicated for the preparation of the surgical alveolus for the installation of dental implants.

- **Lance Drill:** Used to mark the place where the implant will be installed, promoting the rupture of the cortical bone facilitating the insertion of other drills;
- **Helical Drill:** Used to deepen and direct the perforation into the bone according to the surgical plan;
- **Conic Drill:** Used in progressive diameter enlargement in the surgical site until the adequate dimension for implant installation;
- **Countersink Drill:** Used exclusively for external hexagon implants with 4.1mm of platform. The purpose of this drill is to make space for a correct seating of the implant platform;
- **Pilot Drill:** Used in the surgical sequence after the helical drill and before each conic drill to avoid increasing the temperature while drilling.

OPERATION PRINCIPLE

The purpose of the cutters is to drill the surgical socket with the appropriate dimensions for installing

dental implants. The cutters have active cutting points of surgical steel that by shearing mechanical action cut the bone.

HOW TO USE

1. Select the set of drills necessary to obtain the proper drilling of the place taking into account the desired length and width;
2. Ensure that the drills are properly sterilized when starting the procedures (see sterilization conditions contained in this instruction for use);
3. The drills must be fitted in the contra-angle, configure the motor at the speed, torque and irrigation suitable for the type of implant to be installed;
4. Carry out drilling with continuous insertion and removal movements using the cutter with the planned length and diameter;
5. Proceed with surgical procedures.



ATTENTION

The Coated Drills Family are intended for specialized procedures, which must be performed by qualified professionals in Implantology. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTIONS

Before drilling, make sure that the drill fits into the hand piece and that the motor is adjusted for rotation, torque and irrigation. During drilling the pressure must not be excessive, and intermittent movements must be

made. The drills are not capable of sharpening and using them without cutting can generate undue bone heating, compromising the success of the procedure. The use of the drills or the inappropriate drills sequence can compromise the performance of the implant resulting in system failures, such as implant loss or fracture. Before each procedure, check the condition of the instruments, always respecting their useful life. It is necessary to replace the instruments in case of damage, erased markings, compromised sharpening, deformations and wear.

RECOMMENDATIONS

The product should only be used by qualified dental professionals who already have all the scientific information necessary for the correct use of the product. Always perform cleaning and sterilization as recommended before the surgical procedure. Care should be taken in cases of patients who show signs of allergy or hypersensitivity to stainless steel. The drills can be used for up to 30 surgical instruments depending on proper handling, cleaning and sterilization. It is necessary to check the sharpening of the instruments after each surgical procedure and if there is a lack of sharpening, the material must be discarded. Being: 20 perforations in high density bones and 30 perforations in low density bones.

CONTRAINDICATIONS

Use of drills without irrigation, which can cause bone necrosis. Use for purposes other than preparing the surgical alveolus for installing dental implants.

SIDE EFFECTS

Side effects can only occur if the drill is not handled according to the instructions for use.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of the instruments. All items may exhibit natural wear and tear and should be replaced whenever the professional identifies loss of fit or accuracy of these products as they may interfere with the end result of the work.

TRACEABILITY

All S.I.N. products - Implant System have sequential batches that allow traceability, thus promoting greater safety to the professional skilled in the procedure. Through this lot number it is possible to know all product history from the manufacturing process to the time of distribution.

STORAGE

The Drills should be stored in a cool, dry place at a maximum temperature of 35 ° C and protected from direct sunlight.

HANDLING

Once sterilized, the instruments should be handled only in a sterile environment by properly attired professionals and in appropriate clothing at the time of surgery to install implants. Scratches or notches of the instruments should be avoided as such factors may increase the possibility of corrosion of the products.

DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

TRANSPORTATION

The Coated Drills Family must be transported adequately to avoid falling and stored under a maximum temperature of 35°C, protected from heat and moisture. Carriage must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Reprocessing Allowed. Refer to the cleaning and sterilization conditions contained in these Instructions. In case of an incident caused by the product, the professional must immediately inform the manufacturer. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplante.com.br or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Remove all internal organic material with running water, and move on to the next step only when this has been done;
2. Prepare the enzymatic detergent according to the manufacturer's recommendation;
3. Immerse all parts of the product into the prepared detergent solution and keep in contact for at least 5 minutes, then using soft bristle brush, scrub the parts to remove organic matter from the products;
4. Remove parts from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each;
5. Visual inspection of each part for cleaning process residue or organic waste from product use;
6. If residue is detected in the product, repeat the cleaning process until the residue is completely removed;
7. Dry with a soft, clean, dry cloth or disposable paper;
8. Follow to sterilization process.

RECOMMENDATIONS

- a. Use the proper PPEs (gloves, masks, goggles, caps, etc.);
- b. Start the cleaning right after the surgical use;
- c. Never let the instruments dry with organic waste after the surgical use;
- d. Never let the instrument dry naturally after cleaning;
- e. Never use saline solutions, include sodium hypochlorite, disinfectant, hydrogen peroxide or alcohol to cleaning or rinsing the surgical instruments and Kits;
- f. Never use steel wool and abrasive products, so that the instruments are not damaged;
- g. Do not stack the instruments in lots to avoid the deformation of smaller and delicate pieces.

STERILIZATION

Reusable product and provided non-sterile. It must be clean and sterilized in autoclave before use.

1. Dry all instruments before the steam sterilization cycle;
2. The product must be enclosed in a steam sterilizable wrap;

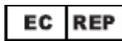
1. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes;
2. Always accommodate the case in autoclave over a plane surface and away of device walls;
3. Never stack objects or other cases.

RECOMMENDATIONS

- a. Sterilize the products in the same day or one day earlier the procedure;
- b. The chemical sterilization is not recommended, once some products may cause the discoloration and damages to the case;
- c. Do not use temperature higher than 60°C to drying process;
- d. Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N. - Implant System.

LIFE TIME

The Coated Cutters Family can be used for up to 30 surgical instrumentations depending on proper handling, cleaning and sterilization. It is necessary to verify the sharpening of the instruments after each surgical procedure and if it is verified lack of sharpening, the material should be discarded. Being: 20 perforations in high density bones; 30 perforations in low density bones.

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|---|--|--|---|
|  | NÃO ESTÉRIL | NON-ESTERILE | NO ESTÉRIL |
|  | CONSULTAR AS INSTRUÇÕES DE USO | CONSULT INSTRUCTIONS FOR USE | CONSULTE LAS INSTRUCCIONES DE USO |
|  | MARCAÇÃO CE | CE MARK | MARCA CE |
|  | MANTENHA SECO | KEEP DRY | MANTÉNGALO SECO |
|  | MANTENHA AO ABRIGO DO SOL | KEEP AWAY FROM SUNLIGHT | MANTÉNGALO LEJOS DE LA LUZ SOLAR |
|  | NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA | DO NOT USE IF PACKAGE IS DAMAGED | NO LO UTILICE SI EL ENVOLTORIO ESTÁ DAÑADO |
|  | ATENÇÃO | CAUTION | PRECAUCIÓN |
|  | REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA | AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY | REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA |
|  | LÍMITE SUPERIOR DE TEMPERATURA | UPPER LIMIT OF TEMPERATURE | LÍMITE SUPERIOR DE TEMPERATURA |
| Rx only | ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTE DISPOSITIVO POR OU POR ORDEM DE UM PROFISSIONAL DE SAÚDE LICENCIADO. | CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER. | PRECAUCIÓN: LAS LEYES FEDERALES (USA) RESTRINGEN LA VENTA DE ESTE DISPOSITIVO POR O EN EL ORDEN DE UN PROFESIONAL DE LA SALUD LICENCIADO. |
|  | FABRICANTE | MANUFACTURE | FABRICANTE |
|  | DATA DE FABRICAÇÃO | DATE OF MANUFACTURE | FECHA DE FABRICACIÓN |
|  | CÓDIGO DE REFERÊNCIA | REFERENCE CODE | CÓDIGO DE REFERENCIA |
|  | DISPOSITIVO MÉDICO | MEDICAL DEVICE | DISPOSITIVO MEDICO |
|  | IDENTIFICADOR ÚNICO DO DISPOSITIVO | UNIQUE DEVICE IDENTIFIER | IDENTIFICADOR DE DISPOSITIVO ÚNICO |
|  | IMPORTADOR | IMPORTER | IMPORTADOR |
|  | DISTRIBUIDOR | DISTRIBUTOR | DISTRIBUIDOR |
|  | PAÍS DE FABRICAÇÃO | COUNTRY OF MANUFACTURE | PAÍS DE FABRICACIÓN |
|  | LOTE | BATCH CODE | LOTE |
|  | EMBALAGEM RECICLÁVEL | RECYCLABLE PACKAGING | EMBALAJE RECICLABLE |

DEVELOPED AND MANUFACTURED BY:

S.I.N. Sistema de Implante Nacional S/A

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74

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PRODUCT:

Coated Drills Family

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