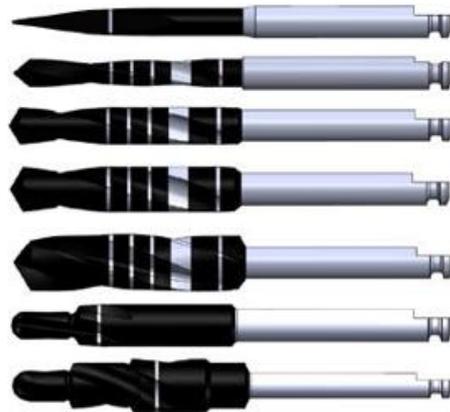


The Coated Drills Family are intended for surgical procedures for installing dental implants, which must be carried out by qualified professionals. The way in which the product is used and surgical techniques are inherent to the professional's training. The product must be used in a surgical environment and under conditions suitable 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 a contra angle (active device) and at the other end there is an active tip with a cut and geometry compatible with the implant to be installed. The drills are laser marked to determine the drilling depth according to the surgical plan. The drills have a DLC (Diamond-Like Carbon) surface.

INDICATIONS OF USE

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

Lance Drill: Used to mark the location where the implant will be installed, promoting disruption of the bone cortex, facilitating the insertion of other drills;

Helical Drill: Used to deepen and direct the drilling in the bone tissue according to the planning carried out by the professional;

Conical Drill: Used in sequence to enlarge the perforation in progressive diameter until the final dimension is suitable for installing the implant following the surgical planning;

Countersink Drill: Used to enlarge the diameter in the cervical region of the implant. Its purpose is to create a bevel for correct seating of the implant platform;

Pilot Drill: Used in the surgical sequence after the helical drill and before each conical drill to mitigate bone heating.

PURPOSE AND OPERATION PRINCIPLE

The purpose of the Coated Drills Family is drilling the surgical alveolus with the appropriated dimensions for the installing dental implants. The Drills have active surgical steel cutting tips that by mechanical shearing action cut the bone.

HOW TO USE THE INSTRUMENT

Select the set of drills necessary to obtain adequate drilling in the area, taking into account the desired length and width. Ensure that the drill are properly sterilized when starting the

procedures (see sterilization conditions contained in this instruction for use). The drill must be fitted to the contra angle, set the motor to the appropriate speed, torque and irrigation for the type of implant that will be installed. Carry out drilling with continuous insertion and removal movements using the cutter with the planned length and diameter. Proceed with surgical procedures.

ATTENTION

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 the drills fits into the counter angle and adjusts the motor in relation to rotation, torque and irrigation. During drilling, pressure must not be excessive, and intermittent movements must be made. The drills cannot be sharpened and using them without cutting can cause undue bone heating, compromising the success of the procedure. The use of inappropriate drills or sequence of drills may compromise the performance of the implant, resulting in system failures, such as loss or fracture of the Implant. 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 clean and sterilize as recommended before the surgical procedure. Care must 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 sharpness of the instrument after each surgical procedure and if a lack of sharpness is found, the material must be discarded. Of which: 20 perforations in high-density bones; 30 perforations in low density bones.

CONTRAINDICATION

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

SIDE EFFECTS

Adverse 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 spots of oxidation/corrosion. 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 have sequential batches that allow traceability, thus promoting greater safety for professionals skilled for 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 Coated Drills Family should be stored in a cool dry place at a temperature of 15°C to 35°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

Once sterilized, the instruments should be handled 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 can 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 at a maximum temperature of 35°C, protected from heat and moisture. Transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for dental use. Reprocessing allowed. Refer to the cleaning and sterilization conditions contained in this instruction for use. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplantsystem.com or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Prepare the enzymatic detergent according to the detergent manufacturer's instructions.

2. Immerse all parts of the product into the prepared detergent solution and leave for 5 minutes. Then, using a soft bristle brush, scrub the parts for at least 2 minutes until complete remove organic matter from the products.
3. Remove the parts from the detergent solution and rinse with tap water for 1 minute until the residue is completely removed. Repeat the rinse two more times.
4. Visually inspect each part to check for process residues or organic residues from the used of the product.
5. If residue in detect in the product, repeat the cleaning process until the residue is completely removed.
6. Dry with a soft, clean, dry cloth or disposable paper.
7. Proceed to the sterilization process.

RECOMMENDATIONS

- a. Wear appropriate clothing (gloves, masks, glasses, hats, etc.)
- b. Begin cleaning immediately after surgical use.
- c. Never let the instrument dry containing organic residues after surgical use.
- d. Never let the instrument dry naturally after cleaning.
- e. Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide or alcohol to clean or rinse surgical instruments and Kit trays.
- f. Never use steel wool or sponges or abrasive products, so that the instruments are not damaged.
- g. Do not accumulate instruments in large quantities on top of each other to avoid 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.
3. 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.
4. Always accommodate the case in autoclave over a plane surface and away of device walls.
5. 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.

LIFE TIME

The Coates Drills Family can be used for up to 30 surgical instruments depending on proper handling, cleaning and sterilization. It is necessary to check the sharpness of the instrument after each surgical procedure and if a lack of sharpness is found, the material must be discarded. Of which: 20 perforations in high-density bones; 30 perforations in low density bones.

	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
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LÍMITE 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	MANUFACTURER	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DISPOSITIVO ÚNICO DE
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DESTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE

**MANUFACTURER****S.I.N. Implant System LTDA.**

CNPJ [Corporate Taxpayer's Registry]: 04.298.106/0001-74
Rua Soldado Ocimar Guimarães da Silva, 421 - Vila Rio Branco
CEP: 03348-060 - São Paulo - SP - Brasil

EU	REP
----	-----

OBELIS S.A.

Bd. Général Wahis 53
1030 Brussels, Belgium

**SERVICE TO PROFESSIONALS**

0800 770 8290 +55 (11) 2169-3000
www.sinimplantsystem.com
e-mail: sin@sinimplantsystem.com

RESPONSIBLE TECHNICIAN

Alessio Di Risio
CREA-SP: 5061207169

PRODUCT

Coated Drills Family