

The Diamond Drills Family are intended for surgical procedures for installing dental implants, which must be performed by qualified professionals. The way of using 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 conditions suitable for the health and safety of the patient.



### PRODUCT DESCRIPTION

The Diamond Drills Family are produced in stainless steel, at one end it has a fitting for a contra-angle handpiece (active device). They have a diamond-coated surface.

### INDICATIONS OF USE

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

**Diamond Drill:** Used to prepare the bone bed to support drills and implants in the externalized zygomatic technique.

**Round Diamond Bur:** Used for initial bone marking, creating retention on the bone surface to be drilled later.

### PURPOSE AND OPERATION PRINCIPLE

The purpose of the Diamond Drills Family is to remove bone to facilitate the insertion of helical drills and implant placement. Its active surface is coated with diamond, which, through mechanical attrition, wears down the bone.

### HOW TO USE THE INSTRUMENT

#### **Round Diamond Bur**

1. Maximum rotation: 1200 RPM.
2. Position the drill bit at an angle over the bone crest and begin drilling with slight pressure.
3. The cutting depth should not exceed half the sphere, otherwise it may cause overheating.
4. Do not make lateral movements during drilling, as this may damage the surgical socket and make implant placement impossible.
5. Use abundant and uninterrupted irrigation.

## Diamond Drill

1. Maximum rotation: 1200 RPM.
2. Position the inactive tip of the drill over the marking previously made with the helical lance drill and begin lateral grinding with slow and intermittent movements to facilitate the entry of larger diameter helical drills.
3. Use abundant and uninterrupted irrigation.

### ATTENTION

The Diamond 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 fit into the counter angle and adjust the motor in relation to rotation, torque and irrigation. During drilling, 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 drills or inappropriate drills can 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 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.

### CONTRAINDICATION

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

Failure may result from factors intrinsic to the surgical procedure, such as the local conditions and health of the implanted individual, and the skill and knowledge of the professional performing it.

## 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 Diamond 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 Diamond 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 is 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 (including shipping), please request by e-mail to [sin@sinimplantsystem.com](mailto:sin@sinimplantsystem.com) or call to 0800 770 8290 will receive until 7 days calendar. Please verify that this version of the instructions for use matches the product you purchased, checking the model, batch and version.

## 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 Diamond 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 in high-density bones perforations and 30 in low-density bones perforations.

	PRODUTO ESTERILIZADO POR RADIAÇÃO GAMA	PRODUCT STERILIZED THROUGH GAMMA RAYS	PRODUCTO ESTERILIZADO POR RADIACIÓN GAMA
	NÃO REUTILIZAR	DO NOT REUSE	NO LO REUTILICE
	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
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO REESTERILIZAR
	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
<b>Rx only</b>	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
	VALIDADE	USE-BY DATE	VALIDEZ
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	SISTEMA DE BARREIRA DUPLO ESTÉRIL	DOUBLE STERILE BARRIER SYSTEM	SISTEMA DE DOBLE BARRERA ESTÉRIL
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DESTribUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN

LOT	LOTE	BATCH CODE	LOTE
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EMBALAGEM RECICLÁVEL

RECYCABLE PACKAGING

EMBALAJE RECICABLE

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

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EU	REP
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**PRODUCT**

Diamond Drills Family