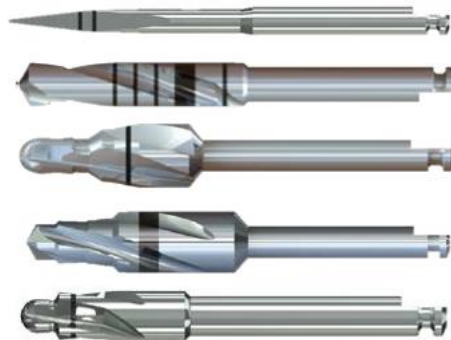


The S.I.N. Diamond Surgical Drills Family are intended for surgical procedures for installing dental implants, which must be performed by qualified professionals. The way of using the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in conditions suitable for the health and safety of the patient.



### PRODUCT DESCRIPTION

S.I.N. Diamond Surgical Drills are produced in stainless steel, at one end it has a fitting for a contra angle (active device) and at the other end an active tip with a 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 a Diamond surface.

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

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

### INDICATIONS OF USE

S.I.N. Diamond Surgical Drills are surgical instruments indicated for the preparation of the surgical alveolus for the installation of dental implants.

### PURPOSE AND OPERATION PRINCIPLE

The purpose of the S.I.N. Diamond Surgical Drills is to drill the surgical alveolus with the appropriate dimensions for the installation of dental implants. The drills have active cutting points of surgical steel that by shearing mechanical action cut the bone.

### HOW TO USE THE INSTRUMENT

1. Select the set of drills necessary to obtain the proper drilling of the place considering 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 to the contra angle, configure the motor to 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 drill with the planned length and diameter.
5. Proceed with surgical procedures.

## ATTENTION

S.I.N. Diamond Surgical Drills 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 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 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 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 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

S.I.N. Diamond Surgical Drills should be stored in a cool dry place at a temperature of 15°C to 25°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

S.I.N. Diamond Surgical Drills must be transported adequately to avoid falling and stored at a maximum temperature of 25°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, 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.

## 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 you completely 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 use of the product.
5. If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
6. Dry with soft, clean, dry cloth or disposable paper.
7. Proceed with 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.








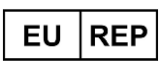











1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed with a sterilizable steam wrap.
3. Steam sterilizes in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave over a plane surface and away from device walls.
5. Never stack objects or other cases.

## **RECOMMENDATIONS**

- a. Sterilize the products on the same day or one day earlier the procedure.
- b. Chemical sterilization is not recommended, since some products may cause discoloration and damage 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.

## **LIFETIME**

S.I.N. Diamond Surgical 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 in high-density bones perforations and 30 in low-density bones perforations.

	NÃO ESTÉRIL	NON-ESTERILE	NON STÉRILE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTER LE MODE D'EMPLOI
	MARCAÇÃO CE	CE MARK	CE MARQUE
	MANTENHA SECO	KEEP DRY	GARDER AU SEC
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	TENIR À L'ABRI DE LA LUMIÈRE DU SOLEIL
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NE PAS UTILISER SI L'EMBALLAGE ENDOMMAGÉ
	ATENÇÃO	CAUTION	ATTENTION
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRÉSENTANT AUTORISÉ DANS LA COMMUNAUTÉ EUROPÉENNE
	LIMITE DE TEMPERATURA	TEMPERATURE LIMIT	LIMITE DE TEMPÉRATURE
<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.	ATTENTION: LES LOIS FÉDÉRALES (AMÉRICAINES) LIMITENT LA VENTE DE CET APPAREIL PAR OU SUR ORDRE D'UN PROFESSIONNEL DE LA SANTÉ AGRÉÉ.
	FABRICANTE	MANUFACTURER	FABRICANT
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	DATE DE FABRICATION
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CODE DE RÉFÉRENCE
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIF MÉDICAL
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICATEUR UNIQUE DE L'APPAREIL
	IMPORTADOR	IMPORTER	IMPORTATEUR
	DISTRIBUIDOR	DESTribUTOR	DISTRIBUTEUR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAYS DE FABRICATION
	LOTE	BATCH CODE	CODE DE LOT
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALLAGE RECYCLABLE
<b>DESCRIPTION ON THE LABEL</b>	CONTÉM: 1 UNIDADE	CONTENT: 1 UNIT	CONTENU: 1 UNITÉ
<b>DESCRIPTION ON THE LABEL</b>	PRODUTO NÃO ESTÉRIL	NON STERILE PRODUCT	PRODUIT NON STÉRILE

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

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

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**RESPONSIBLE TECHNICIAN**

Alessio Di Risio

CREA-SP: 5061207169

**SYSTEM**

S.I.N. Diamond Surgical Drills

**MDL LICENSE CANADA**

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