

## Male Drill

**Male Drills 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.**



### PROUDCT DESCRIPTION

The Male Drill are produced in titanium, at one of its ends it can have a fitting for contra-angle (active device) or a fitting for adapter and torque wrench and at the other end active tip with cutting threads for forming threads in the high density bone, this tip has the implant diameter to be installed, and laser markings to check the length to be instrumented.

### INDICATIONS OF USE

The Male Drill are surgical instruments indicated to form threads in high density bones (type I and II from Lekholm and Zarb 1985) during the surgical procedure, in order to provide a better insertion of the implant.

### OPERATION PRINCIPLE

The finality of Male Drill is the formation of threads in high density bone, it is used after the use of the last drill indicated for the implant installation and, consequently, the final torque for installing dental implants in this bone density is reduced.

### HOW TO USE

The Male Drills can be used in the surgical socket with ratchet or against an angle depending on the fit of the product purchased.

For use, the insertion movement must be performed clockwise. Using the ratchet, the threaded male is positioned in the surgical socket and a rotational manual movement is performed by lightly pressing the

ratchet/male threaded assembly up to the preparation length made with the cutters, the torque must not exceed 60N.cm. For contra-angle, the surgical motor must be programmed for rotation speed between 20 to 40RPM and maximum torque of 60N.cm.

For removal, adjust the ratchet or motor counterclockwise following the same rotation speed and torque criteria.



### ATTENTION

Male 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 starting the procedure, check the fitting of the male drill on the hand piece and the motor adjustment with respect to rotation, torque and irrigation.

The use of male drill improperly 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.

The selected male drill must be of the same geometry and diameter as the implant to be installed.

## CONTRAINDICATIONS

Atrophic bone ridge, where the quantity and quality of the remaining bone cannot provide adequate height and thickness of bone tissue around the implant. Places where bone pathologies or infections are present, low density bone (III and IV from Lekholm and Zarb 1985 classification)..

## SIDE EFFECTS

Failure may occur due to factors intrinsic to the surgical procedure, such as the local and health conditions of the implanted individual and the skill and knowledge of the professional who practices it.

## 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. - Implant System products 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 Male 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

Male Drills 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.

## CLEANING INSTRUCTIONS

1. Disassemble the product (if applicable). Remove all the internal organic matter using tap water and follow to the next step only after performing such procedures.
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**

Product reusable 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**

Male Drills can be used for up to 20 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.

	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
<b>Rx only</b>	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTES DISPOSITIVOS 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

**DEVELOPED AND MANUFACTURED BY:**  
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**PRODUCT:**  
 Male Drill

**ANVISA REGISTRATION** 80108910032

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