

## Screw Tap

**Screw Tap 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 condition for the health and safety of the patient.**



### PRODUCT DESCRIPTION

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

### INDICATIONS OF USE

Screw Tap are surgical instruments indicated to form threads in high-density bones (types I and II of the Lekholm and Zarb 1985 classification) during the surgical procedure, in order to provide better insertion of the implant.

### PURPOSE AND OPERATION PRINCIPLE

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

### HOW TO USE THE INSTRUMENT

Screw Tap can be used in the surgical socket with a 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 mal drill is positioned in the surgical socket and a rotational manual movement is performed by lightly pressing the ratchet/Screw Tap thread 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 and 40RPM and maximum torque of 60N.cm. For removal, adjust the ratchet or motor counterclockwise following the same rotation speed and torque criteria.

## ATTENTION

Screw Tap 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 Screw Tap on the hand piece and the motor adjustment with respect to rotation, torque and irrigation. The use of Screw Tap improperly can compromise the performance of the implant, resulting in system failures, such as 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 screw tap must have the same geometry and diameter as the implant to be installed.

## CONTRAINDICATION

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 of the classification by Lekholm and Zarb 1985).

## 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 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 Screw Tap 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 Screw Tap 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](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 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

Screw Tap can be used for up to 20 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.

	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
<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
	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
	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.**

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**PRODUCT**

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