

S.I.N. Surgical 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

S.I.N. Surgical 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

S.I.N. Surgical Screw Tap are indicated to form threads in high density bones during the surgical procedure, to provide a better insertion of the implant.

PURPOSE AND OPERATION PRINCIPLE

The finality of S.I.N. Surgical 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

S.I.N. Surgical 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

S.I.N. Surgical 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 S.I.N. Surgical Screw Tap on the hand piece and the motor adjustment with respect to rotation, torque and irrigation. The use of S.I.N. Surgical 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 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. Surgical Screw Tap 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. Surgical Screw Tap 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 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. Surgical 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	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
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.	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
DESCRIPTION ON THE LABEL	CONTÉM: 1 UNIDADE	CONTENT: 1 UNIT	CONTENU: 1 UNITÉ
DESCRIPTION ON THE LABEL	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

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SYSTEM

S.I.N. Surgical Screw Tap

MDL LICENSE CANADA

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