

SURGICAL INSTRUMENTALS

Articulated, non-cutting, without connection
with equipment



Articulated, non-cutting, without connection with equipment 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 Articulated, non-cutting, without connection with equipment are produced in stainless steel and have a specific active tip fitting with other instruments (driver).

INDICATIONS OF USE

The Articulated, non-cutting, without connection with equipment are indicated for installation of implants and prosthetic components, assist in the surgical procedure or in the fixation/removal of implants and components.

Prosthetic Torque Wrench: Used to tighten the screw of the prosthetic component with a torque rating of 10N.cm, 20N.cm and 32N.cm.

Surgical Torque Wrench: Used to install the implant, with a torque rating of 30N.cm, 45N.cm, 60N.cm and 80 N.cm.

Surgical Rod Torque Wrench: Used to install the implant with a torque rating of 30N.cm, 45N.cm, 60N.cm and 80N.cm.

OPERATION PRINCIPLE

The finality is to enable the installation of dental implants and prosthetic components, through the aid in the surgical procedure.

Its operating principle is based on the mechanical principle of force transmission, for the activation of secondary elements.

HOW TO USE

1. Open the original packaging and remove the instrument.
2. Before first use or after being used in surgical procedures, perform the cleaning and sterilization procedures contained in this instruction for use.
3. After sterilized, the instruments will be ready for use.



ATTENTION

The Articulated, non-cutting, without connection with equipment are intended for expert procedures, which must be performed by qualified professionals in implant Dentistry. The product must be used in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTIONS

The Articulated, non-cutting, without connection with equipment should be selected according to the implant / component installation recommendations.

Use of excessive force or disengagement between parts can damage the product.

Before each procedure, make sure the perfect fit between the parts, and the conditions 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 be used only 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.

CONTRAINDICATIONS

Use for purposes other than installing or removing implants and prosthetic components.

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

Articulated, non-cutting, without connection with equipment 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

Articulated, non-cutting, without connection with equipment 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 (as step by step demonstrated in this instruction for use). 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.

- 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

It is necessary to check the functionality, fitability or accuracy of these products after each procedure and if there is natural wear and tear generated by use, they must be replaced and discarded.

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.

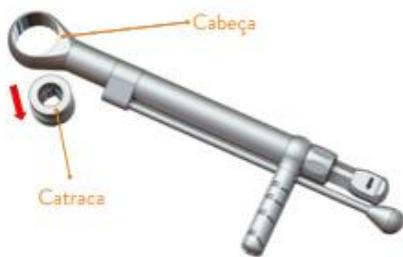
PERFORMING THE DISASSEMBLY OF THE TORQUE WRENCH

Torque Wrench – Model TMECC 02 e TMECC 03

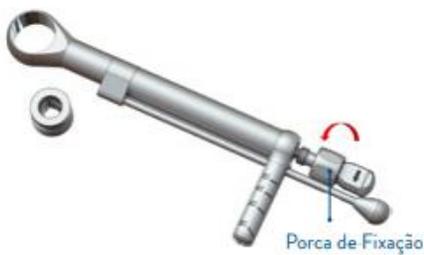
1. Pull the inverter stem back on.



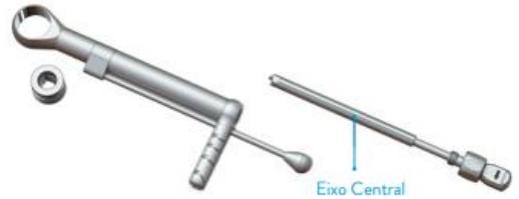
2. Remove the ratchet.



3. Rotate the fastening nut in a counter-clockwise direction.



4. Remove the central axle.



5. Remove the stem torque graduation.



6. Begin the washing procedure.

PERFORMING THE DISASSEMBLY OF THE TORQUE WRENCH

Torque Wrench – Model TMEC

1. Rotate the torque wrench counter-clockwise until it is fully released.



2. After loosening the drum, remove the body and the head from the torque wrench.



3. Remove the spring and washers from the torque wrench.



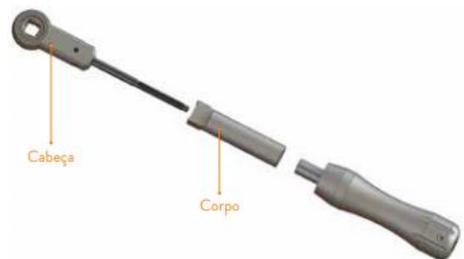
4. Begin washing procedure.

Torque Wrench – Model TMECC

1. Rotate the torque wrench counter-clockwise until it is fully released.



2. After loosening the drum, remove the body and the head from the torque wrench.



3. Begin washing procedure.

After completely drying, assemble the torque wrench following the same disassembly procedures in reverse order.

	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
Rx only	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 REFERENCIA

DEVELOPED AND MANUFACTURED BY:
 **S.I.N. Sistema de Implante Nacional S/A**
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PRODUCT:

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ANVISA REGISTRATION 80108910053