

INSTRUCTIONS FOR USE

This device is indicated for specialized procedures, which must be performed by qualified implantology professionals. For best results, use the product with appropriate techniques. Always apply the product under appropriate conditions, in a surgical setting.

INDICATION FOR USE

The Surgical Torque Wrench is indicated for the application and mechanical control of torque for the insertion of dental implants. It can be used clockwise (IN) for insertion or counterclockwise (OUT) for removal of non- osseointegrated implants . x

DESCRIPTION

DSP Surgical Torque Wrench is made of stainless steel. It has a gear at the end with a ratchet wrench connection. The handle displays possible torque settings: 30, 40, 60, and 80 N.cm. It is disassembled for easy cleaning. This reusable product is sold non-sterile.

CONTRAINDICATIONS

There are none, as long as they are used for their intended purpose.

HOW TO USE

- Select the desired torque on the torque wrench . Simply turn the knob to the indicated mark.
- Fit the desired ratchet wrench into the torque wrench gear according to the side you want to use (IN = Insertion and OUT = Removal)
- Insert the assembly into the implant;
- Start applying torque. When the desired torque is reached, the torque wrench will click and prevent further insertion. If you wish to apply more torque, select the desired torque again and continue the operation.

HYGIENE

- It must be sanitized before and after use;
- Disassemble the key by unscrewing it as shown in the image below:



- Immerse the parts completely in enzymatic detergent (diluted according to the manufacturer).
- Wash in an ultrasonic washer for approximately 10 to 15 minutes.
- Rinse with plenty of distilled water until all solution residue is removed.
- The use of nylon brushes is permitted.
- Dry with a clean, dry cloth or with compressed air.
- Perform a visual inspection, checking for any flaws in the cleaning process. If there is still residue, repeat the process.
- Select packaging according to the sterilization process. Preferably use self-sealing surgical-grade paper packaging with laminated film.

PRECAUTIONS:

- Do not use descaling products;
- Avoid using enzymatic liquid in concentrations higher than 10% and drying parts that still contain cleaning solution residue, as these procedures encourage oxidation.
- The use of steel brushes is also not recommended.
- Drying the parts is extremely important before storage and sterilization, as the accumulation of moisture in the products is harmful and can cause oxidation.
- It is recommended to always use implant insertion/removal instruments parallel to the long axis of the implant.
- Excessive use of force can lead to fracture of the instrument or implant.
- Caution should be exercised in cases of patients who show signs of allergy or hypersensitivity to the chemical components of the material: stainless steel
- Reuse of this product without proper sanitation may cause adverse biological effects resulting from product residues, microorganisms and/or substances resulting from previous use and/or reprocessing;
- Do not use the product if the packaging is broken.
- Do not use the product after its expiration date.
- Before each procedure, make sure the pieces fit together perfectly.
- Ensure that the parts are not swallowed or aspirated by the patient.

- Always use the DSP product sequence. The use of instruments and/or prosthetic components from other manufacturers does not guarantee the perfect function of the DSP Implant System and voids any product warranty.

ADVERSE EFFECTS

- Applying torque much lower than recommended may cause implants to loosen;
- Applying torque that is too high compared to the recommended amount may cause bone injuries or damage to the implant.

PRESENTATION AND STERILIZATION

- This instrument is reusable.
- They are supplied NON-sterile and must be properly sanitized and sterilized before and after use.
- Sterilize the products the day before or on the day of the procedure.
- It is recommended, preferably, to follow the steam autoclave sterilization method and, also, the parameters and procedures established in the ISO 17665-1 standard (Sterilization of health care products . Moist heat Requirements for the development, validation and routine control of a sterilization process for medical devices).
- Recommended parameters: 121°C, 30 min, at 1 atm. Alternatively, you can proceed according to the autoclave manufacturer's instruction manual.
- Sterilization validity: 7 to 15 days, provided the product is stored in a clean, dry environment away from sunlight.

ADDITIONAL INFORMATION FOR THE PROFESSIONAL

Instruct the patient on the need for professional medical monitoring after surgery, and follow the guidelines regarding precautions, hygiene, and medication prescription. These guidelines are the responsibility of the responsible professional.

STORAGE CONDITIONS

This product must be stored in its original packaging, in a clean and ventilated place, at a maximum temperature of 45°C and protected from direct sunlight.

MATERIAL DISPOSAL

All products and consumables used during dental implant surgery can pose a health risk to those who handle them after use. Before disposing of them in the environment, it is recommended to observe and adhere to current legislation.

VALIDITY PERIOD

See packaging.

GUARANTEE







DSP Biomedical guarantees the owner of this product against any material or manufacturing defects. Any defect must be reported immediately to the manufacturer within the legal deadline. The warranty for products manufactured by DSP Biomedical is linked to compliance with the information described in the instructions for use. Improper use of the product, ignoring the instructions, exempts the manufacturer and/or distributor from any liability.



















Note: The warranty does not cover wear and tear due to use of the product.

ASSISTANCE INFORMATION

If further information is required, or if the product presents any adverse effect, with potential risk to the patient, which generates or has the potential to cause injury or threaten public health, or if there is any customer dissatisfaction, please contact DSP by calling 0800 600 88 66, or send an email [to sac@dspbiomedical.com.br](mailto:sac@dspbiomedical.com.br).

SYMBOLS

SYMBOLISM	DESCRIPTION	SYMBOLISM	DESCRIPTION
	Batch number		Consult the instructions for use or consult the electronic instructions for use
	Date of manufacture		Careful
	Produced by		Keep in a dry place

	Non-Sterile		Keep protected from sunlight
	Product code		Expiration date
	Temperature limit		Unique device identification number
	Upper and lower humidity limit		Do not use if packaging is broken and consult instructions for use.
	Authorized representative in the European Community		Manufacturer Country
	Model number		Medical Device
	Fragile, handle with care		Importer
	CE Mark		CE marking with number of Notified body ; SIQ, number 1304
	Do not reuse		FDA-mandated prescription notification for the United States market

MANUFACTURED BY

DSP INDUSTRIAL LTDA
 Marechal Floriano Peixoto Street, 303 – Ouro Verde II
 Campo Largo /PR – Brazil
 CNPJ 03.960.018/0001-23
 Phone: +55 41 3291-2200
www.dspbiomedical.com
 Technical Manager: CREA- PR 25412/D
 ANVISA Registration: 80116980003

REPRESENTATIVE IN THE EUROPEAN COMMUNITY

DSP BIOMEDICAL EUROPA UNIP LDA
 Ocean Avenue, 142 Lt . 4.24 0H
 Nations Park – Lisbon – Portugal
 1990-502
 Phone: (351) 962833592