

USE FOR PREPARATION

The Crown preparation instrument is intended for use in the ultrasonic finishing of the cervical margin.

The "Crown Preparation Kit" (Crown preparation instrument) includes:

- DB2 (Fig. 1 A) stainless steel tip holder;
- AB1 (Fig. 1 B) adapter for K7 torque wrench;
- K7 torque wrench (Fig. 1 C);
- A set of diamond tips (TA or TF), sold separately (Fig. 1 D).

**NOTE:** The diamond tips (TA or TF) are accessories sold separately from the "Crown Preparation Kit". Table 2 reports the technical characteristics of the diamond tips available for the Crown Preparation instrument.

This product has been specifically designed to be used in conjunction with bone surgical devices manufactured by Mectron S.p.A. according to their intended use/applications.

**⚠ WARNING:** The Crown Preparation instrument must be used exclusively in combination with devices produced by Mectron S.p.A. Use only original Mectron parts, the use of non-original parts could damage the device and cause injury to operators or the patient.

**⚠ WARNING:** Use the Crown Preparation instrument only for its intended dental use.

**⚠ WARNING:** This instrument must be used exclusively by specialized and duly trained personnel, such as the Surgeon/Dentist, adult of any weight, age, height, gender and nationality, non-disabled.

**NOTE:** Regarding the intended patient group, patient selection criteria, indications for use, contraindications, and warnings, please refer to the use and maintenance manual supplied with your oral surgery device manufactured by Mectron.

**IMPORTANT:** The words **"WARNING"** and **"CAUTION"** contained in this document carry special meaning and must be carefully reviewed.

**⚠ WARNING:** Identifies conditions and practices that present a risk of death or serious injury for the patient and/or user.

**⚠ CAUTION:** Identifies conditions and practices that may cause minor injuries and/or damage to the devices.

**NOTE:** A condition not associated with a risk or imminent danger.

**IMPORTANT: Information regarding this user guide.** The information contained in these operating instructions is limited to that which is essential for the first use of the product and must be employed in conjunction with the use and maintenance manual supplied with your oral surgery device manufactured by Mectron.

It is therefore necessary to carefully read the use and maintenance manual supplied with your oral surgery device manufactured by Mectron, before starting the treatment, set up the entire system and check each function, paying special attention to the "Safety Precautions" paragraphs.

**⚠ WARNING:** If an adverse event and/or serious accident attributable to the device occurs during correct and intended use, it is recommended to report it to the Competent Authority and to the manufacturer indicated on the product label.

**WARNING: SINGLE-USE ONLY**

The diamond-coated tips (TA and TF) are intended to be used on an individual patient during a single dental treatment only.

- Discard after each use.
- Do not attempt to clean or sterilize after use.

Inserts must be used in accordance with the correct settings described in the attached "APPROPRIATE SETTINGS FOR INSERTS" leaflet (where reference will be found to the DB2 tip holder).

**⚠ WARNING: Before first use (TA/TF, DB2, AB1, K7) and subsequent uses (DB2, AB1, K7).**

All parts of the "Crown Preparation Kit" are not sterile upon receipt, and MUST therefore be treated, before use, according to the procedures described below and reported in the "Cleaning and Sterilization" manual supplied with your oral surgery device manufactured by Mectron.

Once used, and prior reuse, reprocess the tip holder (DB2), the adapter (AB1 ) and the K7 torque wrench again thoroughly following the procedures described below or contained in the "Cleaning and Sterilization" manual supplied with your Mectron oral surgery device.

**1 - Cleaning procedures**

**IMPORTANT:** The cleaning procedures must be performed immediately after each use (Except for the tip (TA or TF) which is single use only).

Submerge the insert and/or instrument in demineralized water in an enzymatic cleaning solution immediately after use. Do not leave residue or blood deposits on the inserts and instruments, eliminate larger impurities with a disposable cloth or paper towel.

The cleaning procedure can be performed using two different methods: manual cleaning and automatic cleaning. These two methods are alternative and only one or the other must be performed.

Repeated reconditioning has a minimal effect on these devices and instruments. The end of service life is generally determined by wear or damage due to use.

**⚠ CAUTION:** Do not use hydrogen peroxide to clean the device.

**⚠ WARNING:** To avoid injury to operators, treat the inserts separately.

Particular attention must be paid while handling sharp and potentially infected instruments to avoid the risk of wounds and infections. Health personnel in charge of use and cleaning of the devices must use suitable protection and always use care when handling instruments with sharp edges and pointed tips.

**1.1 - Manual Cleaning**

**NOTE:** All parts of the kit must be processed separately.

- Do not leave the TA or TF tips inserted in the AB1 adapter.
- Do not leave the TA or TF tips inserted in the DB2 tip holder.
- Do not leave the AB1 adapter inserted in the K7 torque wrench.
- Do not place the support (DB2), the tip (TA or TF), the AB1 adapter or the K7 torque wrench in the same container.
- Do not use the same brush for the tip holder (DB2), the AB1 adapter or the K7 torque wrench.

**NOTE:** Process independently validated with Enzymec enzymatic detergent and 0.8% dilution.

- 1 Prepare a pH-neutral (6-9) enzymatic detergent solution, following the manufacturer's instructions.
- ⚠ CAUTION:** Once used, dispose of the enzymatic cleaner solution properly, do not recycle.
- 2 Place the tip holder (DB2), the AB1 adapter or the K7 torque wrench in a horizontal position. Add enough of the prepared solution to completely cover the device to be cleaned
- 3 Soak the device in the enzyme detergent solution for 10 minutes at room temperature. This process reduces the amount of blood, protein, and mucus on the instrument.
- 4 After 10 minutes of immersion in the enzyme solution, gently brush all surfaces until any visible dirt is removed.  
**For the base insert:** use a clean toothbrush with soft nylon bristles for the outer surfaces, a clean brush with soft nylon bristles for the inner cavities and crevices.  
**NOTE:** Thoroughly clean hard-to-clean areas such as sharp edges and especially gaps between cutting tips.  
**For the torque wrench and the adapter:** Use a clean soft-bristled nylon toothbrush.  
**NOTE:** Brush thoroughly, for about 20 seconds, all of the following parts of the torque wrench:
  - through holes and internal channels;
  - external metal ring;
  - internal cavities, grooves and fissures.
- 5 Remove the device being cleaned from the enzymatic detergent solution.
- 6 Rinse thoroughly and brush all surfaces of the of the device being cleaned (see point 4) under running water for at least 10 minutes.
- 7 For the base insert add the following: use a 20 ml disposable syringe to aspirate and inject the enzyme detergent solution into hard-to-reach areas (through-holes/cannulas). Repeat this step three times to ensure effective removal of dirt from the inner surfaces of the through-hole. Rinse the inner channel of the base insert with demineralized water at a pressure of 3.8 bar (55.1 psi) for at least 10 seconds to remove any remaining dirt.

**NOTE:** All parts of the kit must be processed separately.

- Do not leave the TA or TF tips inserted in the AB1 adapter.
- Do not leave the TA or TF tips inserted in the DB2 tip holder.
- Do not leave the AB1 adapter inserted in the K7 torque wrench.
- Do not place the support (DB2), the AB1 adapter or the K7 torque wrench in the same container.
- Do not use the same brush for the tip holder (DB2), the AB1 adapter or the K7 torque wrench.

- 8 Place the device to be cleaned in a stainless-steel instrument tray with a mesh bottom. Place the tray in the ultrasonic cleaning tub and make sure that in the bath, at 75.2°F ±3.6°F (24°C ±2°C), the instruments are submerged in fresh enzyme solution (see step 1).
- 9 Ultrasonicate the wrench for at least 20 minutes and the base insert and pin for 10 minutes, or as instructed by the manufacturer of the enzyme cleaner and ultrasonic tank.
- 10 Remove the device from the ultrasonic cleaning tank.  
**For the torque wrench and adapter:** repeat step 6.  
**For the base insert:** rinse with running water by brushing with a clean soft-bristled nylon toothbrush for at least 1 minute.
- 11 **For the base insert:** wash the inner channel of the device to be cleaned with injected demineralized water using a 20 ml syringe in order to remove any dirt residues. Soak the device to be cleaned in demineralized water for 1 minute.  
**For the torque wrench and adapter:** Soak the device in demineralized water for 5 minutes.

**1.2 - Automatic Cleaning**

**NOTE:** All parts of the kit must be processed separately.

- Do not leave the TA or TF tips inserted in the AB1 adapter.
- Do not leave the TA or TF tips inserted in the DB2 tip holder.
- Do not leave the AB1 adapter inserted in the K7 torque wrench.

Automatic cleaning involves the use of a thermosdisinfector and the following materials:

- Alkaline detergent. For example, neodisher® FA (0.2 % v/v);
- Neutralizing liquid. For example, neodisher® Z (0.1 % v/v);
- Metal basket;
- Metal Basket Adaptors.

**NOTE:** Make sure that the accessories are appropriately blocked in the basket and cannot move during washing. Any blows could damage them. Position the instruments in a way that the water can flow through all the surfaces, even internal.

**⚠ WARNING:** Avoid overloading the thermal disinfector as this could compromise cleaning effectiveness.

- 1 Place the accessories in a metal basket using the special adaptors (supplied as optionals).
- 2 Set the sequence and parameters for the cycle in the thermal disinfector:
  - 3 min, Pre-wash with deionized cold water ;
  - 5 min, Wash with alkaline detergent at 131°F ± 3.6°F (55°C ±2°C);
  - 2 min, Neutralization with neutralizing liquid and deionized water at 104°F ± 3.6°F (40°C ±2°C);
  - 2 min, Rinse with deionized water at 89.6°F ± 3.6°F (32°C ±2°C);
  - 5 min, Thermal disinfection at 199.4°F (93°C) with deionized water.

Thermal disinfection has not been tested experimentally. In compliance with ISO 15883-1, Table B.1 [4] thermal disinfection at a temperature of 194°F (90°C) for 5 min determines a value of A0 3000.

**⚠ CAUTION: After cleaning**

- The use of alkaline detergents removes the lubricant from the torque wrench, causing malfunctions and increasing its wear. Therefore, it is important to lubricate the torque wrench after each cleaning procedure using medical-grade lubricants (see chapter "2 - Lubrication" ). The dilution of the alkaline detergent required for automatic cleaning is such that it does not damage the silicone parts of the torque wrench (o-ring).
- Make sure that the device is completely dry even internally before starting the sterilization cycle.
- Use filtered compressed air to flush out any moisture from cavities, grooves, crevices, and other hard-to-reach areas. This prevents the appearance of stains or streaks on the surface and oxidation.
- Check that the device is actually clean and repeat the process if the water does not run clear in the final rinse, or if dirt residues are still visible.
- All parts must be inspected before their sterilization. In general, it is sufficient to conduct a visual inspection in good lighting conditions without the use of magnifying means. All parts of the instruments must be checked, looking for visible soil, damage and/or corrosion. All instruments must be carefully visually inspected, looking for damage and signs of wear. Particular attention must be paid to:
  - through-holes,
  - threading
  - internal channels,
  - the edges of the sharp tips
  - edges that may be deformed or largely affected areas: the edges must be continuous.

If the surfaces are not visibly clean, repeat cleaning and inspect again. Eliminate damaged instruments.

**2 - Lubrication**

Before sterilization, the K7 torque wrench must be lubricated with a commercial medical-grade lubricant.

**⚠ CAUTION:** Do not lubricate the AB1 adapter, tip holder (DB2), or tips (TA or TF).

- The lubricant must be applied by spraying it directly onto the peripheral contact surface inside the torque wrench, as indicated in Fig. 3;
- after having applied the lubricant, remove any excess of lubricant using a clean lint-free cloth.

**3 - Packaging**

The tip holder (DB2), adapter (AB1) and torque wrench K7 must be sterilized using a standard, appropriately sized medical steam sterilization pouch.

**⚠ CAUTION:** The tip holder (DB2), adapter (AB1) and torque wrench K7 must be packaged separately.

Do not package multiple inserts and/or torque wrenches in the same pouch.

**⚠ CAUTION:** Make sure the pouch is big enough to hold the instrument without tensioning the seals and without ripping the packaging.

**4 - Sterilization**

Sterilize only by pre-vacuum steam autoclaving.

The steam sterilization parameters have been validated by Mectron S.p.A. to guarantee a sterility level (Sterility Assurance Level - SAL) of 10<sup>-6</sup>.

**⚠ CAUTION:** If multiple instruments need to be sterilized in the autoclave in a single cycle, do not exceed the maximum allowed load.

**⚠ CAUTION:** Risk of contamination. Do not use gravity autoclaves to sterilize the inserts. The operating cycle of gravity autoclaves does not guarantee the suitable sterilization of the internal channel, of the cavities and hard-to-reach points.

**⚠ CAUTION:** Use only a pre-vacuum autoclave to sterilize the inserts and the torque wrench. Do not use other methods of sterilization insofar as they may be incompatible with the materials used to produce the instruments.

Do not use the following methods of sterilization: ethylene oxide sterilization, hot air sterilization, flash autoclaving, STERRAD sterilization, sterilization with STERIS or similar sterilization systems. Do not use the following substances/systems to sterilize the instruments: oxygenated water, peracetic acid, Formaldehyde, Glutaraldehyde based systems or other equivalent solutions/ systems.

**4.1 - Sterilization - Parameters**

Minimum sterilization parameters to guarantee a sterility level (Sterility Assurance Level - SAL) of 10<sup>-6</sup>:

**⚠ WARNING:** these sterilization parameters, validated by an independent laboratory, refer exclusively to a PRE-VACUUM autoclave operating cycle.

- Type of cycle: PRE-VACUUM - (3 pre-vacuum stages).
- Minimum temperature: 270°F (132°C) - (interval between 270°F + 275°F (132°C + 135°C)).
- Minimum exposure time (in package): 4 minutes
- Minimum drying time: 10 minutes.

**⚠ CAUTION:** Do not exceed a temperature of 275°F (135 °C).

All stages of sterilization must be performed by the operator in compliance with the current revision standards: UNI EN ISO 17665-1, UNI EN ISO 556-1 and ANSI/AAMI ST-46.

**5 - Important information relative to safety of inserts:**

**TA, TF and DB2 support (tip holder)**

**⚠ WARNING: Breakage and wear of inserts.**

On rare occasions, the oscillations at high frequency and wear may cause an insert to break. Do not bend, reshape or sharpen the inserts in any way. The alteration of an insert may cause it to break. Altered inserts must never be used. If an insert breaks

during use, recover and remove all fragments of the insert from the patient, with maximum care. During the treatment, ask the patient to breathe through their nose and/or use a dental dam to avoid the risk of swallowing any fragments generated by the breakage of the insert.

**⚠ WARNING:** The inserts are consumable. Thoroughly inspect the inserts before and during every treatment, looking for damage and/or excessive wear. Do not use an insert if it is scratched or rusted. The insert may break during use. If damage or deterioration in performance is noted, replace the insert with a new one.

**NOTE:** A deformed insert may preclude the complete functionality of the device used, and, depending on the model, a message may be displayed.

- Before the treatment, check that the Tip is firmly secured to the Tip Holder. Properly secure the Tip onto the handpiece using the torque wrench. And check that the Tip is firmly secured on the Tip Holder.
- Do not change the shape of the tip in any way. Bending or forcing the tip may cause it to fracture. Never use bent tips.
- Do not attempt to sharpen used tips as they may break during use.
- Replace the tip/s only with original Mectron spare parts. Use of tips other than original Mectron tips shall void the warranty of the device. Never use tips other than original Mectron tips insofar as they will damage the device and may cause injury to operators or the patient. The use of Tip Holder other than original Mectron ones shall damage the threaded pin of the handpiece, thus compromising the secure attachment of tips, even if original, to the handpiece.
- It is advisable to avoid the application of excessive force or prolonged contact of the tip on the soft tissues to avoid thermal damage and / or injury.
- Let the ultrasonic vibrations work, do not exert excessive pressure on the tips during use. Apply a light force on the tip to obtain the best efficacy.
- The application of excessive pressure may cause the Tip to fracture, which may in turn cause injuries. The use of tips other than the original ones will invalidate the device warranty.
- The tip must always be kept moving. If the tip is blocked, it can cause overheating of the treated part. It is recommended to use continuous movement to minimize contact between the tip and the part. Do not block it against the tissue so as not to cause it to overheat. It is advisable to use high levels of irrigation as the power level increases.
- The tips vibrate with a longitudinal oscillation, with forward and backward movement. During treatment, always keep the instrument tangential to the tooth surface. Move the handpiece back and forth while applying light lateral pressure. Do not apply pressure to the tip in the axial direction
- Do not aim the instrument directly on the surface of the enamel or implant. Position the tip/operative part only tangentially to the surface of the tooth or implant.
- When the tip is used in the interproximal spaces, do not block the instrument or leverage the operative part. The tips must be left free to vibrate.
- Check the threaded parts of the Tip Holder and those on the handpiece. These parts must be thoroughly cleaned.
- The tips must be replaced as soon as there is visible wear.
- Use of a worn tip shall lower its performance.

**⚠ WARNING: Hospital waste**

Treat the following objects as hospital waste:

- Tips and/or Tip Holders, when worn or broken.
- Torque wrench, when worn or broken.

**6 - Use of the Torque Wrench**

Refer to Fig. 2

**⚠ WARNING:** During operations to secure and remove the insert, the user must pay special attention to the sharp and cutting edges of the inserts.

**⚠ WARNING:** Hospital waste.

A worn or damaged torque wrench must be treated as hospital waste.

**6.1 - Securing the Insert**

- 1 Tighten the tip holder (DB2) onto the handpiece using the torque wrench supplied with the device (see Chapter 4.1) or using the K7 torque wrench supplied with the "Crown Preparation Kit".
- 2 Screw manually the diamond coated tip (TA or TF) on the stainless steel tip holder (DB2), until it bottoms out.  
**⚠ WARNING:** Care is required in the initial stage of screwing, when the threads must match precisely. If this is not done correctly, the thread of the diamond coated tip (TA or TF) could get damaged, causing it to come unscrewed during treatment.  
**⚠ WARNING:** Do not use the tip holder DB2 without the diamond coated tip, TA or TF, installed on it.  
**⚠ WARNING:** Do not use the diamond coated tip, TA or TF, with any other ultrasonic tip holder. The Mectron tip holder DB2 was designed specifically to be used in combination with the Mectron diamond coated tips TA or TF. The use of the Mectron diamond coated tips TA or TF with any other ultrasonic tip holder may cause it to fracture or injury to your patient.
- 3 Insert the AB1 adapter into the diamond coated tip TA or TF as shown in Fig. 3.
- 4 Use only the K7 torque wrench, supplied with the "Crown Preparation Kit", to secure the diamond coated tip (TA or TF) to the tip holder (DB2). Refer to Fig. 3.
- 5 Tighten the diamond coated tip by turning the torque wrench K7 clockwise until the friction clicks (the external body of the torque wrench turns with respect to the body of the handpiece, emitting mechanical "CLICK" sounds).

**⚠ WARNING:** Before and during the treatment, check that the diamond coated tip (TA or TF) is always tightened against the tip holder (DB2); if the diamond coated tip (TA or TF) is no longer correctly screwed into place, tighten it again hard onto the tip holder.

**⚠ CAUTION:** Do not grip the handpiece by the end and/or cord, but only by the body (Fig. 2 - C). Do not rotate the body while securing the insert. Firmly grip the body of the handpiece and turn the torque wrench only.

**6.2 - Removing the Insert**

Position the torque wrench on the insert and screw in an anti-clockwise direction.

Device Settings		
DB2 + TA/TF		Power Level
MT Bone	Default settings are preset in the device for each insert.	
PIEZOSURGERY® GP		PERIO / SPECIAL
PIEZOSURGERY® touch		PERIO / SPECIAL
PIEZOSURGERY® 3		BONE - Special / ROOT - Perio
PIEZOSURGERY® //		BONE - Special / ROOT - Perio
PIEZOSURGERY®		BOOSTED - A / HIGH 2 - 3

Table 1

Technical characteristics of TA/TF series diamond inserts			
Length 10 mm	Diamond Coating		
Diameter (mm)	D120	D90	D60
1,2	-	TA/TF12D90	TA/TF12D60
1,4	TA14D120	TA14D90	TA14D60
1,6	TA16D120	TA/TF16D90	TA/TF16D60

Table 2

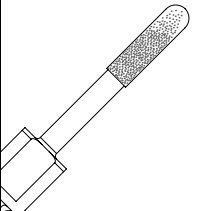
















INSERTS WEARING OUT EXAMPLES	
	EN - Diamond-coated Inserts: loss of diamond particles that makes the insert smooth, indicates a worn insert.

Table 3

SYMBOLS KEY			
	Class IIa device (insert) compliant with Regulation (EU) 2017/745. Notified body: IMQ S.p.A.		Class I device (torque wrench) compliant with Regulation (EU) 2017/745.
	Unique Device Identifier		Health Industry Bar Code
	Manufacturer		Date of manufacture
	Consult instructions for use or consult electronic instructions for use.		Sterilizable up to a max. temperature of 275.00°F (135 °C)
	Caution!		Non-sterile
	Medical Device		Batch Number
	Model number		Distributor
	Catalogue number		Do not re-use
Rx Only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed dentist or physician.		

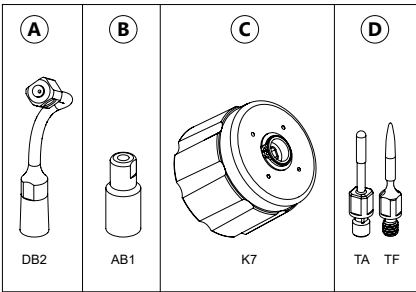


Fig. 1

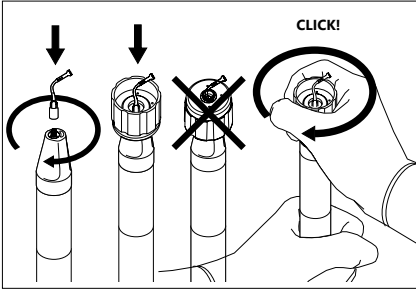


Fig. 2

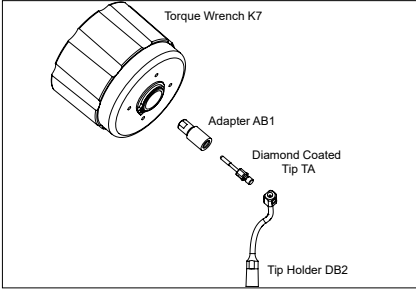


Fig.3

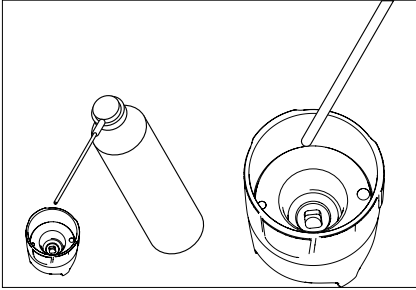
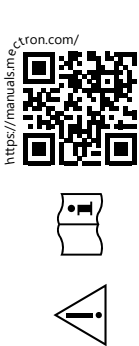


Fig.4

This document and the related translations are available on the "manuals.mectron.com" website.  
Use the QR code to access the site.



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