INSTRUCTIONS FOR USE

The Implant Cleaning Set has been designed for removing plaque or biofilm from the surfaces of implants, metal and ceramic dentures and natural teeth.
This device consists of two parts: a Base Insert and a Tip.

- IC1 (Fig. 1 - A) Tip (operational); can be used on ultrasound oral surgery devices produced by Mectron through the use of dedicated basic inserts:
- ICP (Fig. 1 - B) Base Insert for ultrasonic oral surgery devices produced by Mectron.

⚠ **WARNING:** This device 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 insert 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: Before first use and subsequent uses.** The Base Insert and the Tip are not sterile upon receipt and must be treated, before use (ICP, IC1) and subsequent uses (ICP), according to the procedures described below and/or reported in the "Cleaning and Sterilization" manual supplied with your oral surgery device manufactured by Mectron.
Once used, and prior reuse, reprocess ICP Base Insert again thoroughly following the procedures described below or contained in the "Cleaning and Sterilization" manual supplied with your Mectron oral surgery device.
⚠ **WARNING: SINGLE USE ONLY**
The Tips (IC1) are intended to be used on an individual patient during a single dental treatment and then discarded.
These tips cannot therefore be reprocessed since they cannot be cleaned properly.

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

1 - Cleaning procedures
IMPORTANT: The cleaning procedures must be performed immediately after each use. (Except for the Tip (IC1) 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: The Base Insert and the torque wrench must be processed separately.

- Do not leave the Base Insert inserted into the torque wrench.
- Do not leave the Tip installed on the Base Insert.
- Do not place the Base Insert or the torque wrench in the same container.
- Do not use the same toothbrush for the Base Insert and 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 Base Insert or the torque wrench in a clean container, 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: 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 Thoroughly rinse and brush all the surfaces of the device (see point 4) under running water for:
- at least 10 minutes for the wrench;
- at least 1 minute for the Tip and Base Insert.

7 For the Base Insert add the following steps: use a 20 ml disposable syringe to flush the enzymatic detergent solution into hard-to-reach areas (such as inner channel, through-holes or /cannulas). Repeat this step three times to ensure the effective removal of dirt from the internal surfaces. Each time use freshly prepared solution.
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 torque wrench for at least 20 minutes and the Base Insert 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 and repeat step 6.
11 **For the Base Insert and Tip:** flush three times 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: Soak the device in demineralized water for 5 minutes.

1.2 - Automatic Cleaning
NOTE: The Tip the Base Insert and torque wrench must be processed separately.

- Do not leave the Tip installed on the Base Insert.
- Do not leave the Base Insert inserted into the torque wrench.
- Do not place the Base Insert, Tip or torque wrench in the same container.
- Do not use the same toothbrush for the Base Insert, Tip, and torque wrench.

Automatic cleaning involves the use of a thermodisinfector 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;
- 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 afforded to:
- 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 torque wrench must be lubricated with a commercial medical-grade lubricant.
⚠ **CAUTION:** Do not lubricate the Base Insert or the Tip.

- 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 Base Insert and the torque wrench must be sterilized using a standard, appropriately sized medical steam sterilization pouch.
⚠ **CAUTION:** The Base Insert and the torque wrench 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^{-6}.
⚠ **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, Gluteraldehyde 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^{-6}:
⚠ **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 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: IC1, ICP
⚠ **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 insert is firmly secured to the handpiece. Properly secure the insert onto the handpiece using the torque wrench. And check that the Tip is firmly secured on the Base Insert.
- Do not modify the shape of the insert in any way. Any bending or forcing of the insert may cause it to fracture. Never use deformed inserts.
- Do not attempt to sharpen used inserts insofar as they may break during use.
- Replace the insert/s only with original Mectron spare parts. Use of inserts other than original Mectron inserts shall void the warranty of the device. Never use inserts other than original Mectron inserts insofar as they will damage the device and may cause injury to operators or the patient. The use of inserts other than original Mectron inserts shall damage the threaded Tip of the handpiece, thus compromising the secure attachment of inserts, even if original, to the handpiece.
- The application of excessive pressure may cause the insert to fracture, which may in turn cause injuries.
- Check the threaded parts of the insert and those on the handpiece. These parts must be thoroughly cleaned.
- The inserts must be replaced as soon as there is visible wear of the titanium nitride coating. Use of a worn insert shall lower performance in terms of cutting power.

⚠ **WARNING: Hospital waste**
Treat the following objects as hospital waste:

- Tips and/or Base Inserts, when worn or broken.
- Torque wrench, when worn or broken.

6 - Use of the torque wrench.
⚠ **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 base insert ICP (Fig. 1 - B) onto the handpiece using the torque wrench (see Figure 3).
2 Select the power and irrigation levels depending on the Mectron device to be used (see Table 1);
⚠ **WARNING:** Base and insert and Tip (ICP+IC1) must be used together respecting the "Power level" and "Irrigation level" as shown in Table 1. Irrigation must always be present and adequate for the treatment.
3 Run the CLEAN function to load the cord/handpiece/insert system with the irrigation liquid. If the CLEAN function is not provided on the device, press the footswitch until the liquid starts spilling out of the Base Insert;
⚠ **WARNING**: If the liquid is not loaded beforehand into the cord/handpiece/Base Insert system, there will be a risk of breakage of the IC1 Tip.
4 Screw the IC1 Tip onto the Base Insert, position it against the surface and tighten it hard with the strength of your fingers (see Fig. 1 - C).
⚠ **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 IC1 Tip could get damaged, causing it to come unscrewed during treatment.
5 Press the footswitch to start the treatment. Do not apply excessive pressure when using the IC1 Tip. A slight pressure will ensure greater care for the surface of the implant.
⚠ **WARNING**: During the operation, check that the IC1 Tip is always tightened against the Base Insert; if the IC1 Tip is no longer correctly screwed into place, tighten it again hard onto the Base Insert.
⚠ **CAUTION**: The IC1 Tip is prone to deterioration in the form of wear and deformation.Wear will lead to a reduction in the length of the Tip. Deformation, normally localized on the end of the Tip, will make the shape unsuitable for use. In both case, the damage will lead to a progressive drop in functional performance. When it becomes visible, it will be necessary to replace the IC1 Tip.
⚠ **CAUTION:** While securing the Base Insert onto the handpiece make sure not to grip the handpiece by the end and/or cord part, but only by the body (Fig. 2 - C). Do not rotate but firmly grip the body of the handpiece, while rotating the torque wrench only. (Fig. 4)

6.2 - Removing the Insert

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

Device Settings		
ICP + IC1	**Power Level**	**Irrigation Level**
MT Bone	Default settings are preset in the device for each insert.	
PIEZOSURGERY® white	Endo / Perio	2
PIEZOSURGERY® touch	Endo / Perio	2
PIEZOSURGERY® 3	ROOT - Endo / Perio	2
PIEZOSURGERY® //	ROOT - Endo / Perio	2
PIEZOSURGERY®	High 2-3 / Low 1	2

Table 1

SYMBOLS KEY			
CE 0051	Class IIa device (insert) compliant with Regulation (EU) 2017/745. Notified body: IMQ S.p.A.	CE	Class I device (torque wrench) compliant with Regulation (EU) 2017/745.
UDI	Unique Device Identifier	HIBC	Health Industry Bar Code
	Manufacturer		Date of manufacture
	Consult instructions for use or consult electronic instructions for use.	135°C	Sterilizable up to a max. temperature of 275.00°F (135 °C)
	Caution	NON STERILE	Non-sterile
MD	Medical Device	LOT	Batch Number
#	Model number		Distributor
REF	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.		

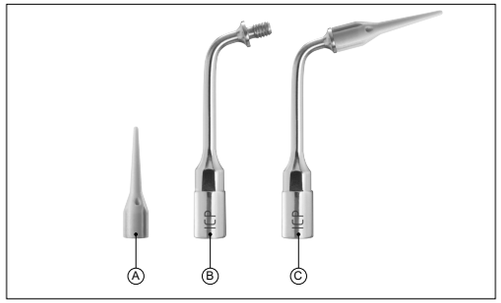

Fig. 1

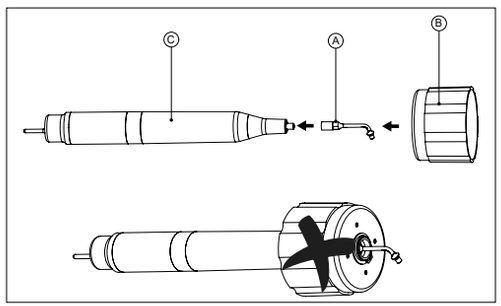

Fig. 2

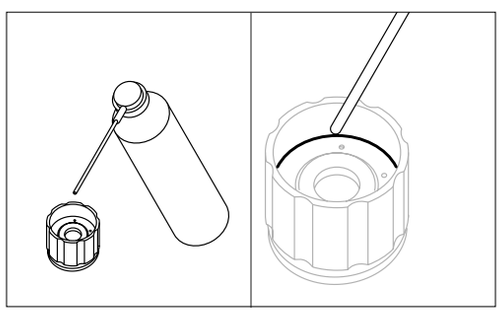
Fig. 3

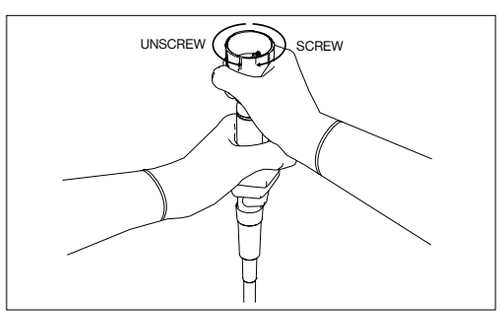

Fig. 4

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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