Use and maintenance manual

PIEZOSURGERY® flex
# TABLE OF CONTENTS

## 01 INTRODUCTION
- 01.1 Intended use of the PIEZOSURGERY® flex .......................... 4
- 01.2 Description of the device ........................................... 5
- 01.3 Responsibility waiver ................................................. 5
- 01.4 Safety precautions ..................................................... 6
- 01.5 Symbols used .......................................................... 8

## 02 IDENTIFICATION DATA
- 02.1 Identification plate of the device ................................... 9
- 02.2 Identification data of the handpiece ............................... 9
- 02.3 Identification data of the inserts .................................... 9

## 03 DELIVERY
- 03.1 List of the components of the PIEZOSURGERY® flex .......... 10

## 04 INSTALLATION
- 04.1 First installation ....................................................... 11
- 04.2 Safety precautions during the installation ......................... 11
- 04.3 Connection of the accessories .................................... 12

## 05 USE
- 05.1 Switching the device on and off ................................... 14
- 05.2 Description of the keyboard ....................................... 15
- 05.3 Foot pedal button ..................................................... 16
- 05.4 Safety precautions before and during use ......................... 17
- 05.5 Instructions for use .................................................. 20
- 05.6 Important information on the inserts ............................. 22
06 → MAINTENANCE ................................................................. 23

07 → DISPOSAL MODES AND PRECAUTIONS .................. 23

08 → TECHNICAL DATA ........................................................... 24
  08.1 Electromagnetic compatibility EN 60601-1-2 .................... 25

09 → TROUBLESHOOTING ..................................................... 29
  09.1 Diagnostic system and symbols on the keyboard ............. 29
  09.2 Quick solution to problems ......................................... 30
  09.3 Replacement of the fuses .......................................... 32
  09.4 Sending the device to an Authorized Mectron Service .... 33

10 → WARRANTY ................................................................. 34
PIEZOSURGERY® flex

01 → INTRODUCTION

Before proceeding with the installation, use, maintenance, or other operations on the device please read this manual carefully. Always keep this manual within easy reach.

IMPORTANT: to avoid potential serious injury to the user and the patient and/or this device or other equipments, read all the “Safety precautions” present in the manual with particular attention. Depending on their degree of seriousness, the safety precautions are classified with the following indications:

⚠️ WARNING
(always refers to personal injury)

⚠️ CAUTION
(refers to possible damage to property)

01.1 → INTENDED USE OF THE PIEZOSURGERY® flex

PIEZOSURGERY® flex is a piezoelectric surgical system intended for use in bone cutting, equipped with special insert tips to perform osteotomy, osteoplasty and drilling in a variety of surgical procedures:
- Otolaryngology
- Oral/Maxillofacial Surgery
- Hand and foot Surgery
- Plastic/Reconstructive Surgery

It may also be used with endoscopic assistance to perform the above listed procedures.

⚠️ WARNING: Use the device only for the intended use. Failure to meet these requirements may cause serious injuries to the patient, the operator, and damages/breakdowns of the device.

⚠️ WARNING: Carefully read this manual and follow its recommendations in order to avoid to compromise the patient and/or the user safety. Failure to meet these requirements may cause serious injuries to the patient and/or the operator.

⚠️ WARNING: Qualified and specialized personnel only. The use of the device is restricted solely to qualified, trained and competent health care practitioners such as a Surgeon. The device does not cause side effects if it is used correctly. Misuse might cause tissues heating.

⚠️ WARNING: The device must be used in a hospital environment, such as an operating theatre.
01.2 DESCRIPTION OF THE DEVICE

The user interface has been optimized with the PIEZOSURGERY® flex making all the functions readily available by integrating them in the touch keyboard.

The PIEZOSURGERY® flex is a device that uses ultrasonic piezoelectric technology to generate mechanical microvibrations of the inserts (from 20 to 60 µm), to effectively cut mineralized tissues. This allows an efficient and safe cutting which preserves the integrity of the osteotomized surfaces.

The micrometric, ultrasonic vibrations of the inserts provide greater precision and a selective cutting action compared to traditional methods such as drills or oscillating saws (which act with macrovibrations), therefore minimizing traumatic effect on soft tissues.

The cavitation effect of the irrigating solution helps to keep the operatory field blood-free. This provides an optimal intra-operative visual control thus increasing safety, even in areas that are anatomically most difficult to access.

01.3 RESPONSIBILITY WAIVER

The manufacturer Mectron disclaim any liability, expressed or implied, and shall have no responsibility for any direct, indirect or other damages and personal injury arising out in connection with any improper practice in the use of the device and its accessories.

The manufacturer Mectron shall be under no liability, expressed or implied, with respect to any damages (personal injury and/or damage to property) which might arise or be caused, whether by the customer or by any of the users of the product and its accessories, as result of:

1 Procedures different than those specified in the intended use of the product;
2 The environmental conditions for the preservation and storage of the device are not compliant with the precautions indicated in the Chapter 08 - TECHNICAL DATA;
3 The device is not used in compliance with all the instructions and precautions described in this manual;
4 The electrical system of the relevant operating room is not compliant with the applicable regulations and with electrical safety requirements;
5 The assembly operations, extensions, adjustments, updates, and repairs on the device are performed by personnel not authorized by Mectron;
6 Improper use, mistreatments, and/or incorrect interventions;
7 Any and all attempts to tamper with or modify the device, under any circumstance;
8 Use of non-original Mectron inserts that damage the threading of the handpiece, thus compromising correct operation and causing risk of harm to the patient;
9 Use of non-original Mectron inserts, even if they are used in accordance to designed and tested settings of Mectron original inserts. The correct use of the settings is guaranteed only with original Mectron inserts;
10 Lack of stock materials (handpiece, inserts, wrenches) to be used in the event of device stop due to fault or of inconveniences.
**Piezosurgery® flex**

**01.4 SAFETY PRECAUTIONS**

⚠️ **WARNING:** Risk of explosion.
The device cannot operate in environments where the atmosphere is saturated with flammable gases (anesthetic mixtures, oxygen, etc.).

⚠️ **WARNING:** Contraindications. Interference with other devices.
The PIEZOSURGERY® flex device complies with the standard IEC 60601-1-2. However, it may interfere with other devices in its vicinity. Install the PIEZOSURGERY® flex at safety distance from life-support systems. If adjacent or stacked use of the device is necessary, normal operation of the equipment and the PIEZOSURGERY® flex, in the configuration in which they will be used, should be verified prior their use.

⚠️ **WARNING:** Contraindications. Interference from other devices.
An electrosurgical knife or other electro-surgical units placed in the vicinity of the PIEZOSURGERY® flex device may interfere with its correct functioning.

⚠️ **WARNING:** Checking device status before the treatment.
Always check that there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are efficient. If anything unusual is noted during operation, do not perform the treatment. If the problem concerns the device, contact an Authorized Mectron Service Center.

⚠️ **WARNING:** Prior to any use, system components should be inspected for damage. Do not use if damage is apparent.

⚠️ **WARNING:** Do not start using the device in case the handpiece is defective, damaged or broken. Immediately replace the handpiece.

⚠️ **WARNING:** Only use original Mectron inserts, accessories, and spare parts.

⚠️ **WARNING:** Do not perform treatments on prosthetic artifacts made of metal or ceramics. The ultrasonic vibrations could lead to the de-cementing of the artifacts.

⚠️ **WARNING:** Infections control.
To ensure maximum safety of the patient and the operator, verify the reusable
parts and accessories has been cleaned and sterilized prior to use, following the instructions of the Cleaning and Sterilization Manual.

⚠️ **WARNING: All the accessories of the new or repaired devices are not sterile.** All new and repaired accessories are supplied in non-sterile conditions. Before use, and after each treatment, they must be cleaned and sterilised in strict compliance with the instructions given in the Cleaning and Sterilization Manual.

⚠️ **CAUTION: Contraindications.** When the reusable items (the handpiece, the torque wrench, and any other accessory that can be sterilized) have been autoclave sterilized, wait for them to cool down to room temperature prior to usage. The cooling process must not be accelerated.

⚠️ **WARNING: Breakage and wear-out of the inserts.** In rare cases, high frequency oscillations and wear-out may lead to breakage of an insert. Deformed or otherwise damaged inserts are susceptible to breakage during their use. These inserts must never be used. Should an insert fracture during use, extreme care must be exercised to ensure that all the fragments of the insert are retrieved and removed from the surgical site and, at the same time, that an effective suction is applied. During surgery, frequently check that the insert is intact, especially in its apical part. During surgery, avoid prolonged contact with retractors or other metal objects being used. During surgery, do not apply excessive pressure on the inserts.
01.5 —— SYMBOLS USED

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>LOT</td>
<td>Lot number</td>
</tr>
<tr>
<td>REF</td>
<td>Product code</td>
</tr>
<tr>
<td>!</td>
<td>CAUTION: read the instructions for use</td>
</tr>
<tr>
<td>i</td>
<td>Operating instructions</td>
</tr>
<tr>
<td></td>
<td>Temperature limitation - transport and storage conditions</td>
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<tr>
<td></td>
<td>Humidity limitation - transport and storage conditions</td>
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<tr>
<td></td>
<td>Atmospheric pressure limitation - transport and storage conditions</td>
</tr>
<tr>
<td>CE</td>
<td>Conformità alla direttiva CE 93/42, CEE EN 60601-1 e EN 60601-1-2 incluse. Ente notificato: KIWA CERMET ITALIA.</td>
</tr>
<tr>
<td>MET</td>
<td>MET Mark</td>
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<tr>
<td>UL-CSA</td>
<td>UL-CSA conformity</td>
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<tr>
<td></td>
<td>Manufacturer</td>
</tr>
<tr>
<td></td>
<td>Do not allow fingers to contact moving parts</td>
</tr>
<tr>
<td>QTY.1</td>
<td>Quantity of parts in the pack = 1</td>
</tr>
<tr>
<td></td>
<td>Single-use</td>
</tr>
<tr>
<td></td>
<td>Applied part of type “B” as per norm EN 60601-1</td>
</tr>
<tr>
<td></td>
<td>Can be sterilized in autoclave up to a maximum temperature of 135°C</td>
</tr>
<tr>
<td></td>
<td>Non-sterile</td>
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<tr>
<td></td>
<td>The device and its accessories must not be disposed of or treated as solid urban wastes</td>
</tr>
<tr>
<td>Biohazard</td>
<td></td>
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<tr>
<td></td>
<td>Activation switch “on”</td>
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<td></td>
<td>Activation switch “off”</td>
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<td></td>
<td>Alternating current</td>
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<tr>
<td></td>
<td>Connection of the foot pedal</td>
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<tr>
<td></td>
<td>Equi-potentiality</td>
</tr>
<tr>
<td>Rx Only</td>
<td>For US market only</td>
</tr>
<tr>
<td></td>
<td>CAUTION US Federal Law restricts this device to sale by or on the order of a physician</td>
</tr>
</tbody>
</table>
An exact description of the model and of the serial number of the device will enable our After-Sales Service to provide fast and efficient support. Always refer these data whenever you contact an Authorized Mectron Service Center.

### 02.1 IDENTIFICATION PLATE OF THE DEVICE

Every device has an identification plate that bears the technical characteristics and the serial number. The identification plate is located on the inferior panel of the device. Additional specifications are reported in this manual (See Chapter 08 - TECHNICAL DATA).

### 02.2 IDENTIFICATION DATA OF THE HANDPIECE

Each handpiece is laser-marked with:
- its serial number (ref. 1);
- the Mectron and PIEZOSURGERY® Medical logos (ref. 2).

### 02.3 IDENTIFICATION DATA OF THE INSERTS

The following data are laser-marked on each insert:
- the name of the insert (ref. 3);
- the Mectron logo (ref. 4);
- the lot number to which the insert belongs (ref. 5);
- the symbols “Single-use” and “CAUTION: read the instructions for use” (ref. 6).
PIEZOSURGERY® flex

03 DELIVERY

03.1 LIST OF THE COMPONENTS OF THE PIEZOSURGERY® flex

See inside cover

PIEZOSURGERY® flex consists of:

A device body
B peristaltic pump
C drip stand for supporting the saline bags
D manual of use and maintenance and manual of cleaning and sterilization
E electrical power supply cable
F foot pedal with bracket, cord and connector
G handpiece complete with cord

⚠️ CAUTION the handpiece and the cord cannot be separated

H single use inserts
I irrigation kit
J torque wrench
K case

The PIEZOSURGERY® flex consists of accessories that can be ordered separately. The package of the device is sensitive to strong collisions, because it contains electronic components. Therefore, special precautions must be taken for transport and storage. All the materials shipped by Mectron have been inspected upon their delivery. The device is delivered duly protected and packed.

When receiving the device, check if the shipping packaging is damaged or the protective material shows signs of stress. Should that be the case, notify the carrier.

After unpacking the PIEZOSURGERY® flex save the original package. During prolonged periods of disuse pack the equipment in its original packaging. Should the PIEZOSURGERY® flex equipment need servicing or repair, return it to an Authorized Mectron Service Center in the original packaging.

⚠️ WARNING: Before starting to operate with the device, make sure that you have stock material (handpiece, inserts, wrenches) available to use in case the device stops due to a fault or of inconveniences.
04.1 FIRST INSTALLATION

To ensure correct operation of the device, it must be installed by a person authorized by Mectron. The device must be installed in a suitable place that is handy for its use. The technician will do the following 6 steps:

1. Unpack the device;
2. Explain to the user the precautions to be followed so that the installation is correctly performed;
3. Explain to the user the possible configurations of the device;
4. Explain how to clean, sterilize and maintain the system;
5. Fill in the installation form;
6. Send to Mectron S.p.A. the installation form filled in to ensure traceability and the warranty activation.

04.2 SAFETY PRECAUTIONS DURING INSTALLATION

⚠️ WARNING: Contraindications. Interference with other devices. The PIEZOSURGERY® flex device complies with the standard IEC 60601-1-2. However, it may interfere with other devices in its vicinity. Install the PIEZOSURGERY® flex at safety distance from life-support systems. If adjacent or stacked use of the device is necessary, normal operation of the equipment and the PIEZOSURGERY® flex, in the configuration in which they will be used, should be verified prior their use.

⚠️ WARNING: Contraindications. Interference from other devices. An electrosurgical knife or other electrosurgical units placed in the vicinity of the PIEZOSURGERY® flex device may interfere with its correct functioning.

⚠️ WARNING: Risk of explosion. The device cannot operate in environments where the atmosphere is saturated with flammable gases (anesthetic mixtures, oxygen, etc.).

⚠️ CAUTION: The electrical system of the relevant operating room, where the device is installed and used, must comply with the applicable regulations and with electrical safety requirements.

⚠️ CAUTION: To avoid any risk of electric shock this device must be grounded.

⚠️ WARNING: Do not operate the foot pedal of the PIEZOSURGERY® flex when the peristaltic pump cover is open. Moving parts could injure the operator.

⚠️ WARNING: Install the device in a place protected against impacts or accidental splashes of water or other liquids.

⚠️ WARNING: Do not install the device on top of or close to sources of heat. When installing, make sure that adequate air circulates around the device. Leave sufficient room around it, with particular reference to the fan on the rear.

⚠️ CAUTION: Do not expose the device to direct sunlight or to sources of UV light.

⚠️ CAUTION: The device is transportable but must be handled with care when moved. Position the footswitch on the floor in such a way that it can only be activated intentionally by the operator.

⚠️ CAUTION: Before connecting the handpiece cord to the device, make sure that the electrical contacts are perfectly dry. If necessary, dry them with compressed air.

⚠️ CAUTION: Do not allow the device console and the foot pedal to get wet. If liquid enters the console or footswitch, damage could occur.

⚠️ CAUTION: No modification of this equipment is allowed.
04.3 CONNECTION OF THE ACCESSORIES

Equipotential plug: The device is equipped with an additional equipotential plug located on the rear of the console. This plug is in accordance with DIN 42801. Insert the connector of the equipotential cord (optional) to the plug on the rear of the device’s console. The purpose of additional potential equalization is to reduce differences of potential which can occur during operation between the device’s body and conductive parts of other objects within the medical environment;

Plug the power supply cord into the power socket on the back of the device and then into the mains power outlet;

**NOTE:** The foot pedal comes equipped with a bracket that allows it to be moved to the place most suitable for the operation, without the need to use your hands to move it;

The bracket can also be positioned horizontally if it is not used;

Connect the foot pedal to the back of the device in the socket marked with the symbol ↩️ by means of the plug of the pedal cable, until you hear a “click” sound. In order to disconnect the foot pedal from the device grab the connector of the foot pedal, press the release flap and pull the connector back;

**NOTE:** the button on the back of the device, left hand side, under the symbol ⏪️ can be used to bring the treatment to its end in case the foot pedal is not functioning.
**04 → INSTALLATION**

5. Fit the drip stand for supporting the saline bag into the dedicated hole;

6. **STEPS TO BE CARRIED OUT IN THE “STERILE AREA”:**
   - Open the sterile package of the handpiece and of the irrigation kit, remove the tube and the clips;
   - Connect the end of the irrigation tubing onto the dedicated handpiece irrigation nozzle;
   - Use the 6 clips provided in order to clip together the irrigation tubing and handpiece cable;

7. **STEPS TO BE CARRIED OUT IN THE “NOT STERILE AREA”:**
   - Open the pump lid completely;

8. Insert the thicker and 15 cm long tubing segment of the sterile line into the pump;
   - Close completely the irrigation pump lid;

9. Hang the saline bag to its specific drip stand;
   - Remove the protective cap from the spike and connect it to the irrigation bag;
**Turning the device on**

Facing the front of the device, press the power switch on the left of the device body to the “I” position, being careful not to press the foot pedal. The device does a self-test and 4 symbols appear on the device (ref. P inside cover). At the end of the self-test the symbols turn off one by one, the device sets on the default setting and is ready to be used.

**Turning the device off**

Facing the front of the device, press the power switch on the left of the device body to the “O” position, being careful not to press the foot pedal.

The device turns off.

**NOTE:** Whenever the device is started, the following default setting is programmed:
- “Power” 1
- “irrigation” 1
- “mode” 1
**05.2 DESCRIPTION OF THE KEYBOARD**

**Touch keyboard**
The user can set the device by simply touching on the touch keyboard. Depending on the selected setting, the electronic feedback system automatically adjusts the correct operating frequency.

**POWER (ref. L inside cover)**
The desired level of power is adjustable from 7 levels, from 1 to 7, by selecting the numbers on the touch keyboard in the “power” column.

**IRRIGATION (ref. M inside cover)**
The delivery rate of the peristaltic pump is adjustable from 6 levels, by selecting the numbers on the touch keyboard in the “irrigation” column: From 1 to 6= the pump flow goes from 8 ml/min to approximately 65 ml/min.

**MODE (ref. N inside cover)**
Depending on the type of surgery, it is possible to choose one of the 3 options available from the “mode” list:
1: dedicated to the most delicate surgeries and to the lift of the sinus membrane
2: dedicated to the cut and to the removal of the mineralized bone
3: dedicated to the cut and to the removal of very thick mineralized bone
PIEZOSURGERY® flex

FILLING THE IRRIGATION TUBING KIT
(ref. O inside cover)
The device is equipped with the “pump” key which allows to perform the PUMP function.
The PUMP function can be used at the beginning of the treatment, to fill the entire irrigation tubing up to the insert, so that the surgery can be started with the necessary irrigation (see paragraph 05.5).

SYMBOLS (ref. P inside cover)
The PIEZOSURGERY® flex is equipped with a diagnostic system able to detect operating anomalies. Icons are displayed on the touchpanel according to the detected operating anomalies.
To help the user identify the malfunctioning part, four symbols are foreseen which are described in paragraph 09.1.

05.3 FOOT PEDAL BUTTON
In case the foot pedal is not functioning, the button on the back of the device, left hand side, under the symbol , can be used to bring the treatment to its end.

⚠️ CAUTION: in the event you need to use the foot pedal button, first disconnect it from the socket of the unit.
⚠️ WARNING: Use the foot pedal button only upon user request. The users must train their staff on how and when they have to use this button.

⚠️ WARNING: the foot pedal button must be used only in case of malfunction of the foot pedal supplied with the unit. This button allows to end the surgical treatment in the event of a foot pedal malfunction.
05.4 → SAFETY PRECAUTIONS BEFORE AND DURING USE

⚠️ WARNING: Before starting to operate with the device, make sure that you have stock material (handpiece, inserts, wrenches) available to use in case the device stops due to a fault or of inconveniences.

⚠️ WARNING: Only use original Mectron inserts, accessories, and spare parts.

⚠️ WARNING: Use of non-original Mectron inserts: this use may damage the threading of the handpiece, thus compromising correct operation and risking to cause harm to the patient.

⚠️ CAUTION: Contraindication. Do not perform treatments on prosthetic artifacts made of metal or ceramics. The ultrasonic vibrations could lead to the de-cementing of the artifacts.

⚠️ WARNING: Contraindications. Do not use the PIEZOSURGERY® flex on patients with heart stimulators (Pace-makers) or other implantable electronic devices. This precaution also applies to the operator.

⚠️ WARNING: Checking device status before the treatment. Always check that there is no water underneath the device. Before every treatment, always check that the device works perfectly and that the accessories are efficient. If anything unusual is noted during operation, do not perform the treatment. If the problem concerns the device, contact an Authorized Mectron Service Center.

⚠️ WARNING: Infections control. First use: All new and repaired accessories are supplied in NON STERILE conditions. Before use, and after each treatment, they must be cleaned and sterilised in strict compliance with the instructions given in the Cleaning and Sterilization Manual. Subsequent uses: After every treatment, clean and sterilize all the reusable parts and accessories, following the instructions provided in the Cleaning and Sterilization Manual.

⚠️ WARNING: When the reusable items (the handpiece, the torque wrench, and any other accessory that can be sterilized) have been autoclave sterilized, wait for them to cool down to room temperature prior to usage. The cooling process must not be accelerated.

⚠️ CAUTION: The electrical contacts inside the cord connector must be dry. Upon completion of the sterilization cycle, before connecting the handpiece cord to the device, make sure that the electrical contacts are perfectly dry. If necessary, dry them with compressed air.

⚠️ WARNING: To ensure that the handpiece cools down, do not operate it without the irrigation circuit correctly installed and filled. To fill the irrigation circuit, always use the PUMP function.

⚠️ WARNING: Always check delivery of the irrigation before and during use. Make sure the fluid comes out from the insert. Do not operate the device if the water is not delivered or if the pump is defective.

⚠️ WARNING: Check the level of the physiological solution inside the relative saline bag. Replace the irrigation bag with a new saline bag before it is empty.

⚠️ WARNING: The PIEZOSURGERY® Medical irrigation kit is guaranteed for one treatment only. Remove and dispose of the sterile line according to local regulations related to the hospital waste.

⚠️ WARNING: Before using PIEZOSURGERY® Medical Irrigation Kit inspect the sterile package and the product for any damage. Do not use the irrigation kit if package is opened or damaged. Irrigation kit loses sterility in case of broken or damaged packaging. In case of damaged packaging, dispose of the irrigation kit. Do not sterilized or re-use the kit.

⚠️ WARNING: Verify that the irrigation clamp is in the ‘Open’ position before
operation, and that it is closed before disconnecting the irrigation tubing from the bag at the end of the procedure.

⚠️ CAUTION: Never force the connector into the console port as this may damage the connector and/or console. If the connector and the port do not join with reasonable ease, they probably don’t match. Make sure that the marked dot on the handpiece-cord connector is facing upwards.

⚠️ CAUTION: Check that the PIEZOSURGERY® Medical handpiece is correctly connected before using the system.

⚠️ WARNING: Before every treatment, make sure that the insert appropriate for the treatment is securely attached to the handpiece. Use exclusively the PIEZOSURGERY® Medical torque wrench to securing the insert to the handpiece. Do not use any other tool such as pliers, pincers, etc.

⚠️ WARNING: Before every treatment, make sure that the selected insert has been correctly screwed onto the handpiece. This happens when the PIEZOSURGERY® Medical torque wrench used to tighten the insert emits a mechanical “CLICK” sound.

⚠️ CAUTION: Hold only the connector when connecting/disconnecting the foot pedal. Never actually pull on the cord itself.

⚠️ CAUTION: Do not attempt to screw or twist the connector during insertion or removal: the connector could get damaged by twisting.

⚠️ CAUTION: The foot pedal is specifically designed to be used only in connection with the PIEZOSURGERY® flex device. Only use an original foot pedal otherwise damages or malfunctions can happen.

⚠️ CAUTION: Do not activate the handpiece while the insert is in contact with the part to be treated. Doing so will not allow the electronic control circuit of the console to recognise the best point of resonance of the insert required for efficient, optimum performance.

⚠️ WARNING: The patient must not come into contact with the device body or the foot pedal.

⚠️ WARNING: Single use - Before the surgery. - Before using any PIEZOSURGERY® Medical insert inspect the sterile package and the product for any damage. Insert loses sterility in case of broken or damaged packaging. In case of damaged packaging, the insert can be re-sterilized by following the procedures described in the Manual of Cleaning and Sterilization, Chapter 3. Before starting the surgery correctly tighten the insert onto the handpiece by means of the torque wrench.

⚠️ WARNING: Do not change the insert while the handpiece is operating to prevent possible user injury.

⚠️ WARNING: During the tightening and removing operations, the user must pay particular attention to avoiding injury from inserts with sharp points and cutting edges.

⚠️ WARNING - Breakage and wear-out of the inserts. In rare cases, high frequency oscillations and wear-out may lead to breakage of an insert. Do not bend, reshape or re-sharpen an insert in any way. Bending or prying the insert tip may cause it to fracture. Deformed or otherwise damaged inserts are susceptible to breakage during their use. These inserts must never be used. During surgery, excessive pressure applied on the insert tip may cause it to fracture. If the insert tip contacts with metal objects, it may break, leaving pieces in the surgical site. Should an insert fracture during use, extreme care must be exercised to ensure
that all the fragments of the insert are retrieved and removed from the surgical site and, at the same time, that an effective suction is applied.

During surgery, frequently check that the insert is intact, especially in its apical part.

During surgery, avoid prolonged contact with retractors or other metal objects being used.

⚠️ **WARNING:** The PIEZOSURGERY® Medical device is intended for bone cutting. However, prolonged contact and/or excessive force of the instrument tip on soft tissues should be avoided as this may cause thermal and/or blunt injury. Particular care should be exercised when sharp tip inserts are used. Prolonged mechanical action of a sharp insert may also result in the soft tissue being cut. In close proximity to soft tissues/nerves (e.g. the perinevrium of the peripheral nerve system, or dura mater of central nerve system), it is recommended to complete the cut with a blunt tip diamond coated insert, to minimize the potential for soft tissue damage.

⚠️ **WARNING:** Carefully check that the PIEZOSURGERY® Medical handpiece is correctly working in all its parts before using it on the patient.

⚠️ **CAUTION: Intermittent operation.**

Long operational periods could cause overheating of the handpiece body. Refer to the Chapter 08 TECHNICAL DATA for the recommended duty cycle.

⚠️ **WARNING:** Sterility. The insert tip is supplied sterile by prior exposure to ethylene oxide gas (ETO).

⚠️ **WARNING:** Single-use. The PIEZOSURGERY® Medical insert is intended to be used on an individual patient during a single surgical procedure and then discarded. The insert is not intended to be reprocessed, re-sterilized and used again. Remove and discard the insert following local regulations for proper disposal of contaminated surgical materials.
Screw the chosen insert onto the PIEZOSURGERY® Medical handpiece till it bottoms out;

Use the Mectron torque wrench to secure the insert;
To use the Mectron torque wrench correctly, operate as follows:

Fit the insert into the wrench as shown;

Firmly hold the central body of the handpiece;

**CAUTION:** Do not hold the handpiece by its end and/or cord, but only by its central body. The handpiece casing must not turn, but must be grasped firmly, and you must only rotate the wrench.

Turn the wrench clockwise until it clicks (the external body of the wrench turns with respect to the body of the handpiece, making “CLICK” sounds). The insert is now properly tightened;
5. Fill the irrigation tubing by selecting the PUMP function on the touch keyboard. The irrigation circuit starts to fill up;

6. As soon as the peristaltic pump starts, the entire scale of values of the “irrigation” column lights up and during the liquid passage the value of the irrigation shifts from 6 to 1;

7. As soon as the irrigation comes out from the PIEZOSURGERY® Medical handpiece, the cycle can be stopped by pressing PUMP again or, alternatively, by pressing the foot pedal. The PUMP function is disabled and the keyboard is enabled again, and displays the last setting used;

8. On the keyboard, select the necessary power, irrigation and mode;

**CAUTION:** According to the selected insert, for the correct setting of the parameters consult the Chart annexed to this manual titled “Recommended settings for the inserts” on the PIEZOSURGERY® flex or the illustrative leaflet of the PIEZOSURGERY® Medical insert you’ve purchased.
**WARNING:**

- Do not activate the handpiece while the insert is in contact with the part to be treated. Doing so will not allow the electronic control circuit of the console to recognise the best point of resonance of the insert required for efficient, optimum performance.

- Use original PIEZOSURGERY® Medical inserts only. Use of non-original inserts, in addition to voiding the warranty, damages the threading of the PIEZOSURGERY® Medical handpiece, with the risk of no longer being able to screw the original inserts correctly during subsequent use. Moreover, the device settings are tested and guaranteed to operate correctly only when original PIEZOSURGERY® Medical inserts are used.

- Do not reshape, bend or re-sharpen an insert in any way. Doing so may cause the insert to fracture.

- Deformed or otherwise damaged inserts must never be used.

- Always check that the threaded parts of the insert and of the handpiece are perfectly clean – see the Cleaning and Sterilization Manual.

- During surgery, excessive pressure applied on the insert tip may cause it to fracture, resulting in harm to the patient.

- For information on how to correctly use the inserts, consult the Chart annexed to this manual titled “Recommended settings for the inserts” on the PIEZOSURGERY® flex or the illustrative leaflet of the PIEZOSURGERY® Medical insert you’ve purchased.

- Before using the PIEZOSURGERY® flex, make sure you have prepared the surgical site by moving away the soft tissues, to avoid damaging them. While cutting the bone, an accidental contact of certain parts of the insert with the soft tissues may cause them small injuries. To minimize this risk, use specific protective instruments.
If the device is not used for prolonged time, observe the following recommendations:
1 Disconnect the device from the electrical system;
2 If the period of disuse is prolonged, put the device back in its original package and store it in a safe place;
3 Prior to using the device again, clean and sterilize the handpiece and the wrench following the instructions provided in the Cleaning and Sterilization Manual;

⚠️ WARNING: Periodically check that the electrical power supply cable is intact; if it is damaged, replace it with an original Mectron spare part.

07 DISPOSAL MODES AND PRECAUTIONS

⚠️ WARNING: Hospital waste.
Treat the following items as hospital waste:
- Inserts at the end of each surgery;
- Irrigation kit at the end of each surgery;
- Torque wrench: when worn out or broken.

The use and throw-away materials and materials that entail a biological risk must be disposed according to local regulations related to the hospital waste.

 PIEZOSURGERY® flex must be disposed of and treated as a waste for separate collection. Disregard of the previous points may entail a fine, pursuant to Directive 2002/96/CE. It is up to the purchaser to hand over the device for its disposal to the retailer who supplies him new equipment; the instructions for proper disposal are available from Mectron.
### TECHNICAL DATA

| **Device compliant to Dir. 93/42/CEE:** | Class IIa |
| **Classification as per EN 60601-1:** | I  
Applied part type B (handpiece, insert)  
IP 20 (device)  
IP X8 (foot pedal) |
| **Device for intermittent operation:** | 60sec. ON - 30sec. OFF with irrigation |
| **Power supply voltage:** | 100-240 ~ 50/60 Hz |
| **Max. power absorbed:** | 120 VA |
| **Fuses:** | Tipo 5 x 20 mm T 2AL, 250V |
| **Operating frequency:** | Automatic scan  
From 24 KHz to 36 KHz |
| **Power types:** | Adjustable on the touch screen:  
7 power levels, from 1 to 7 |
| **Modes:** | Adjustable on the touch screen: from 1 to 3 |
| **Peristaltic pump capacity:** | Adjustable on the touch screen: 6 flow levels, from 1 to 6 (from 8 ml/min to approximately 65ml/min) |
| **Protections of the APC circuit:** | No handpiece detected  
Cord interruption  
Insert not tightened correctly or broken |
| **Operating conditions:** | from +10°C to +35°C  
Relative humidity from 30% to 75%  
Pressure of air P: 800hPa/1060hPa |
| **Transport and storage conditions:** | from -10°C to +70°C  
Relative humidity from 10% to 90%  
Pressure of air P: 500hPa/1060hPa |
| **Weights and sizes:** | 3,2 Kg  
L · W · H  300 x 250 x 95 mm |
**08.1 ELECTROMAGNETIC COMPATIBILITY EN 60601-1-2**

⚠️ **WARNING: Contraindications. Interference with other devices.** The PIEZOSURGERY® flex device complies with the standard IEC 60601-1-2. However, it may interfere with other devices in its vicinity. Install the PIEZOSURGERY® flex at safety distance from life-support systems. If adjacent or stacked use of the device is necessary, normal operation of the equipment and the PIEZOSURGERY® flex, in the configuration in which they will be used, should be verified prior their use.

⚠️ **WARNING: Portable and mobile radio communication devices may influence the correct functioning of the device.**

⚠️ **WARNING: Contraindications. Interference from other devices.** An electro-surgical knife or other electro-surgical units placed in the vicinity of the PIEZOSURGERY® flex device may interfere with its correct functioning.

⚠️ **WARNING:** The device requires specific EMC precautions and must be installed and activated in conformity with the EMC information contained in this paragraph.

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**Guidance and manufacturer’s declaration - Electromagnetic emissions**

The PIEZOSURGERY® flex is intended for use in the electromagnetic environment specified below. The customer or user of the PIEZOSURGERY® flex should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The PIEZOSURGERY® flex only uses RF energy for internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The PIEZOSURGERY® flex is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and manufacturer’s declaration - Electromagnetic immunity

The PIEZOSURGERY® flex is intended for use in the electromagnetic environment specified below. The customer or user of the PIEZOSURGERY® flex should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level IEC 60601</th>
<th>Compliance level</th>
<th>Electromagnetic environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact ±8 kV air</td>
<td>The device continues to work regularly and in safety</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>The device continues to work regularly and in safety</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential mode ±2 kV common mode</td>
<td>The device continues to work regularly and in safety</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5 % Uₚ (&gt;95 % dip in Uₚ) for 0,5 cycles 40 % Uₚ (60 % dip in Uₚ) for 5 cycles 70 % Uₚ (30 % dip in Uₚ) for 25 cycles &lt;5 % Uₚ (&gt;95 % dip in Uₚ) for 5 s</td>
<td>The device can vary from the required levels of immunity with a duration of &lt;5% / &gt;95% / 5 s as long as the device remains in safety, no malfunctions have been detected and can be restored to pre-test status with the intervention of the operator</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>3 A/m</td>
<td>The device continues to work regularly and in safety</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

N.B.: Uₚ is the AC mains voltage prior to application of the test level.
## Guidance and manufacturer’s declaration - Electromagnetic immunity

The PIEZOSURGERY® flex is intended for use in the electromagnetic environment specified below. The customer or user of the PIEZOSURGERY® flex should ensure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level IEC 60601</th>
<th>Compliance level</th>
<th>Electromagnetic environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 V eff from 150 kHz to 80 MHz</td>
<td>The device continues to work regularly and in safety</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m from 80 MHz to 2,5 GHz</td>
<td></td>
<td>Recommended separation distance $d = 1,2 \ \text{VP}$</td>
</tr>
</tbody>
</table>

\[ d = \frac{1,2 \ \text{VP}}{\sqrt{P}} \text{ from } 80 \text{ MHz to } 800 \text{ MHz} \]
\[ d = \frac{2,3 \ \text{VP}}{\sqrt{P}} \text{ from } 800 \text{ MHz to } 2,5 \ \text{GHz} \]

where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, may be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

**N.B.:**

1. at 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with any reasonable accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PIEZOSURGERY® flex is used exceeds the applicable RF compliance level given above, the PIEZOSURGERY® flex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PIEZOSURGERY® flex.

b Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
The PIEZOSURGERY® flex is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the PIEZOSURGERY® flex can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PIEZOSURGERY® flex as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter ‘W’</th>
<th>Separation distance according to the frequency of transmitter ‘m’</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>from 150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>$d = 1,2 \sqrt{P}$</td>
</tr>
<tr>
<td>0,01</td>
<td>0,12</td>
</tr>
<tr>
<td>0,1</td>
<td>0,38</td>
</tr>
<tr>
<td>1</td>
<td>1,2</td>
</tr>
<tr>
<td>10</td>
<td>3,8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be calculated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**N.B.**

(1) at 80 MHz and 800 MHz, the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
### 09.1 DIAGNOSTIC SYSTEM AND SYMBOLS ON KEYBOARD

The PIEZOSURGERY® flex is equipped with a diagnostic system able to detect operating anomalies. Icons are displayed on the touchpanel according to the detected operating anomalies. By using the following chart, the user is guided toward the identification and possible solution of the malfunction detected.

<table>
<thead>
<tr>
<th>Symbols on keyboard</th>
<th>Possible cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece cord contacts wet</td>
<td>Thoroughly dry the contacts with compressed air</td>
<td></td>
</tr>
<tr>
<td>PIEZOSURGERY® Medical handpiece not connected to device</td>
<td>Connect the handpiece</td>
<td></td>
</tr>
<tr>
<td>Handpiece failure</td>
<td>Replace the handpiece</td>
<td></td>
</tr>
<tr>
<td>Sync circuit malfunction</td>
<td>Contact an Authorized Mectron Service Center</td>
<td></td>
</tr>
<tr>
<td>Insert not correctly tightened on handpiece</td>
<td>Unscrew the insert and correctly screw it on again with the Mectron torque wrench (see paragraph 05.5)</td>
<td></td>
</tr>
<tr>
<td>Insert broken, worn-out or deformed</td>
<td>Replace the insert</td>
<td></td>
</tr>
<tr>
<td>Handpiece cord contacts wet</td>
<td>Thoroughly dry the contacts with compressed air</td>
<td></td>
</tr>
<tr>
<td>Peristaltic pump malfunction</td>
<td>Check that there are no impediments to pump rotation</td>
<td></td>
</tr>
<tr>
<td>Irrigation kit not positioned correctly inside the pump</td>
<td>Correctly reposition the Irrigation kit inside the pump (see paragraph 04.3)</td>
<td></td>
</tr>
<tr>
<td>The device has been turned off and on again without waiting 5 seconds</td>
<td>Turn device off and wait 5 seconds before turning it on again</td>
<td></td>
</tr>
<tr>
<td>Anomalies on electrical network or excessive electrostatic discharges or internal anomalies</td>
<td>Turn device off and wait 5 seconds before turning it on again If the signal persists, contact an Authorized Mectron Service Center</td>
<td></td>
</tr>
<tr>
<td>Turn-on procedure incorrect: the device has been turned on with the foot pedal pressed</td>
<td>Check that the foot pedal is not pressed. If the problem persists, disconnect the pedal and, if needed, contact an Authorized Mectron Service Center</td>
<td></td>
</tr>
</tbody>
</table>
### QUICK SOLUTION TO PROBLEMS

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device does not turn on after having brought the switch into position “I”</td>
<td>The electrical power cable terminal is badly inserted in the rear plug of the device</td>
<td>Check that the power supply cable is firmly connected</td>
</tr>
<tr>
<td></td>
<td>The electrical power cable is defective</td>
<td>Check that the power supply socket works properly. Replace the electrical power cable</td>
</tr>
<tr>
<td></td>
<td>The fuses are out of order</td>
<td>Replace the fuses (see paragraph 09.3)</td>
</tr>
<tr>
<td>The device is on but not working. The display does not signal any error</td>
<td>The foot pedal plug is incorrectly inserted in the device socket</td>
<td>Correctly insert the pedal plug in the socket on the back of the device</td>
</tr>
<tr>
<td></td>
<td>The foot pedal does not work</td>
<td>During the surgery: disconnect the foot pedal from the console and use the button replacing the pedal (see paragraph 05.3). At the end of the intervention contact an Authorized Mectron Service Center</td>
</tr>
<tr>
<td>The device is on but not working. One of the following symbols appears on the screen:</td>
<td>See paragraph 09.1 for the possible cause, according to the symbol that has been displayed</td>
<td>See paragraph 09.1 for the action to undertake, according to the symbol that has been displayed</td>
</tr>
<tr>
<td>A slight whistling sound coming from the PIEZOSURGERY® Medical handpiece is heard during operation.</td>
<td>The insert is not correctly tightened on the handpiece</td>
<td>Unscrew and correctly screw the insert again with the Mectron torque wrench (see paragraph 05.5)</td>
</tr>
<tr>
<td></td>
<td>The irrigation circuit has not been completely filled</td>
<td>Fill the irrigation circuit via the PUMP function (see paragraph 05.5)</td>
</tr>
</tbody>
</table>
### Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No irrigation comes out from the insert during operation</strong></td>
<td>The insert is obstructed</td>
<td>Unscrew the insert from the handpiece and free the insert water passage by blowing compressed through it. If the problem persists, replace the insert with a new one</td>
</tr>
<tr>
<td></td>
<td>The handpiece is obstructed</td>
<td>Contact an Authorized Mectron Service Center</td>
</tr>
<tr>
<td></td>
<td>The saline bag is empty</td>
<td>Replace the bag with a full one</td>
</tr>
<tr>
<td></td>
<td>The air inlet of the flow adjuster has not been opened</td>
<td>Open the air inlet of the flow adjuster</td>
</tr>
<tr>
<td></td>
<td>Irrigation kit not positioned correctly inside the pump</td>
<td>Check that the Irrigation kit is properly connected</td>
</tr>
<tr>
<td><strong>The device works properly but the pump strains/stresses</strong></td>
<td>Excessive pressure of the impeller on the peristaltic pump tube</td>
<td>Check that the tube inside the peristaltic pump is properly positioned (See paragraph 04.3)</td>
</tr>
<tr>
<td><strong>The pump turns correctly, but when it stops, irrigation comes out from the handpiece</strong></td>
<td>The lid of the peristaltic pump is not closed correctly</td>
<td>Check that the lid of the peristaltic pump is perfectly closed (See paragraph 04.3)</td>
</tr>
<tr>
<td><strong>Insufficient performance</strong></td>
<td>The insert is not correctly tightened on the handpiece</td>
<td>Unscrew and correctly screw the insert again with the Mectron torque wrench</td>
</tr>
<tr>
<td></td>
<td>Insert broken, worn-out, or deformed</td>
<td>Replace the insert with a new one</td>
</tr>
</tbody>
</table>
**PIEZOSURGERY® flex**

**09.3 REPLACEMENT OF THE FUSES**

**WARNING:** Switch the device off. Always turn the device off with the main switch and disconnect it from the electrical power socket before performing the following intervention.

Apply leverage with a flat screwdriver, inserting its tip in the seat of the fuse-holder drawer located under the power supply socket;

Pull out the fuse-holder drawer;

**WARNING:** Replace the fuses, complying to the characteristics indicated in Chapter 08 - TECHNICAL DATA

Reinsert the drawer in its housing.
09.4 Sending the device to an authorised Mectron service centre

In the event that technical assistance is needed on the device, contact one of the Authorized Mectron Service Centers or your Retailer. Do not attempt to repair or modify the device and its accessories.

Clean and sterilize all the parts that need to be sent to an Authorized Mectron Service Center, following the instructions provided in the Cleaning and Sterilization Manual supplied with the device. Leave the sterilized parts in the packet, procedure that confirms the sterilization process has been performed.

The cleaning and sterilization requirements are in line with those in force concerning the safeguarding of health and safety on the workplace, as per Law Decree 626/94 and DLgs 81/08 and its subsequent amendments, both laws of the Italian State. In the case that the customer does not fulfill the requirements, Mectron reserves the right to charge him or her the cleaning and sterilization expenses, or to reject the goods received in unsuitable conditions, returning them to the customer, at his or her expense, for them to be correctly cleaned and sterilized.

The device must be returned properly packaged, accompanied by all the accessories and by a sheet bearing the:
• Data of the owner with telephone number
• Product name
• Serial number and/or lot number
• Reason for goods returned / description of the malfunction
• Photocopy of delivery note or purchase invoice of the device

⚠️ CAUTION: Package
Pack the device in its original package to prevent damages during transport.

Once the material has been received by the Authorized Mectron Service Center, qualified technical personnel will provide its evaluation to the given circumstance. The repair works will be performed only upon their prior acceptance by the end customer. For further details, contact the closest Authorized Mectron Service Center or your retailer.

Unauthorized repair works may damage the system and make the warranty void, and absolve Mectron of any responsibility for direct or indirect harm to persons or damages to things.
All the Mectron devices are subjected to an accurate end inspection that ascertains their full functionality before they are placed on the market.

Mectron provides warranty on the PIEZOSURGERY® flex purchased new from a retailer or a Mectron importer to cover material or manufacturing defects for:

- 2 YEARS (TWO) on the device from the date of purchase;
- 1 YEAR (ONE) on the handpiece complete with cord from the date of purchase.

The accessories are not included in the warranty.

During the period in which the warranty is valid, Mectron commits itself to repair (or at its own free choice, replace) those product parts that were to prove defective according to its judgment, free of charge.

The warranty of the manufacturer and the homologation of the device are not valid in the following cases:

- The device is not used in accordance to the intended use foreseen for it.
- The device is not used in compliance to all the instructions and precautions described in this manual.
- The electrical system of the relevant operating room, where the device is installed and used, does not comply with the applicable regulations and with electrical safety requirements.
- The assembly operations, extensions, adjustments, updates, and repair works are performed by personnel not authorized by Mectron.
- The environmental conditions for the preservation and storage of the device are not compliant to the precautions indicated in the Chapter 08 - TECHNICAL DATA.
- Use of non-original Mectron inserts, accessories, and spare parts that can compromise correct device operation and cause harm to the patient.
- Accidental breakage due to transport.
- Damages due to incorrect use or negligence, or to connection to a power voltage other than the one foreseen.
- Warranty expiry.

**PLEASE NOTE** The warranty period starts from the installation date, as written on the installation and test module.

The warranty is void in case the device has been tampered with, or repaired by not authorized personnel.

See paragraph 09.4 for the details relative to the procedure to send the device to an Authorized Mectron Service Center.