Piezosurgery GP is manufactured and sold internationally by Mectron Spa under the name Piezosurgery White.
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INTRODUCTION

Read this manual and follow its instructions carefully before proceeding with the installation, use, maintenance, or other operations on the device. Always keep this manual within easy reach.

The words WARNING and CAUTION, contained in this document, carry special meanings and must be carefully reviewed.

WARNING: Implies that death or serious injury could occur if the advice is not followed.

CAUTION: Implies that minor injury or device damage could occur if the advice is not followed.

NOTE: Implies advice that is not related to harm.

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. The purpose of this manual is to make the operator knowledgeable of the safety precautions, the installation procedures, and the instructions for a correct use and maintenance of the device and its accessories.

Use of this manual for purposes other than those strictly tied to the installation, use and maintenance of the device is forbidden. The information and illustrations in this manual are updated as of the date of issue reported on the last page. The manufacturer Mectron SpA is committed to continuously update its products with possible modifications to device components. In case you uncover discrepancies between what is described in this manual and the device in your possession, contact Piezosurgery Inc. for clarifications and support.

01.1 INTENDED USE OF THE PIEZOSURGERY® GP

The PIEZOSURGERY® GP is a piezoelectric ultrasonic device, consisting of handpiece/s and associated inserts intended for:

- Bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontics and surgical endodontics procedures;

Scaling applications including:
- Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits;

- Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning;

- Endodontics: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation;

- Restorative and Prosthetics: Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.

WARNING: Qualified and specialized personnel. The device must be used exclusively by specialized personnel such as a licensed dentist completely familiar with the required techniques and instructions for use of the equipment and with proper medical culture; no training activities are foreseen for the use of the device.

The use of the device does not cause side effects if it is used correctly. An improper use might cause tissues heating.

WARNING: Use the device only for the intended use. Failure to observe this precaution may cause serious injuries to the patient, the operator, and damages/breakdowns to the device.
01.2 → DESCRIPTION OF THE DEVICE

The PIEZOSURGERY® GP is a device that uses ultrasonic piezoelectric technology to generate mechanical microvibrations of the inserts, 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 and the importer Piezosurgery Inc. 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 errors in the use of the device and its accessories.

The manufacturer Mectron and the importer Piezosurgery Inc. 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. Use or 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 to 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 in the premises in which the device is used is not compliant to the norms in force and to the relative precautions;
5. The assembly operations, extensions, adjustments, updates, and repairs on the device are performed by personnel not authorized by Piezosurgery Inc;
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 Piezosurgery/Mectron inserts that entail a finite damage to the threading of the handpiece, thus compromising correct operation and causing risk of harm to the patient;
9. Use of non-original Piezosurgery/Mectron inserts, used in accordance to designed and tested settings of Piezosurgery/ Mectron original inserts. The correct use of the settings is guaranteed only with original Piezosurgery/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.
01.4 ➔ SAFETY PRECAUTIONS

⚠️ WARNING: Do not install the device in places where there is a risk of explosion.
The device cannot operate in environments where flammable atmospheres are present (anesthetic mixtures, oxygen, etc.)

⚠️ CAUTION: In the case that the end user, when operating in his or her own medical study or clinic, must subject the electro-medical equipment and systems to periodical inspections in order to adhere to imposed requirements, the test procedures that must be applied to electro-medical equipment and systems to evaluate safety must be performed in line with standard IEC 62353 ‘Recurrent Test and Test after repair of medical electrical equipment’.

⚠️ 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. DO NOT use the device and its accessories if damage is apparent. Contact Piezosurgery Inc. if the abnormalities concern the device.

⚠️ CAUTION: The electrical system of the premises in which the device is installed and used must be compliant to the norms in force and to the relative electrical safety precautions.

⚠️ CAUTION: Only connect the console to hospital grade receptacles to ensure electrical grounding reliability. This device must be grounded.

⚠️ WARNING: Do not operate the footswitch of the PIEZOSURGERY® GP device when the pump head of the peristaltic pump is open. Moving parts could injure the operator.

⚠️ WARNING: Control of infections.
First Use The reusable accessories (brand new or returned by service) and the single-use accessories (diamond coated inserts) are delivered in NON-STERILE conditions and must be prepared prior to use by applying the procedures described in the Cleaning and Sterilization manual provided with the device.

Every use Once used, each reusable accessory must be thoroughly reprocessed prior to reuse, according to the procedures described in the Cleaning and Sterilization manual provided with the device.

⚠️ WARNING: Breakage and wear-out of the inserts. High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the 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, check that none of its fragments remain in the treated part and, at the same time, apply effective suction to remove them. The patient must be instructed to breathe through his nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken inserts.

When the nitride coating wears out, the cutting efficiency decreases; re-sharpening the insert damages it and is therefore forbidden. Check that the insert is not worn out. Use of a worn-out insert reduces the cutting performance and can cause necrosis of the bone surface treated.

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

During the intervention, avoid prolonged contact with retractors or with metallic instrumentation in use. Do not exert excessive pressure on the inserts during their use.

⚠️ WARNING: Diamond coated inserts are intended for single use only.

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

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

⚠️ WARNING: Interference from other equipment. The use of an electrical scalpel or other electro-surgical unit/s near the PIEZOSURGERY® GP may interfere with its correct functioning.

⚠️ CAUTION: Do not perform treatments on metal or ceramic/porcelain prosthetic artifacts (unless otherwise specified). The ultrasonic vibration could cause decementation/loosening of such artifacts.

⚠️ WARNING: Interference with other equipment. Though compliant to the standard IEC 60601-1-2, the PIEZOSURGERY® GP may nonetheless interfere with other devices nearby. The PIEZOSURGERY® GP must not be used near to or stacked on other devices. If adjacent or stacked use is necessary, the PIEZOSURGERY® GP and the other devices must be observed and checked to verify normal operation in the configuration in which they will be used.

⚠️ CAUTION: Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage. The cooling process must not be accelerated.

⚠️ CAUTION: No modification of this equipment is allowed.
01.5 → SYMBOLS

Serial number
Lot number
Product code
Warning: read the instructions for use
Operating instructions
Temperature limitation - transport and storage conditions
Humidity limitation - transport and storage conditions
Atmospheric pressure limitation - transport and storage conditions
It indicates compliance with the CE 93/42 CEE EN 60601-1 and EN 60601-1-2.
Notified body: KIWA CERMET ITALIA.
MET Mark
UL-CSA conformity
Manufacturer
Date of manufacture
Do not allow fingers to contact moving parts
Quantity of parts in the pack = 1
Single-use
Applied part of type “B” as per norm EN 60601-1
Can be sterilized in autoclave up to a maximum temperature of 135° C
Non-sterile
The device and its accessories must not be disposed of or treated as solid urban wastes
Biohazard
Activation switch “on”
Activation switch “off”
Alternating current
Connection of the foot pedal
Equi-potentiality
For US market only
CAUTION US Federal Law restricts this device to sale by or on the order of a dentist
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 Piezosurgery Inc.'s Service.

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), Mectron logo, Piezosurgery® touch logo (on the handpiece with light) or PIEZOSURGERY® (on the handpiece without light), (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) and the lot number to which the insert belongs (ref. 5).

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03 → DELIVERY

03.1 → LIST OF THE COMPONENTS OF THE PIEZOSURGERY® GP (See inside cover)

The PIEZOSURGERY® GP device is supplied with the following components:

- **A** Device console
- **B** Peristaltic pump
- **C** Irrigation bag support rod
- **D** PIEZOSURGERY® handpiece fixed support
- **E** Manual of use and maintenance and manual of cleaning and sterilization
- **F** Electrical power supply cable
- **G** Foot pedal with cord connector
- **H** Back-up push-button switch
- **I** Torque Wrench
- **J** Peristaltic pump tubing kit (The kit is composed by a set of 8 peristaltic pump tubing)
- **K** Case

The following components/accessories are sold separately from the PIEZOSURGERY® GP device:

- **L** Handpiece complete with cord (without light or with led light)
  
  **CAUTION** the handpiece and the cord cannot be separated

- **M** PIEZOSURGERY® handpiece mobile support
- **N** Bone grafting kit
- **O** Insert/s- Insert Kit/s

The PIEZOSURGERY® GP consists of accessories that can be ordered separately. The quantity and type of accessories supplied with the device you have purchased can vary according to promotional campaigns and to the Country where the unit is sold. 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. Do not overlap multiple boxes, in order not to squash the packages underneath. All the materials shipped by Piezosurgery Inc. have been inspected upon their delivery. The device is delivered duly protected and packed. When receiving the device, check for the possible presence of damages incurred during the transport.

**WARNING:** Carefully unpack the device and check if any damage occurred during shipment. If the shipping packaging is damaged or the protective material shows signs of stress, DO NOT USE the device and file a complaint with the transporter. Keep the shipping material for carrier inspection. Keep the original packaging until the device is to be disposed of permanently. Pack the equipment in its original packaging during prolonged periods of disuse. Should the PIEZOSURGERY® GP equipment need servicing or repair, return it to the Piezosurgery Inc. Customer Service 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

The device must be installed in a comfortable place suitable for its use.

Place the console on a sturdy, flat, dry and horizontal surface.

04.2 SAFETY PRECAUTIONS DURING INSTALLATION

⚠️ **WARNING:** Interference with other equipment. Though compliant with the standard IEC 60601-1-2, the PIEZOSURGERY® GP may nonetheless interfere with other devices nearby. The PIEZOSURGERY® GP must not be used near to or stacked on other devices. If adjacent or stacked use is necessary, the PIEZOSURGERY® GP and the other devices must be observed and checked to verify normal operation in the configuration in which they will be used.

⚠️ **WARNING:** Interference from other equipment. The use of an electrical scalpel or other electro-surgical unit/s near the PIEZOSURGERY® GP may interfere with its correct functioning.

⚠️ **WARNING:** The electrical system of the premises in which the device is installed and used must be compliant to the norms in force and to the relative electrical safety precautions.

❗ **CAUTION:** Only connect the console to hospital grade receptacles to ensure electrical grounding reliability. This device must be grounded.

⚠️ **WARNING:** Do not install the device in places where there is a risk of explosion. The device cannot operate in environments where flammable atmospheres are present (anesthetic mixtures, oxygen, etc.)

⚠️ **WARNING:** Do not operate the footswitch of the PIEZOSURGERY® GP device when the peristaltic pump cover is open. Moving parts could injure the operator.

⚠️ **WARNING:** Install the device in a place protected against collisions or against accidental sprays of water or liquids.

⚠️ **WARNING:** Do not install the device above or near heat sources. Foresee adequate air circulation around the device when installing it. Leave adequate space, especially near the fan placed on the back part of the device.

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

❗ **CAUTION:** The device can be transported, but it must be handled with care when moved. Position the foot pedal on ground, so 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 need be, dry them with compressed air.
With the writing UP facing upward, insert the connector of the handpiece cord into the handpiece receptacle on the PIEZOSURGERY® GP console;

Insert the peristaltic pump tubing, supplied with the device, into the connector of the handpiece cord;

**CAUTION:** Use original Piezosurgery/Mectron peristaltic pump tubing only, as damage or substandard performance could result.

Insert the peristaltic pump tubing in the peristaltic pump, proceeding as follows:
- open the pump cover completely;
6. Insert the tubing by placing it over the pump rollers; close the pump cover completely.

**WARNING:** Do not operate the footswitch of the PIEZOSURGERY® GP device when the peristaltic pump cover is open. Moving parts could injure the operator.

7. Connect the peristaltic pump tubing to the flow adjuster (not supplied);

8. Connect the flow adjuster (not supplied) to the liquid bag used for the treatment (bag not supplied). Hang the bag to its specific support rod;

9. 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;

**NOTE:** Back-up Push-button switch. In the case of foot-pedal failure intraoperatively, the back-up push-button switch, provided with the device allows the operative staff to manually turn the handpiece operation on and off. Please make reference to the paragraph 05.5 “Back-up Push-button Switch”.

**CAUTION:** The user must pay particular attention to the foot pedal positioning, so that the pedal can only be activated by the operator, intentionally.
**Piezosurgery® GP**

Connect the power supply cord into the receptacle on the back of the console. Connect it only to hospital grade receptacles;

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.

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**05 USE**

**05.1 SWITCHING THE DEVICE ON AND OFF**

**Turning the device on**

Facing the front of the console, set the power switch on the left side to the "I" position, taking care not to press the foot pedal. The console will switch on and four symbols (ref. 5 inside the cover) are temporarily displayed on the keyboard and then turned off. At this point, the device sets on the default factory settings and it is ready to operate.

**Turning the device off**

Facing the front of the console, turn the switch on the left side to the "O" position, taking care not to press the foot pedal. The console turns off.

**PLEASE NOTE** When the PIEZOSURGERY® GP is switched on, the following operational modes are set:

- "function" ENDO
- "irrigation" 3
05.2 DESCRIPTION OF THE KEYBOARD

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

**FUNCTIONS (ref. P inside cover)**
Depending on the type of clinical application, it is possible to choose one of the 6 options available from the “function” list:

- **ENDO**: dedicated to endodontic surgery, to Schneider’s membrane detachment and conventional endodontic treatments
- **PERIO**: dedicated to periodontal surgery and conventional scaling and periodontal treatments
- **SPECIAL**: dedicated only to the inserts for osteotomies with thicknesses of 0.35 mm and for prosthetic applications
- **CANCELLOUS**: dedicated to the cutting and removal of poorly mineralized bone
- **CORTICAL**: dedicated to the cutting and removal of highly mineralized bone
- **IMPLANT**: dedicated to bone perforation in the technique of the implant site preparation

**FILLING AND FLUSHING THE IRRIGATION CIRCUIT (ref. Q inside cover)**
The device is equipped with the “pump/flush” key which, depending on the mode of use, allows to perform the PUMP function or the FLUSH function. The PUMP function can be used at the beginning of the treatment, to fill up the entire irrigation line up to the insert, so that the surgery can be started with the necessary irrigation (see paragraph 05.4). The FLUSH function allows to run a flushing cycle of the irrigation circuit of the handpiece(s) used during the treatment.

⚠️ **CAUTION:** The FLUSH function must be used after every patient treatment, before starting the cleaning and sterilization procedures. Failure to carry out flushing of the handpiece tubing will lead to salt crystallisation that can seriously damage the device.

⚠️ **WARNING:** The “FLUSH” function does not substitute for the cleaning and sterilization procedures described in the Cleaning and Sterilization manual. After having carried out the “FLUSH” function, the cleaning and sterilization procedures must be followed meticulously in order to prepare the device accessories ready for the next patient and minimize any risk of patient-to-patient contamination.
**PIEZOSURGERY® GP**

**IRRIGATION** (ref. R inside cover)

The irrigation flow rate can be adjusted by selecting the numbers on the touch keyboard in the “irrigation” column.

7 capacity levels are foreseen:

- **0** = operation of the pump is closed: no irrigation outflows from the insert
- From 1 to 6 = the pump flow goes from 8 ml/min to approximately 75 ml/min.

The possibility of choosing the irrigation capacity levels is tied to the type of function selected, in the following manner:

- **ENDO** - 7 flow levels: from 0 to 6 (from 0 to approximately 75ml/min)
- **PERIO** - 7 flow levels: from 0 to 6 (from 0 to approximately 75ml/min)
- **SPECIAL** - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)
- **CANCELLOUS** - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)
- **CORTICAL** - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)
- **IMPLANT** - 6 flow levels: from 1 to 6 (from 8 to approximately 75ml/min)

**NOTE** treatment without irrigation is possible only with the **ENDO** and **PERIO** functions, setting the irrigation capacity level on “0”.

In the event that an irrigation capacity lower than 8 ml/min is required, use the “bone grafting kit” (accessory that can be ordered separately), inserting it between the flow adjuster and the tube in silicon of the handpiece, making it pass through the peristaltic pump, and selecting 1 as the level of irrigation.

⚠️ **WARNING:** If the “bone grafting kit” tube is kept inserted for the entire duration of the intervention, the capacity of the pump on all its levels is limited, independently of which insert is used.
HANDPIECE WITH LIGHT (optional)
The PIEZOSURGERY® GP unit is compatible with the PIEZOSURGERY® touch handpiece (only available as optional).

By connecting the PIEZOSURGERY® touch handpiece the LED light on the front terminal of the handpiece is switched on by pressing the foot pedal, and automatically switches off 3 seconds after the pedal is released.

The position of the LED light on the front terminal of the handpiece can be adjusted in the following way:

• Hold the body of the handpiece and lightly unscrew the metal ring nut located at the base of the front terminal, rotating it counter-clockwise.

• Rotate the front terminal so that the LED light goes into the desired and necessary position.

• To fasten it into position, screw the metal ring nut, rotating it clockwise.

SYMBOLS (ref. S inside cover)
The PIEZOSURGERY® GP is equipped with a diagnostic circuit that allows to detect operating abnormalities and to view their type on the keyboard via their relative symbol.

To help the user identify the malfunctioning part, four symbols are foreseen which are described in paragraph 09.1.
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.

**CAUTION:** Contra-indication. Do not perform treatments on metal or ceramic/porcelain prosthetic artifacts. (unless otherwise specified). The ultrasonic vibration could cause decementation/loosening of such artifacts.

**WARNING:** Contra-indications. Do not use the PIEZOSURGERY® GP on patients who carry 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. DO NOT use the device and its accessories if damage is apparent. Contact Piezosurgery Inc. if the abnormalities concern the device.

**CAUTION:** FLUSH function. After the device is used with aggressive and non-aggressive solutions, it is necessary to perform a flushing cycle on the tubes and the handpiece with the FLUSH function (see Cleaning and Sterilization Manual). If the tubes are not cleaned, the crystallization of the salts may seriously damage the device.

**CAUTION:** Allow reusable, autoclavable items to gradually return to room temperature after steam sterilization and prior to usage. The cooling process must not be accelerated.

**WARNING:** Control of infections. **First Use** The reusable accessories (brand new or returned by service) and the single-use accessories (diamond coated inserts) are delivered in NON-STERILE conditions and must be prepared prior to use by applying the procedures described in the Cleaning and Sterilization manual provided with the device.

**Every use** Once used, each reusable accessory must be thoroughly reprocessed prior to reuse, according to the procedures described in the Cleaning and Sterilization manual provided with the device.

**CAUTION:** The electrical contacts inside the cord connector must be dry. Before connecting the handpiece to the device, make sure that the electrical contacts of the connector are perfectly dry, especially after the sterilization cycle in autoclave. If need be, dry the contacts by blowing compressed air onto them.

**CAUTION:** FLUSH function. The FLUSH function must be used after every treatment, before starting the cleaning and sterilization procedures.

**WARNING:** To provide adequate cooling for the handpiece, always activate it with the irrigation circuit correctly installed and filled. To fill the irrigation circuit, always use the PUMP function.

**WARNING:** Treatments that require irrigation. Always check operation of the irrigation before and during use. Make sure the fluid outflows from the insert. Do not use the device if the irrigation does not work or if the pump is defective.

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

**WARNING:** Use of non-original Piezosurgery/Mectron inserts: this use entails finite damage to the handpiece threading, thus compromising correct operation and risking to cause harm to the patient.

**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 recognize the best point of resonance of the insert, required for efficient and optimum performance.

**WARNING:** Before every treatment, make sure that the insert appropriate for the treatment is inserted on the...
handpiece. Exclusively use the original Piezosurgery/Mectron torque wrench to fasten the insert to the handpiece.

⚠️ CAUTION: The handpiece, because of its shape, can roll. The handpiece must always be placed on its holder when not in use.

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

⚠️ WARNING: Do not change the insert with handpiece running, to prevent causing wounds to the operator.

⚠️ 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. High frequency oscillations and wear-out may, in rare circumstances, lead to the breakage of the insert. Do not bend, change shape of, or re-sharpen an insert in any way. Bending an insert or applying leverage on it can lead to its breakage.

Deformed or otherwise damaged inserts are susceptible to breakage during their use. These inserts must never be used. Excessive pressure applied to insert during its use can cause insert fracture. Should an insert fracture during use, check that none of its fragments remain in the treated part and, at the same time, apply effective suction to remove them. The patient must be instructed to breathe through his nose during the treatment, or a dental dam must be used to prevent the patient from ingesting fragments of broken inserts.

When the nitride coating wears out, the cutting efficiency decreases; re-sharpening the insert damages it and is therefore forbidden. Prior to each use check that the insert is not worn out. Use of a worn-out insert reduces the cutting performance and can cause necrosis of the bone surface treated. During the intervention, frequently check that the insert is intact, especially its top. During the intervention, avoid prolonged contact with retractors or with metallic instrumentation in use.

05.4 INSTRUCTIONS FOR USE

After having connected all the accessories as illustrated in Paragraph 04.3, proceed as follows:

1. Open both the air socket on the flow adjuster and the liquid passage
To fill the irrigation circuit, use the PUMP function.
To activate the FLUSH function, press and hold the button PUMP/FLUSH on the touch keyboard till the irrigation liquid outflows from the handpiece:
all the other buttons present on the console’s keyboard are disabled and the LED of the level 6 of the “irrigation” function starts flashing.

PLEASE NOTE You can stop, at any time, the Flush function by releasing the button PUMP/FLUSH on the console’s touch keyboard.

Screw manually the chosen insert onto the PIEZOSURGERY® handpiece till it bottoms out.

Tighten the insert by using the Piezosurgery/Mectron torque wrench.
To correctly use the Piezosurgery/Mectron torque wrench, operate as follows:

Put the insert inside the wrench as shown;
On the keyboard, select the type of function and irrigation necessary.

**CAUTION:** For the correct setting of the Function parameters with the specific insert you wish to use, consult the Chart annexed to this manual titled “Appropriate settings for the inserts on the PIEZOSURGERY® GP” or the illustrative leaflet of the Mectron insert you’ve purchased.

Firmly hold the central body of the handpiece.

**CAUTION:** The handpiece must not be grabbed by its terminal part and/or cord, but only by its central body. The handpiece must not be rotated, but must be grasped firmly, and you must only rotate the wrench.

Rotate the wrench clockwise until the friction snaps (the external body of the wrench rotates compared to the handpiece, emitting mechanical “CLICK” sounds). The insert is now perfectly tightened.

On the keyboard, select the type of function and irrigation necessary.

**CAUTION:** For the correct setting of the Function parameters with the specific insert you wish to use, consult the Chart annexed to this manual titled “Appropriate settings for the inserts on the PIEZOSURGERY® GP” or the illustrative leaflet of the Mectron insert you’ve purchased.

After having used the PIEZOSURGERY® GP carry out a flushing cycle of the hydraulic circuit of the handpiece by using the FLUSH function. Turn the unit off by means of the switch O/I on the console’s device. Disassemble device components before carrying out the cleaning procedures. Please make reference to the “Cleaning and Sterilization manual” supplied with your units.

**05.5 ➔ BACK-UP PUSH-BUTTON SWITCH**

In the case of foot-pedal failure intraoperatively, the back-up push button switch allows the operative staff to manually turn the handpiece operation on and off.

**USE:** In the event of foot-pedal malfunction, disconnect it from the socket on the back of the console and connect the back-up push-button switch. Proceed with the surgical treatment by operating - press/depress the button.

**WARNING:** Use the back-up push-button switch only upon user request. The users must train their staff on how and when they have to use this component.

**WARNING:** The back-up push button switch must be used only in case of malfunction of the foot-pedal supplied with the device. The back-up push-button allows completing the surgical treatment in the event of a foot-pedal malfunction.
**WARNING: Diamond coated inserts**

Diamond coated inserts are SINGLE USE. The diamond coated inserts are intended to be used on an individual patient during a single surgical procedure and then discarded. The diamond coated inserts cannot therefore be reprocessed since they cannot be cleaned properly. Bone and soil residues might remain adhered to the diamond coating even after cleaning and sterilization and enter into the oral cavity of another patient.

**WARNING:**
- When the titanium nitride coating is visibly worn out, the insert must be replaced. Use of a worn out insert reduces its cutting efficiency.
- 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 recognize the best point of resonance of the insert, required for efficient and optimum performance.
- Check the condition of wear of the insert and that it is intact before and during every use. If a damage or drop in performance is noted replace it with a new one.
- Use original Piezosurgery/Mectron inserts only. Use of non-original inserts, in addition to voiding the warranty, damages the threading of the 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/Mectron inserts are used.
- Do not change the shape of the insert in any way by either bending or filing it. This could cause it to break.
- Do not use an insert that has suffered any type of deformation.
- Do not attempt to sharpen the insert used.
- Always check that the threaded parts of the insert and of the handpiece are perfectly clean – see the Cleaning and Sterilization Manual.
- If excessive pressure is applied on the insert, it can cause the insert to break and possibly harm the patient.
- For information on how to correctly use the inserts, consult the annexed sheet “Appropriate settings for the inserts on the PIEZOSURGERY® GP” or the illustrative leaflet provided with the Piezosurgery/Mectron insert you’ve purchased.
- Before using the PIEZOSURGERY® GP, make sure you have prepared the operatory site by having first moved away the soft tissues, to avoid damaging them. It may happen that, while cutting the bone, accidental contact of certain parts of the insert with the soft tissues inflicts small traumas. To minimize this risk, use specific protective instruments.
06 MAINTENANCE

If the device is not used for prolonged time, observe the following recommendations:

1. Run a complete flushing cycle on the irrigation circuit with the FLUSH function (see the Cleaning and Sterilization Manual)
2. Disconnect the device from the electrical network
3. If the period of disuse is prolonged, put the device back in its original package and store it in a safe place
4. Prior to using the device again, clean and sterilize the handpiece, the inserts, the wrench, the tubes, and the connectors, following the instructions provided in the Cleaning and Sterilization Manual.
5. Check that the inserts are not worn out, deformed, or broken, placing special attention to the integrity of their tip

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

07 DISPOSAL MODES AND PRECAUTIONS

**WARNING:** Hospital wastes.
Hospital wastes. Treat the following items as hospital waste:
- Inserts: when they are worn out or broken;
- Flow adjuster: at the end of each intervention;
- Peristaltic pump tube: after 8 sterilization cycles;
- Torque wrench for inserts: when worn out or broken.

Discharging of biohazard and/or non-reusable materials must be done following local and federal regulations for proper disposal of contaminated materials.
### TECHNICAL DATA

| Device compliant to Dir. 93/42/CEE: | Class II a |
| Classification as per EN 60601-1: | I  
| | Type B (Applied parts: handpiece and inserts)  
| | IP 20 (device)  
| | IP 22 (foot pedal) |
| Device for intermittent operation: | 60sec. ON - 30sec. OFF with irrigation  
| | 30sec. ON - 120sec. OFF without irrigation (ENDO, PERIO) |
| Power supply voltage: | 100-240 Vac 50/60 Hz |
| Max. power absorbed: | 120 VA |
| Fuses: | Type 5 x 20 mm T 2AL, 250V |
| Operating frequency: | Automatic scan  
| | From 24 KHz to 36 KHz |
| Power types: | ENDO  
| | PERIO  
| | SPECIAL  
| | CANCELLOUS  
| | CORTICAL  
| | IMPLANT |
| Peristaltic pump capacity: | Adjustable on the touch screen:  
| | ENDO / PERIO - 7 flow levels: from 0 to 6  
| | (from 0 to approximately 75ml/min)  
| | SPECIAL / CANCELLOUS / CORTICAL / IMPLANT  
| | 6 capacity levels: from 1 to 6  
| | (from 8 to approximately 75ml/min) |
| LED system of the handpiece: | When a PIEZOSURGERY® touch handpiece is used, the Led light on the front terminal of the handpiece lights up when the foot-pedal is activated. The Led light automatically switches off 3 seconds after the foot-pedal is released. |
| 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% |
| Transport and storage conditions: | from -10°C to +70°C  
| | Relative humidity from 10% to 90%  
| | Pressure of air P: 500hPa/1060hPa |
| Peristaltic pump tube: | It is advisable not to exceed 8 sterilization cycles |
| Weights and sizes: | 3.2 Kg  
| | L - l - h  300 x 235 x 95 mm |
08.1 ELECTROMAGNETIC COMPATIBILITY EN 60601-1-2

⚠️ WARNING: Interference with other equipment. Though compliant with the standard IEC 60601-1-2, the PIEZOSURGERY® GP may nonetheless interfere with other devices nearby. The PIEZOSURGERY® GP must not be used near to or stacked on other devices. If adjacent or stacked use is necessary, the PIEZOSURGERY® GP and the other devices must be observed and checked to verify normal operation in the configuration in which they will be used.

⚠️ WARNING: Portable and mobile radio communication appliances may affect the correct functioning of the device.

⚠️ WARNING: Interference from other equipment. The use of an electrical scalpel or other electro-surgical unit/s near the PIEZOSURGERY® GP may interfere with its correct functioning.

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

Guidance and manufacturer’s declaration - Electromagnetic emissions

The PIEZOSURGERY® GP is intended for use in the electromagnetic environment specified below. The customer or user of the PIEZOSURGERY® GP 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® GP only uses RF energy for internal function. Therefore, its FR 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® GP 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® GP is intended for use in the electromagnetic environment specified below. The customer or user of the PIEZOSURGERY® GP 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) IEC 61000-4-2</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>Electrical fast transient/burst IEC 61000-4-4</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>Surge IEC 61000-4-5</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>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5 % U&lt;sub&gt;r&lt;/sub&gt; (&gt;95 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 0,5 cycles 40 % U&lt;sub&gt;r&lt;/sub&gt; (60 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 5 cycles 70 % U&lt;sub&gt;r&lt;/sub&gt; (30 % dip in U&lt;sub&gt;r&lt;/sub&gt;) for 25 cycles &lt;5 % U&lt;sub&gt;r&lt;/sub&gt; (&gt;95 % dip in U&lt;sub&gt;r&lt;/sub&gt;) 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>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</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>
</tbody>
</table>

N.B.: U<sub>r</sub> is the AC mains voltage prior to application of the test level.
### Guidance and manufacturer’s declaration - Electromagnetic immunity

The PIEZOSURGERY® GP is intended for use in the electromagnetic environment specified below.
The customer or user of the PIEZOSURGERY® GP 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>IEC 61000-4-6</td>
<td>3 Veff from 150 kHz to 80 MHz</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>IEC 61000-4-3</td>
<td>3 V/m from 80 MHz to 2,5 GHz</td>
<td>Recommended separation distance $d = 1,2 \sqrt{P}$</td>
</tr>
</tbody>
</table>

**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® GP is used exceeds the applicable RF compliance level given above, the PIZOSURGERY® GP should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PIZOSURGERY® GP.

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

| Rated maximum output power of transmitter ‘W’ | Separation distance according to the frequency of transmitter ‘m’ |  
|-----------------------------------------------|---------------------------------------------------------------|---|
|                                               | from 150 kHz to 80 MHz                                      | from 80 MHz to 800 MHz                                      | from 800 MHz to 2,5 GHz|
|                                               | \[d = 1,2 \sqrt{P}\]                                        | \[d = 1,2 \sqrt{P}\]                                       | \[d = 2,3 \sqrt{P}\] |
| 0,01                                          | 0,12                                                        | 0,12                                                        | 0,23 |
| 0,1                                           | 0,38                                                        | 0,38                                                        | 0,73 |
| 1                                             | 1,2                                                         | 1,2                                                         | 2,3  |
| 10                                            | 3,8                                                         | 3,8                                                         | 7,3  |
| 100                                           | 12                                                          | 12                                                          | 23   |

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 TROUBLESHOOTING

#### 09.1 DIAGNOSTIC SYSTEM AND SYMBOLS ON KEYBOARD

PIEZOSURGERY® GP is equipped with a diagnostic circuit that allows to detect operating abnormalities and to view their type on the keyboard via their relative symbol. 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></td>
<td>Handpiece cord contacts wet</td>
<td>Thoroughly dry the contacts with compressed air</td>
</tr>
<tr>
<td></td>
<td>Handpiece not connected to device</td>
<td>Connect the handpiece</td>
</tr>
<tr>
<td></td>
<td>Handpiece defective</td>
<td>Replace the handpiece</td>
</tr>
<tr>
<td></td>
<td>Sync circuit malfunction</td>
<td>Contact Piezosurgery Inc.'s Service</td>
</tr>
<tr>
<td></td>
<td>Insert not tightened correctly on handpiece</td>
<td>Unscrew the insert and correctly screw it on again with the Piezosurgery/Mectron torque wrench (see paragraph 05.4)</td>
</tr>
<tr>
<td></td>
<td>Insert broken, worn-out or deformed</td>
<td>Replace the insert</td>
</tr>
<tr>
<td></td>
<td>Handpiece cord contacts wet</td>
<td>Thoroughly dry the contacts with compressed air</td>
</tr>
<tr>
<td></td>
<td>Peristaltic pump malfunction</td>
<td>Check that there are no impediments to pump rotation</td>
</tr>
<tr>
<td></td>
<td>Silicon tubing not positioned correctly inside the pump</td>
<td>Correctly reposition the silicon tubing inside the pump (see paragraph 04.3)</td>
</tr>
<tr>
<td></td>
<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>
</tr>
<tr>
<td></td>
<td>Abnormalities on electrical network or excessive electrostatic discharges or internal abnormalities</td>
<td>Turn device off and wait 5 seconds before turning it on again If the signal persists, contact Piezosurgery Inc.'s Service</td>
</tr>
<tr>
<td></td>
<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 need be, contact Piezosurgery Inc.'s Service</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 power on when mains power switch is set to the “I” position</td>
<td>Power cord unplugged or not correctly plugged into the socket on the rear of the console.</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 not correctly inserted into the socket on the rear of the console.</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>Replace the no-working foot pedal with the back-up push-button switch supplied with the device (see paragraph 05.5) and contact Piezosurgery Inc's Service.</td>
</tr>
<tr>
<td>The device is on but not working. One of the following symbols is active on the screen:</td>
<td>See paragraph 09.1 for the possible cause, according to the symbol active on the display.</td>
<td>See paragraph 09.1 for the action to undertake, according to the symbol active on the display.</td>
</tr>
<tr>
<td>A slight whistling sound coming from the 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 05.4)</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 05.4)</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible cause</td>
<td>Solution</td>
</tr>
<tr>
<td>---------</td>
<td>---------------</td>
<td>----------</td>
</tr>
<tr>
<td>The insert type does not foresee liquid passage</td>
<td>Use an insert type with liquid passage</td>
<td></td>
</tr>
<tr>
<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>
<td></td>
</tr>
<tr>
<td>The handpiece is obstructed</td>
<td>Contact Piezosurgery Inc.’s Service</td>
<td></td>
</tr>
<tr>
<td>The irrigation level on the screen is adjusted on “0”</td>
<td>Adjust the irrigation level</td>
<td></td>
</tr>
<tr>
<td>The liquid bag is empty</td>
<td>Replace the bag with a full one</td>
<td></td>
</tr>
<tr>
<td>The air inlet of the flow adjuster has not been opened</td>
<td>Open the air inlet of the flow adjuster</td>
<td></td>
</tr>
<tr>
<td>The peristaltic pump tubing is incorrectly installed</td>
<td>Check the connections of silicon tubing</td>
<td></td>
</tr>
</tbody>
</table>

**No liquid outflows from the insert during operation**

<table>
<thead>
<tr>
<th>The device works properly but the pump strains/stresses</th>
<th>Excessive pressure of the impeller on the peristaltic pump tube</th>
<th>Check that the tube inside the peristaltic pump is properly positioned (See paragraph 04.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The pump turns correctly, but when it stops, liquid outflows from the handpiece</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>
</tbody>
</table>

**Insufficient performance**

<table>
<thead>
<tr>
<th>The insert is not correctly tightened on the handpiece</th>
<th>Unscrew and correctly screw the insert again with the Mectron torque wrench</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insert broken, worn-out, or deformed</td>
<td>Replace the insert with a new one</td>
</tr>
</tbody>
</table>
09.3 REPLACEMENT OF THE FUSES

⚠️ WARNING: Switch the device off.
Always switch console OFF and disconnect power cord 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.

1

Pull out the fuse-holder drawer.

2

⚠️ WARNING: Replace exclusively with the type of fuse indicated on the rear of the console or in the Chapter 08 - TECHNICAL DATA.

Reinsert the drawer in its housing.

3
For all Piezosurgery products unless otherwise specified.

Any non-approved usage of the PIEZOSURGERY® GP device will void the warranty.

Any usage of non-Piezosurgery parts, inserts, components or procedures will void the warranty.

The manufacturer, Mectron S.p.a., warrants to the first original purchaser (customer) that their products have been tested, inspected and shipped in proper working order.

All Piezosurgery products, with the exception noted below, are covered by warranty for a period of one year from the date of purchase.

Products are warranted to be free from defects in material and workmanship.

This limited warranty is extended only to the first customer purchasing the Piezosurgery products directly from Piezosurgery Inc.

This limited warranty does not apply to any device/accessory which has been subject to abnormal wear and tear, misuse, abuse, neglect, improper installation or operation or that has been altered, adjusted or tampered with by any person other that Piezosurgery Inc. authorized service personnel.

The warranty is valid only if Piezosurgery Inc. is notified within thirty (30) days following discovery of a defect.

For returning procedure make reference to the paragraph:
"CUSTOMER SERVICE – RETURNS and/or REPAIRS"

Returns must be authorized by Piezosurgery Inc. Piezosurgery Inc. cannot accept responsibility for returns which have not been authorized.

Contact Piezosurgery Inc. Customer Service at 1-888-87-PIEZO for return authorization.

This warranty is valid only if the product is returned to Piezosurgery Inc. within thirty (30) days of Piezosurgery Inc. receiving notice of such defect, as described above.

The customer is responsible for returning the defective equipment to the Piezosurgery Inc., service location at his or her own expense.

Within a reasonable time after receipt of product/s, Piezosurgery Inc., service will investigate and shall correct any defect covered by warranty by providing, at its option, one of the following: service or repair of the product, or a replacement of the product.

If upon examination by Piezosurgery Inc.’s service personnel it is determined that the malfunction is caused by abnormal wear and tear or by damage caused by misuse, abuse, tamper with, or by failure to perform normal and routine maintenance as set out in the instructions for use and maintenance booklet originally provided with the device, warranty provisions will not apply.

In this case an estimate for the cost of repair will be given to the customer prior servicing and repairing the product.

The repair will be billed to the customer in the same manner as out of warranty repair.

For selected products:
- **Diamond coated inserts are not warranted.**
If you need technical assistance regarding the use, or you encounter a problem that requires servicing or repair, contact PIEZOSURGERY Inc. Customer Service at (1 888 87 PIEZO).

Returning products for any reason, requires a return authorization number that can be obtained by contacting Piezosurgery Inc. Customer Service. Please provide the following information:

- Product name
- Serial number/lot number (if applicable)
- Reason of return
- Original Invoice Number
- Date of purchase

REPAIRS

Products returned for repair must have a return authorization number that must be included on all paperwork and clearly visible on the package sent to Piezosurgery Inc. Contact Piezosurgery Inc. Customer Service and provide the following information to obtain a return authorization number prior to returning any product for repairing. Make reference to this number for inquiries regarding the repair status.

- Product name
- Serial number/lot number (if applicable)
- Detailed description of the problem
- Original Invoice Number
- Date of purchase

If you require a quote – Notify Customer Service, when requesting the return authorization number that a quote is required. If a quote is not requested the repair will be processed and your account billed accordingly – provided the repair is not covered under warranty.

RETURNED GOODS

All returns must have a return authorization number that must be included in all the shipping documents and clearly visible on the package sent to Piezosurgery Inc. All returns must be shipped prepaid freight, otherwise they will not be accepted.

**CAUTION:** Packaging. Pack the equipment in its original packaging to ensure it is not damaged during shipment.

**WARNING:** If the products must be cleaned and sterilized before returning. Piezosurgery Inc. will not accept and process potentially bio-contaminated products which do not meet this requirement. Contaminated products will be immediately returned to you, at your expense, for decontamination and sterilization.

This warranty gives you specific legal rights and you may have other rights which vary by state and municipality.

The foregoing limited warranty is in lieu of all other warranties, expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Except claims for personal injury, in no case shall the company be liable for any special, incidental or consequential damages based upon breach of warranty or any other legal theory.

Some jurisdictions do not allow limits on warranties, or on remedies, and, in such jurisdictions, the limit in this and the preceding paragraphs may not apply.