Cleaning and Sterilisation Manual
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Disconnect the device foot pedal: press the foot pedal connector release sleeve and pull the connector backwards;

⚠️ **WARNING:** Do not attempt to unscrew or rotate the connector when disconnecting: the connector may become damaged.

⚠️ **WARNING:** When disconnecting the foot pedal cable, always hold the cord connector only. Never pull the cord.

⚠️ **DANGER:** Cleaning and sterilisation of new or repaired tools. All new and repaired device accessories are supplied in non-sterile conditions. At FIRST USE, and after each treatment, they must be cleaned and sterilised in strict compliance with the instructions given in this manual.

⚠️ **DANGER:** Infection control. Special care must be taken in handling contaminated inserts as they are a cause of a potential danger of infection. Hospital personnel must wear suitable personal protection equipment.

⚠️ **DANGER:** Handle sharp and pointed instruments carefully.

**DISMANTLING OF PARTS**

Before moving onto the cleaning procedure described in Chapter 04 - CLEANING, disconnect all device accessories and components.

⚠️ **DANGER:** Disconnect the device from the power supply using the GENERAL SWITCH on the device console and disconnect it from the electricity supply. Disconnect all leads from the device (handpiece cord and foot pedal).

⚠️ **DANGER:** Supplementary equipotential cable. If present, disconnect the supplementary equipotential cable before cleaning or sterilising.

1. **on/off**

2. Disconnect the device foot pedal: press the foot pedal connector release sleeve and pull the connector backwards;
3. Disconnect the handpiece from the device;

**WARNING:** Grip the connector only when carrying out this operation. Do not carry out this manoeuvre using the cord. Do not attempt to unscrew the connector when disconnecting the handpiece. The connector may become damaged.

**WARNING:** The handpiece and its cord cannot be separated.

4. Remove the irrigation kit as follows:
   - Remove the spike from the irrigation bag;
   
   **NOTE** - Close the irrigation kit clamps before disconnecting it from the irrigation bag.

5. Open the peristaltic pump fully and remove the tube;
   - Re-close the peristaltic pump;

6. Remove the tube and clips from the handpiece cord;

7. Disconnect the tube from the nozzle on the back of the handpiece;
   - Dispose of the irrigation kit in accordance with current regulations governing hospital waste;
Remove the insert from the handpiece using the torque wrench supplied with the device; Dispose of the insert in accordance with current regulations governing hospital waste;

1 WARNING: Only use the Piezosurgery® medical torque wrench to tighten and remove the insert on/from the handpiece. Do not use any other tools, such as pliers, scissors, etc.

Unscrew the insert cover or metallic front cone of the handpiece by twisting in an anticlockwise direction; Dispose of the insert cover in accordance with current national regulations governing hospital waste;

1 WARNING: The metallic cone should not be disposed of; rather it should be reprocessed with the other Piezosurgery® medical instruments.

FOR INSERTS WITH EXTENSION
Remove the extension from the handpiece using the torque wrench supplied; Dispose of the extension in accordance with current national regulations governing hospital waste;

Connect the protection cap to the end part of the cord, at the connector cable gland; Insert the cap into the handpiece cord connector.

1 WARNING: Always install the protection cap before cleaning.
1 WARNING: Before starting cleaning, always visually inspect the protection cap for any damage. Replace if any anomalies are seen.
This table is approximate only. For the complete procedures for cleaning and sterilising the individual parts, please refer to the paragraphs specified in the table.

**WARNING:** Do not use any methods not specified in the table below.

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**DANGER:** Sterile single-use. Sterile single-use objects must only be used in one surgical procedure and on one patient. Single-use objects must not be reused. Separate and dispose of each single-use object in accordance with current regulations governing hospital waste.

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### Device Console and Foot Pedal

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Device console and foot pedal:
The only cleaning method applicable is the manual method.

Accessories
(Handpiece and torque wrench):
The operator needs to choose from the following cleaning procedures:
- Manual cleaning;
- Combined manual/automatic cleaning;
- Automatic cleaning.
The procedures applicable to the Piezosurgery® medical accessories described in the following manual have been validated by an independent entity.

04.1  CLEANING THE DEVICE CONSOLE AND FOOT PEDAL

PREPARATION

- Check that all the following accessories have been removed/disconnected from the device (see Chapter 02):
  • electric power supply lead
  • irrigation kit
  • handpiece
  • irrigation bag support rod
  • supplementary equipotential cable connector (if present)
  • foot pedal

⚠️ DANGER: Always turn the device off by means of the switch and disconnect it from the electric grid before cleaning or disinfecting.

⚠️ DANGER: The device console is not protected against the penetration of liquids. Do not spray liquids directly onto the surface of the device.

⚠️ WARNING: Do not soak the device console or foot pedal in liquids and/or solutions of other types.

⚠️ WARNING: Do not sterilise the device console or pedal.

⚠️ WARNING: Do not use machinery/devices to clean the device console or foot pedal.

⚠️ WARNING: Do not rinse the electric contacts of the foot pedal under running water.

MATERIALS REQUIRED

- Clean, soft lint-free cloths
- Detergent (pH 6-9) and, if necessary, a non-aggressive neutral pH (pH 7) disinfectant solution

⚠️ WARNING: If intending to disinfect, we recommend using water-based disinfectants with neutral pH (pH 7). Alcohol- and oxygenated water-based disinfectant solutions are not recommended as they may discoulour and/or otherwise damage plastic materials. This also applies for chemical products such as acetone and alcohol.
CLEANING AND DISINFECTING

1. Clean the device and foot pedal surfaces with a clean, soft lint-free cloth, imbued with a detergent solution (pH 6-9), following the manufacturer’s instructions; If intending to use a disinfectant, use a non-aggressive neutral pH (pH7) solution prepared according to the manufacturer’s instructions;

2. Dry the device body using a clean, non-abrasive, soft lint-free cloth;

3. Dry the foot pedal using a clean, non-abrasive, soft lint-free cloth;
04.2 CLEANING ACCESSORIES: MANUAL

PREPARATION

The process applies to the following accessories:
- Handpiece;
- Metallic front cone;
- Torque wrench;

After having disconnected the accessories, following the instructions given in chapter 02 of this manual, implement the cleaning procedure as described below.

WARNING:
- Before cleaning the handpiece, remove the insert.
- Always install the protection cap before cleaning.
- Before starting cleaning, always visually inspect the protection cap for any damage. Replace if any anomalies are seen.
- Do not soak the handpiece in ultrasound tank.

MATERIALS REQUIRED

- Enzymatic detergent;
- Neutral pH cleaner;
- Tap water;
- Suitably-sized container;
- Clean soft bristled, nylon brush;
- Ultrasound tank;
- Demineralised/distilled water;
- Syringe;
- Water jet pistol.

DANGER:
- Start the reprocessing procedures at the end of the intervention. Do not allow contaminated instruments to dry before reprocessing.
SOAKING IN ENZYMATIC DETERGENT - HANDPIECE, FRONT CONE, TORQUE WRENCH

⚠️ WARNING: During cleaning, do not use detergents with a pH outside the range of 6-9. Do not use organic solvents such as acetone or isopropyl alcohol to clean the instruments. Saline cleaning agents containing aldehydes, mercury, active chlorine, chloride, bromine or bromide, iodine or iodide or fixing or corrosive proteins must never be used. Do not place or soak instruments in a rinsing solution. Do not use solvents, lubricants or other products with chemical characteristics that differ from those specified. Use of these products can cause the instruments to malfunction or the release of undesired substances at the operating site.

⚠️ WARNING: If intending to disinfect, we recommend using water-based disinfectants with neutral pH (pH 7). Alcohol- and oxygenated water-based disinfectant solutions are not recommended as they may discolour and/or otherwise damage plastic materials. This also applies for chemical products such as acetone and alcohol.

⚠️ WARNING: Cleaning instruments. Use appropriate cleaning instruments as specified in this manual. Never use brushes, metallic sponges, abrasive instruments or sharp objects to remove residues during manual cleaning. These may ruin the product surface and permanently and definitively damage the instruments. Only use brushes with soft, nylon bristles.

⚠️ WARNING: Use either tap water or demineralised water, as indicated by this manual.

⚠️ WARNING: Dispose of the enzymatic detergent correctly once used. Do not recycle.

1. Prepare an enzymatic detergent solution according to the manufacturer’s instructions;

   * Process validated by independent body with enzymatic detergent Cidezime® (Enzo®).

2. Place the handpiece, metallic front cone and torque wrench in a container. Add sufficient enzymatic detergent solution to completely cover the accessories;

   ⚠️ WARNING: Do not soak the handpiece if warm.
**DANGER:** The following parts must be brushed carefully:
- Handpiece
  - Threaded part onto which the inserts are screwed;
  - Threaded part onto which the metallic front cone is screwed;
  - Parts adjacent to threaded parts;
- Metallic front cone
  - The internal threaded part;
- Torque wrench
  - External metallic ring;
  - Internal channels and cavities;

**NOTE:** Rinse the cavities, grooves and fissures and critical parts thoroughly.

**WARNING:** To prevent the accumulation of enzymatic detergent residues, rinse the instrument surfaces thoroughly.
**Handpiece:** Use a single-use syringe (min. 50 ml) to inject the enzymatic detergent solution into the cavities and internal channels of the handpiece three times in order to effectively remove the residues from the internal channel surfaces;

**Rinse the internal channels,** injecting cold distilled/demineralised water at a pressure of 3.8 bars for 10 seconds, to eliminate all enzymatic detergent residues;

*NOTE:* Rinse the channel within the handpiece by injecting the liquid from the back, taking care to use a waste water container to avoid sprays. Leave the water to drain through the internal channel. Repeat the procedure until the rinsing water is free from residues.

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**SOAKING IN MILD DETERGENT - HANDPIECE, FRONT CONE**

**Prepare a neutral pH cleaner solution** according to the manufacturer’s instructions;

* Process validated by independent body with Renu-Klenz® (Steris®) detergent

**Place the handpiece and metallic front cone in a container. Add sufficient neutral pH cleaner solution to the container to completely cover the handpiece and front cone;**
Use a clean soft bristled, nylon brush under running water to clean thoroughly but without damaging the surfaces of the handpiece and cone. Do this to remove all visible traces of contamination. Also rinse the handpiece cord;

**DANGER:** The following parts must be brushed carefully:
- **Handpiece**
  - Threaded part onto which the inserts are screwed;
  - Threaded part onto which the metallic front cone is screwed;
  - Parts adjacent to threaded parts;
- **Metallic front cone**
  - The internal threaded part.

Rinse the internal channels, injecting cold distilled/demineralised water at a pressure of 3.8 bars, to eliminate all detergent residues;

**NOTE:** Rinse the channel within the handpiece by injecting the liquid from the back, taking care to use a waste water container to avoid sprays. Leave the water to drain through the internal channel. Repeat the procedure until the rinsing water is free from residues.
Prepare an enzymatic detergent solution* according to the manufacturer’s instructions and place it into an ultrasound bath;

* Process validated by independent body with enzymatic detergent Cidezime® (Enzo®)

Place the wrench into a suitable container (stainless steel washing machine tray with partitions). Place the tray in an ultrasound cleaner for 10 minutes at 40°C;

Remove the torque wrench from the ultrasound cleaner and rinse with cold demineralised water;

**NOTE:** Rinse the cavities, grooves and crevices and all difficult-to-reach areas thoroughly.

Brush the torque wrench surface gently with a clean soft bristled, nylon brush;
04.3 → CLEANING ACCESSORIES: COMBINED MANUAL/AUTOMATIC

The combined manual/automatic cleaning cycle must always be preceded by the manual cleaning stage described below.

PREPARATION

The process applies to the following accessories:
- Handpiece;
- Metallic front cone;
- Torque wrench;

After having disconnected the accessories, following the instructions given in chapter 02 of this manual, implement the cleaning procedure as described below.

MATERIALS REQUIRED

- Washer/disinfector;
- Enzymatic detergent or alkaline solution and neutralising solution;
- Tap water;
- Suitably-sized container;
- Clean soft bristled, nylon brush;
- Demineralized/distilled water;
- Syringe.

WARNING: Before cleaning the handpiece, remove the insert.

WARNING: Always install the protection cap before cleaning.

WARNING: Before starting cleaning, always visually inspect the protection cap for any damage. Replace if any anomalies are seen.

WARNING: Do not soak the handpiece in ultrasound tank.

WARNING: Dispose of the detergent correctly once used. Do not recycle.

WARNING: Alcohol-based disinfectant solutions and hydrogen peroxide are contra-indicated as they may discolour and/or otherwise damage plastic materials. This also applies for chemical products such as acetone and alcohol. Always rinse with sterile water to keep disinfection.

WARNING: Cleaning instruments. Use appropriate cleaning instruments as specified in this manual. Never use brushes, metallic sponges, abrasive instruments or sharp objects to remove residues during manual cleaning. These may ruin the product surface and permanently and definitively damage the instruments. Only use brushes with soft, nylon bristles.

WARNING: When cleaning, do not use organic solvents such as acetone or isopropyl alcohol to clean the instruments. Saline cleaning agents containing aldehydes, mercury, active chlorine, chloride, bromine or bromide, iodine or iodide or fixing or corrosive proteins must never be used. Do not place or soak instruments in a rinsing solution. Do not use solvents, lubricants or other products with chemical characteristics that differ from those specified. Use of these products can cause the instruments to malfunction or the release of undesired substances at the operating site.
SOAKING IN ENZYMATIC DETERGENT -
HANDPIECE, FRONT CONE, TORQUE WRENCH

1. Prepare an enzymatic detergent solution* according to the manufacturer’s instructions;

* Process validated by independent body with enzymatic detergent Enzymec (Mectron)

2. Place the handpiece, metallic front cone and torque wrench in a container. Add sufficient enzymatic detergent solution to the container to completely cover the accessories;

**WARNING:** Do not soak the handpiece if warm.

3. Leave the handpiece, metallic front cone and torque wrench soaking for 10 minutes at 40°C ± 2°C. This will reduce the organic residues on the instruments;

4. **HANDPIECE:**
   Use a single-use syringe (min. 20 ml) to inject the enzymatic detergent solution into the cavities and internal channels of the handpiece three times in order to effectively remove the residues from the internal channel surfaces;

5. Whilst soaking in the enzymatic detergent solution, gently brush the surface of the metallic front cone and wrench, using a clean soft bristled, nylon brush to eliminate all visible traces of soil;
Use a clean soft bristled, nylon brush under running water (minimum quality: tap water, temperature 20°C ± 2°C) to clean thoroughly but without damaging the surfaces of the handpiece, front cone and torque wrench. Do this for at least 30 seconds, until all visible traces of soil have been removed. Also rinse the handpiece cord.

⚠️ **DANGER:** The following parts must be brushed carefully:
- **Handpiece**
  - Threaded part onto which the inserts are screwed;
  - Threaded part onto which the metallic front cone is screwed;
  - Parts adjacent to threaded parts;
- **Metallic front cone**
  - The internal threaded part;
  - **Torque wrench**
    - External metallic ring;
    - Internal grooves and cavities;

**NOTE:** Rinse the cavities, grooves and fissures and critical parts thoroughly.

⚠️ **WARNING:** To prevent the accumulation of enzymatic detergent residues, rinse the instrument surfaces thoroughly.

Rinse the internal channels, injecting cold distilled/demineralised water from a disposable 20 ml syringe three times, to eliminate all enzymatic detergent residues;

**NOTE:** Rinse the channel within the handpiece by injecting the liquid from the back, taking care to use a waste water container to avoid sprays. Leave the water to drain through the internal channel. Repeat the procedure until the rinsing water is free from residues.
Lay the handpiece, metallic front cone and torque wrench in a metallic tray. Arrange the material in a washer/disinfector into which the detergent solution and/or neutralising solution have been previously loaded, in accordance with the manufacturer’s instructions;

**NOTE:** Place the instruments in the washer/disinfector so that dead zones do not arise and the water can properly drain. Also, make sure that the handpiece and the metal front cone are properly held in place in the washing tray and cannot move during the washing process, as shocks could damage them.

**DANGER:** Avoid overloading the washer/disinfector as this may compromise cleaning effectiveness.

**WARNING:** Do not kink the handpiece cord; this may damage it.

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It is possible to choose between two different cleaning cycles: neutral pH detergent cycle or alkaline detergent cycle.

**NEUTRAL PH DETERGENT CYCLE**
Sequence and parameters applicable to the cycle:
- 3 mins., Pre-wash with cold water;
- 5 mins., Washing with 0,5% neutral pH detergent at 45°C;
- 2 mins., Rinsing with tap water;
- 2 mins., Rinsing with cold demineralised water;
- 5 mins., Thermodisinfection at 93°C with demineralised water.

The automated thermodisinfection was not experimentally tested. According to standard ISO 15883-1, Table 2.1 [4] the thermodisinfection at a temperature of 90°C for 5 mins. determines an A0 value of 3000);

**WARNING:** The automatic cleaning cycle, as described above, must always be preceded by the manual cleaning steps.

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* Validated in compliance with standard ISO 15883-1 with Miele G 7735 CD Miscellaneous Programme TD; Detergent: Renu-Klenz® (Steris®).
ALKALINE DETERGENT CYCLE*
- 1 min, Pre-washing with cold water;
- 5 min, Washing with alkaline detergent at 55°C ±2°C;
- 1 min, Neutralization with proper solution (1/3 cold water, 2/3 warm water);
- 1 min, Rinsing with water (1/3 cold water, 2/3 warm water);
- 5 min, Thermodisinfection at 93°C with demineralized water.

The automated thermodisinfection was not experimentally tested. According to standard ISO 15883-1, Table B.1 [4] the thermodisinfection at a temperature of 90°C for 5min determines an A0 value of 3000.

⚠️ WARNING: The automatic cleaning cycle, as described above, must always be preceded by the manual cleaning steps.

* Validated in compliance with standard ISO 15883-1 with Miele PG8535 Miscellaneous Programme TD: Detergent: Neodisher FA (0.2% v/v cleaning solution) and Neodisher Z (0.1% v/v neutralising solution).
04.4 CLEANING ACCESSORIES: AUTOMATIC

WASHER/DISINFECTOR

1. Lay the handpiece, metallic front cone and torque wrench in a metallic tray. Arrange the material in a washer/disinfector into which the detergent solution liquid and neutralising solution have been previously loaded, in accordance with the manufacturer’s instructions;

   **NOTE:** Place the instruments in the washer/disinfector so that dead zones do not arise and the water can properly drain. Also, make sure that the handpiece and the metal front cone are properly held in place in the washing tray and cannot move during the washing process, as shocks could damage them.

   **DANGER:** Avoid overloading the washer/disinfector as this may compromise cleaning effectiveness.

   **WARNING:** Do not kink the handpiece cord; this may damage it.

2. Connect the specific adapter (supplied as optional) to the back of the handpiece and then to the appropriate water-jet connections of the washer/disinfector machine.

3. Sequence and parameters applicable to the cycle*:
   - 1 min, Pre-wash with cold water;
   - 5 min, Washing with alkaline detergent at 55°C ± 2°C;
   - 1 min, Neutralisation with suitable solution (1/3 cold e 2/3 warm);
   - 1 min, Rinsing with tap water (1/3 cold e 2/3 warm);
   - 5 min, Thermodisinfection at 93 °C with demineralized water.

   The automatic disinfection was not experimentally tested. According to ISO 15883-1, the thermodisinfection at a temperature of 90 °C for 5 minutes determines an A0 value of 3000.

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* Validated in compliance with standard ISO 15883-1 with Miele PG535 Miscellaneous Programme DES-VAR-TD: Alkaline detergent: Neodisher FA (0.2% v/v cleaning solution) and Neodisher Z (0.1% v/v neutralising solution).
All instruments must be inspected before they are prepared for sterilisation. A visual inspection must be performed by means of a magnifier under a suitable light source. All instrument surfaces must be controlled to reveal the presence of soils, corrosion and wear. Special attention must be paid to the control of critical points such as lumens, threaded parts, etc. If soils should be seen, repeat the cleaning cycle by following the combined manual/automatic cycle as described in Paragraph 04.3.
Dry the handpiece, metallic front cone and torque wrench with a clean lint-free cloth;

Use filtered medical compressed air to effectively dry the handpiece, metallic front cone and torque wrench;

**DANGER:** Dry the following thoroughly:
- Handpiece: Internal channel;
- Torque wrench: Cavities, grooves and fissures and critical parts.

Lubricate the wrench using a medical lubricant for surgical instruments. Spray the lubricant directly on the internal peripheral contact surfaces of the torque wrench. After the lubrication remove the excess oil with a cloth.

**WARNING:** It is important to lubricate the wrench and gearing after each cleaning cycle, only using a medical lubricant for surgical instruments in order to avoid any malfunction.
07 ➤ STERILISATION

PREPARATION

The following products require sterilisation:
- Handpiece with cord;
- Metallic front cone;
- Torque wrench.
The packaging must ensure the sterility of the instruments until opened for use at the sterile field.
The instruments must be packed with a double medical grade steam sterilization pouch, in compliance with the ISO 11607-1:2006 requirements.

MATERIALS REQUIRED

- Single-use pouches for steam sterilisation;
- Steam steriliser.

⚠️ WARNING: Ensure that the inner pouch is large enough to contain the instruments without stressing the seals or tearing the packaging.

NOTE - The handpiece must be packed with the handpiece protection cap open.

NOTE - Each instrument must be packaged individually.

⚠️ WARNING: Sterilise only using a steam autoclave. Do not use any other sterilisation method as this may be incompatible with the materials used. Do not use the following sterilisation methods:
- Ethylene oxide sterilisation;
- Hot air sterilisation;
- Sterilisation with a flash cycle;
- STERRAD sterilisation;
- STERIS sterilisation;
- Gravity displacement autoclave;
- Other comparable sterilisation systems.

⚠️ WARNING: During the sterilisation cycle, do not exceed the allowed load of the steam sterilizer.

⚠️ DANGER: Do not sterilise the instruments using:
- Hydrogen peroxide;
- Peracetic acid system;
- Sterilisation with formaldehyde vapours;
- Sterilisation with glutaraldehyde vapours;
- Other comparable sterilisation systems.
The sterilisation process must be carried out in a steam autoclave with a pre-vacuum cycle. Mectron S.p.A. guarantees SAL 10<sup>-6</sup>, by setting the parameters according to only one of the two validated procedures listed below.

Procedure A:

**Cycle type:** 3 times pre-vacuum (min. pressure 60 mBar).

- **Minimum Sterilisation temperature:** 132°C (range 0°C ÷ +3°C).
- **Sterilisation time:** 4 mins.
- **Drying time:** 10 mins.

or Procedure B:

- **Cycle type:** 3 times pre-vacuum (min. pressure 60 mBar).
- **Minimum Sterilisation temperature:** 134°C (range -1°C ÷ +1°C).
- **Sterilisation time:** values equal to or between 3 mins and 18 mins.
- **Drying time:** 10 mins.

All the stages of sterilisation must be carried out by the operator in accordance with UNI EN ISO 17665-1:2007 and UNI EN ISO 556-1:2002 standards.

1. **WARNING:** Do not sterilise the device console or pedal.

Sterile instruments must be stored in a clean, dry place at a storage temperature of between 5°C and 40°C.

- **WARNING:**
  - The handpiece and its cord cannot be separated.
  - Do not sterilise the handpiece with the insert screwed into it.
  - After sterilisation, the handpiece can only be used when it has cooled down to room temperature. The cooling process must not be accelerated.
  - Re-screw the front cone to the handpiece before use.
The instructions given in this publication are not binding and may be altered without notice. The Italian version of this manual is the original document from which the translations have been obtained. If there should be any discrepancies, the Italian version shall apply.

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