

→ Cleaning and sterilization

# COMBI *touch*



## 08 → CLEANING AND STERILIZATION

This table is purely indicative.  
For the complete cleaning and sterilization procedures of the individual parts, refer to the paragraphs indicated in the table.

⚠ **CAUTION:** Methods not included in the table below must not be used.

⚠ **WARNING: Sterile disposable.**  
The sterile disposable subgingival perio tips must be used in just one surgical treatment and dedicated to just one patient. The disposable subgingival perio tips must not be re-used. Separate and dispose of each disposable subgingival perio tip in compliance with the current regulations regarding hospital waste.

EN

**Device body, Pedal, Polisher handpiece, scaler handpiece end part**

Phase	Paragraph	Procedure
I	08.1	Preparation
II	08.2	Manual cleaning with enzymatic detergent

**Irrigation solution container and cap**

Phase	Paragraph	Procedure
III	08.3	Manual cleaning with enzymatic detergent and running water

**Accessories (Scaler handpiece scaler front tip, Inserts, Polisher tips, K9 wrench, Dynamometric wrench)**

Phase	Paragraph	Procedure	Scaler handpiece	Scaler front tip	Inserts	Polisher tips.	K9 wrench	Dynamo-metric wrench
IV	08.4.1	Manual cleaning	Manual cleaning with enzymatic detergent		Immersion into enzymatic detergent			
					Ultrasonic washing			
	08.4.2	Combined cleaning manual/ automatic	Manual cleaning with enzymatic detergent		Immersion into enzymatic detergent			
			Thermal disinfectant with detergent					
	08.4.3	Automatic cleaning	Thermal disinfectant with detergent					
V	08.5	Check cleaning	Visual inspection -> 2.5X lens					
VI	08.6	Drying and lubrication	Drying					Drying + Lubrication
VII	08.7	Sterilization	Packaging, Sterilization and Storage					

Particular information: Sterilization parameters, in steam autoclave, used in Great Britain: - temperature: 134° C , time: 3 minutes.

## 08.1 → PREPARATION

### PREPARATION

- Run the "flush" function (see chapter 02);
- Check that all of the following accessories have been removed/disconnected from the device body (see Chapter 07):
  - Electric power supply cable;
  - Pedal;
  - Scaler handpiece;
  - Inserts;
  - Polisher tip;
  - Water and air pipe.

⚠ **CAUTION:** The cleaning and sterilizing operations described in the following paragraphs are to be performed upon initial use and prior to all successive uses.

⚠ **WARNING:** Always turn the device off by its the switch and disconnect it from the electrical network before performing the cleaning and disinfection procedures.

⚠ **CAUTION:** The polisher handpiece and the cable cannot be separated.

⚠ **CAUTION:** Always disconnect the insert from the handpiece before cleaning and sterilizing it.

⚠ **CAUTION:** Do not immerge the handpiece in disinfectant solutions or other liquids, because it could become damaged.

⚠ **CAUTION:** Do not immerge the handpiece in an ultrasonic tank.

⚠ **ATTENTION:** Where the powder is excessively wet, remove/disconnect the cleaner terminal from the handpiece, remove powder residue from the channel of the cleaner handpiece using the Ø 0,8 mm cleaning needle supplied and then perform the "flush" function without the cleaner terminal.

## 08.2 → POLISHING PARTS THAT CANNOT BE STERILIZED

The following procedure must be performed on all device parts that cannot be sterilized, except for the irrigation solution container and its cap. The parts in question are:

- Device body;

- Pedal and relative connection cable to the device;
- Polisher handpiece and relative lead;
- End part of the scaler handpiece and relative lead.

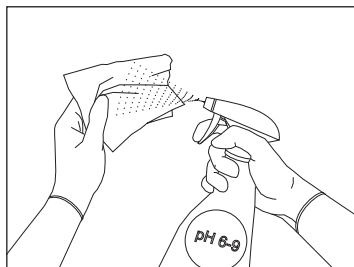
### MATERIALS NECESSARY

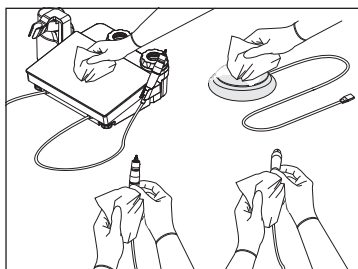
- Clean, soft cloths with low fiber-release
- Detergent solution (pH 6-9).

### CLEANING METHOD

Clean the surface of the parts using a clean, dry cloth with low fibre release, dampened with a detergent solution (pH 6-9);

1





2

Dry the parts using a dry, non-abrasive cloth with low fiber release.

EN

**⚠ WARNING:** Do not sterilize the scaler handpiece: it could stop working and cause harm to persons and/or damage to items.

**⚠ WARNING:** Always turn the device off by its switch and disconnect it from the electrical network before performing the cleaning and disinfection procedures.

**⚠ WARNING:** The device and the scaler handpiece are not protected against penetration of liquids. Do not spray liquids directly onto the touch surface of the device and the scaler handpiece (these cannot be sterilized).

**⚠ CAUTION:** Do not clean the foot pedal under running tap water.

**⚠ CAUTION:** Do not immerse the foot pedal in liquids and/or solutions of various nature.

**⚠ CAUTION:** Do not immerse the handpiece in disinfectant solutions or other liquids, because it could become damaged.

**⚠ CAUTION:** Do not immerse the handpiece in an ultrasonic tank.

## 08.3 → CLEANING THE IRRIGATION SOLUTION CONTAINER AND CAP

### PREPARATION

- Disconnect the irrigation solution container from the device body (see Chapter 07);
- Unscrew the cap from the irrigation solution container.

**⚠ CAUTION:** Do not sterilize the irrigation solution container and its cap in an autoclave, they could become damaged.

### MATERIALS NECESSARY

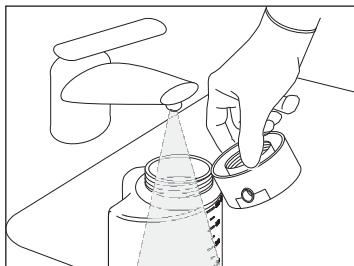
- Water
- Detergent solution (pH 6-9).
- Clean and soft cloth with low fiber-release
- Sterile water

**⚠ CAUTION:** If you intend to disinfect the irrigation solution container and its cap, we recommend that you use water-based disinfectant solutions with a neutral pH (pH7). Alcohol-based disinfectant solutions and hydrogen peroxide are contra-indicated, because they can fade the color and/or damage the plastic materials. This also holds true for chemical products such as acetone and alcohol. Always rinse with sterile water to preserve the disinfection.

### CLEANING METHOD - Irrigation solution container and cap

Carefully rinse under running water the internal and the external surfaces of the irrigation solution container and of the cap;

1



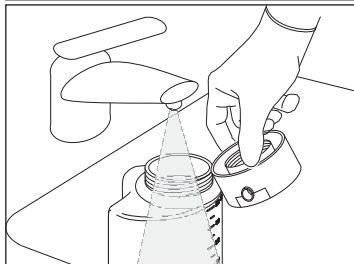
Clean the external surfaces of the irrigation solution container and of the cap with a clean, soft cloth with low fiber-release, dampened with a detergent solution (pH 6-9);

2



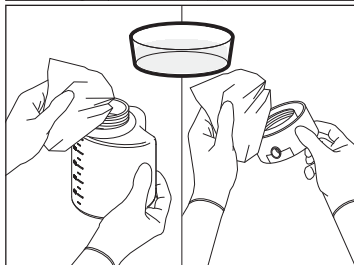
Thoroughly rinse the inside and outside of the irrigation solution container under running water to eliminate all residues of the detergent solution;

3



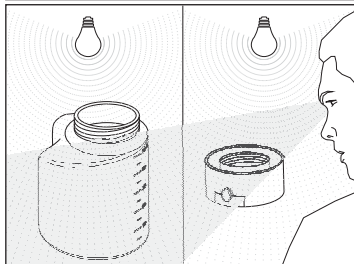
Remove any detergent remaining with a soft cloth with low fiber-release dampened with sterile water in order to maintain the disinfection;

4



Once you've finished the cleaning procedure, check the irrigation solution container and the cap under an adequate source of light, paying attention to the areas that could conceal dirt residues (cavities, grooves) and, if need be, repeat the cleaning cycle.

5



## 08.4 → CLEANING ACCESSORIES THAT CAN BE STERILIZED

## PREPARATION

The following parts of the device can be sterilized:

- Scaler handpiece;
- Scaler front tip;
- Inserts;
- Inserts torque wrench;
- Polisher tips;
- K9 wrench.

Before verifying the cleaning (paragraph 08.5), drying and lubrication (paragraph 08.6) and then sterilization (paragraph 08.7), depending on requirements, one of the three possible cleaning methods must be selected, which are explained in-depth in the following sub-paragraphs.

**⚠ CAUTION:** The instructions provided below have been validated by the manufacturer of the medical device as ABLE to prepare a medical device for re-use. The person in charge of the process is responsible for ensuring that the processes repeated are effectively performed using the equipment, materials and staff in the reprocessing structure in order to obtain the desired result. This generally requires the validation and systematic monitoring of the process. Similarly, all deviations from the instructions provided by the process manager must be adequately assessed to judge their efficiency and potential undesired consequences.

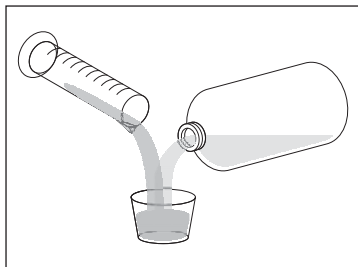
## 08.4.1 → MANUAL CLEANING

## MATERIALS NECESSARY

- Enzymatic detergent at pH 6-9;
- Ø 0,4 mm polishing needle;
- Water;
- Container for immersion in the enzymatic liquid;
- Ultrasonic tank;
- Clean, soft cloths with low fibre release;
- Brush with soft nylon bristles;
- Syringe;
- Demineralised water.

**⚠ CAUTION:** If you intend to disinfect, we recommend that you use water-based disinfectant solutions with a neutral pH (pH7). Alcohol-based disinfectant solutions and hydrogen peroxide are contraindicated, because they can fade the color and/or damage the plastic materials. This also holds true for chemical products such as acetone and alcohol. Always rinse with sterile water to preserve the disinfection.

**⚠ CAUTION: Do not use hydrogen peroxide.** If you intend to disinfect the accessories, do not use hydrogen peroxide, but only disinfectants with neutral pH (pH7); always rinse with sterile water to preserve the disinfection.



1

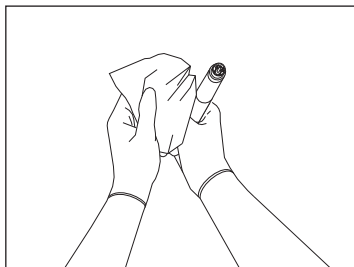
Prepare an enzymatic detergent solution with pH 6-9, as per the instructions of the manufacturer;

**⚠ CAUTION:** Once used, dispose of the enzymatic detergent correctly, do not recycle it.

## SCALER HANDPIECE

Clean the surface of the scaler handpiece and of its connector with a clean, soft cloth with low fiber-release, dampened with a detergent solution (pH 6-9).

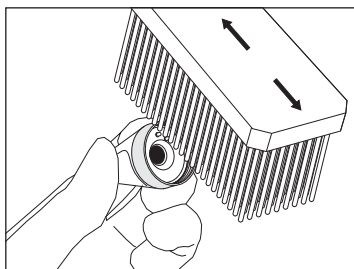
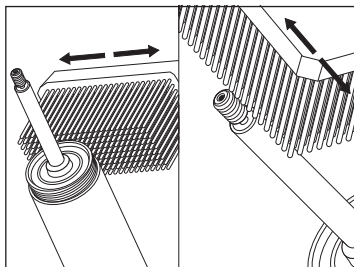
2



Delicately clean the surface of the scaler handpiece using the enzymatic detergent solution with the aid of a brush with soft nylon bristles, placing special care to the following areas:

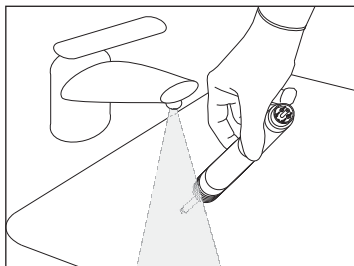
3

- threading of the handpiece
- titanium stem
- front terminal in its external and internal parts



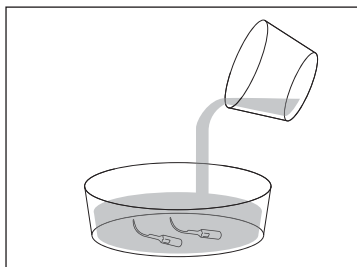
Accurately rinse with tap water to eliminate any detergent residues and perform the last rinse with distilled water;

4



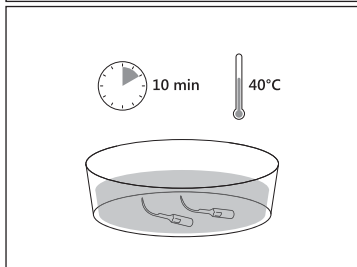
Process validated by independent bodies with enzymatic detergent.

## INSERTS



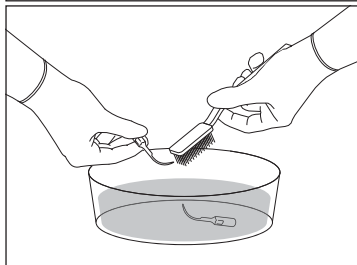
5

Place the insert horizontally in a clean container and add enzymatic detergent solution until the insert is covered completely;



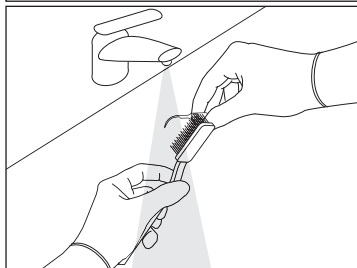
6

Let the insert soak for 10 minutes at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . This procedure reduces the amount of blood, protein and mucous present on the insert;



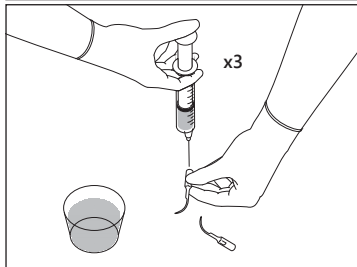
7

During immersion in the enzymatic solution, delicately brush the surface of the insert using the brush with soft nylon bristles to eliminate all traces of visible dirt. Thoroughly clean the difficult areas such as sharp edges;



8

Delicately brush the surface of the insert under running water using the brush with soft nylon bristles;



9

Using a syringe, inject the enzymatic detergent solution 3 times inside the cavity of the insert to effectively remove the residues from the internal surface;

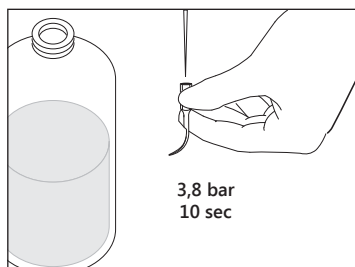
EN



## COMBI touch

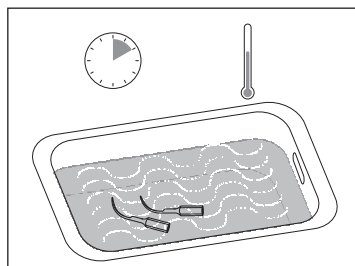
Rinse the internal canal of the insert with distilled water injected under pressure (3,8 bar) for at least 10 seconds to eliminate all residues;

10



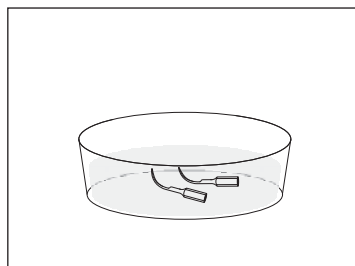
Place the insert in the ultrasound tank submerged by the enzymatic detergent solution at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ , for at least 10 minutes;

11



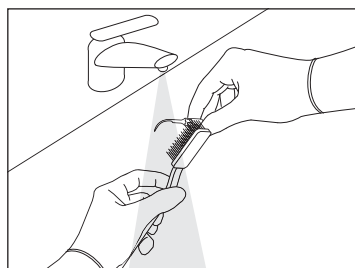
Remove the insert from the ultrasonic tank and rinse with distilled water;

12



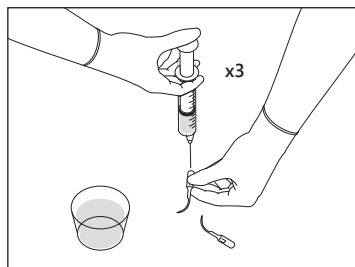
Delicately brush the surface of the insert again using the brush with soft nylon bristles;

13



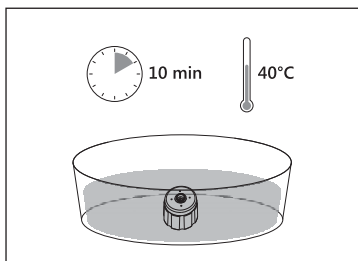
Rinse the internal canal of the insert with distilled water injected under pressure (3,8 bar) for at least 10 seconds to eliminate all residues;

14



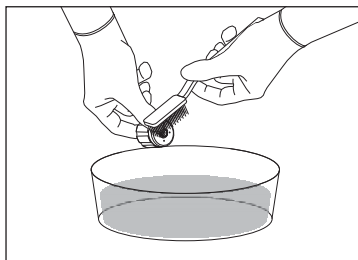
Process validated by independent bodies with enzymatic detergent.

## INSERTS TORQUE WRENCH



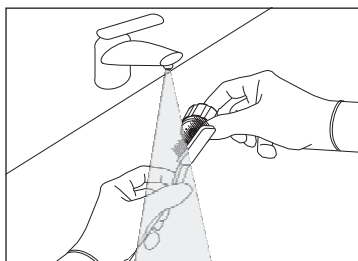
15

Soak the wrench in the enzymatic detergent solution for 10 minutes at 40°C  $\pm 2^\circ\text{C}$ ;



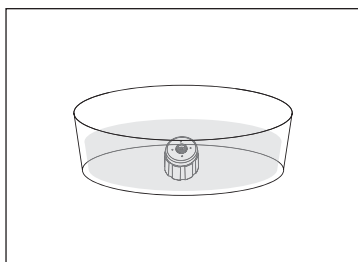
16

During immersion in the enzymatic solution, delicately brush the surface of the wrench using the brush with soft nylon bristles to eliminate all traces of visible dirt both in the internal and external part;



17

Delicately brush the surface of the wrench with a brush with soft nylon bristles under running water;



18

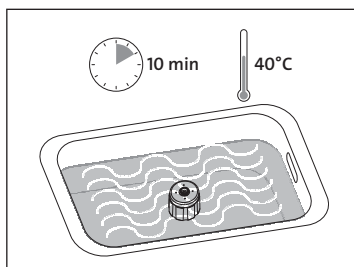
Rinse the wrench with demineralised water until all contaminants have been visually removed;

EN

## COMBI touch

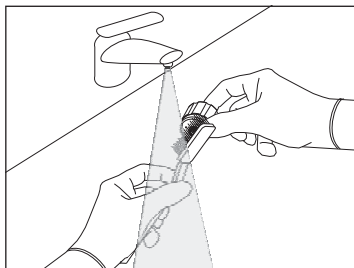
Place the insert in the ultrasound tank submerged by the enzymatic detergent solution at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ , for at least 10 minutes;

19



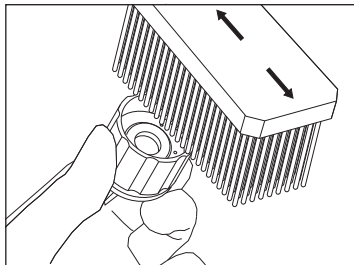
Rinse with tap water to eliminate all residues;

20



Delicately brush the surface of the wrench with a brush with soft nylon bristles using distilled water;

21

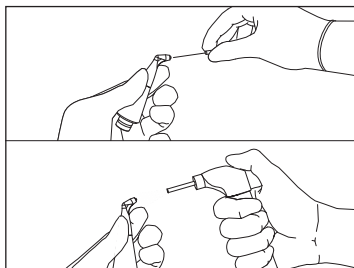


Process validated by independent bodies with enzymatic detergent.

## POLISHER TIPS

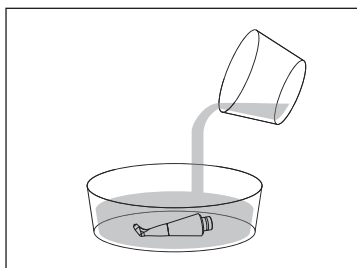
Free the channel of the polisher tip from residues of powder using the  $\varnothing 0,4$  mm cleaning needle supplied. Blow compressed air into the central hole in the tip, from both ends;

22



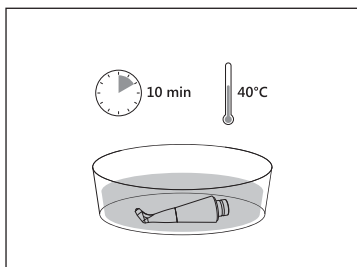
❗ **CAUTION:** Clean the nozzle channel exclusively using the  $\varnothing 0,4$  mm cleaning needle supplied with the device.

❗ **CAUTION:** If the subgingival perio tip is present on the polisher tip, remove it and dispose of it.



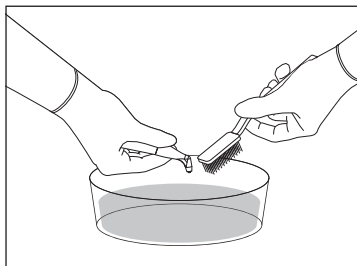
23

Place the polisher tip horizontally in a clean container and add enzymatic detergent solution until the polisher tip is covered completely;



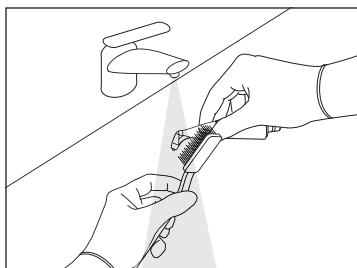
24

Let the polisher tip soak for 10 minutes at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . This procedure reduces the amount of blood, protein and mucous present on the polisher tip;



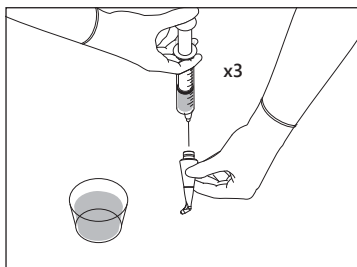
25

During immersion in the enzymatic solution, delicately brush the surface of the polisher tip using the brush with soft nylon bristles to eliminate all traces of visible dirt. Thoroughly clean the difficult areas such as edges and, in particular, the gaps;



26

Delicately brush the surface of the polisher tip under running water using the brush with soft nylon bristles;



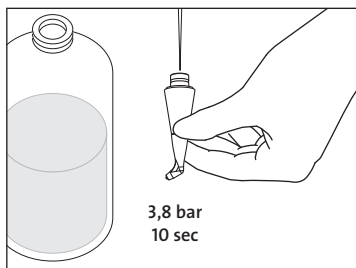
27

Using a syringe, inject the enzymatic detergent solution three times inside the cavity of the polisher tip to effectively remove the residues from the internal surface;

## COMBI touch

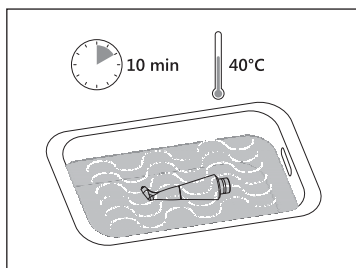
Rinse the cavity of the polisher tip using demineralised water injected under pressure (3.8 bar) for at least 10 seconds, to eliminate all residues of detergent;

28



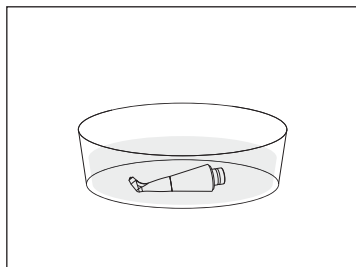
Place the polisher tip in an ultrasonic tank in an enzymatic detergent solution at 40°C  $\pm 2^{\circ}\text{C}$ , for at least 10 minutes;

29



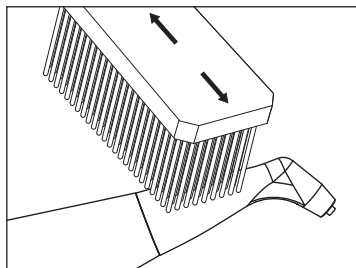
Remove the polisher tip from the ultrasonic tank and rinse with demineralised water;

30



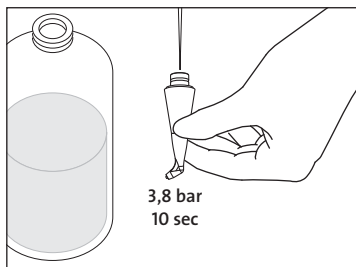
Delicately brush the surface of the polisher tip again using the brush with soft nylon bristles;

31



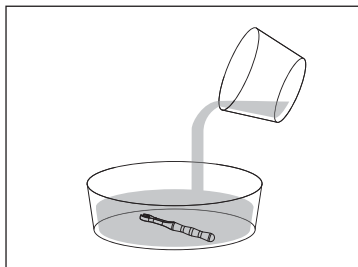
Rinse the internal channel of the polisher tip using demineralised water injected under pressure (3.8 bar) for at least 10 seconds, to eliminate all residues;

32



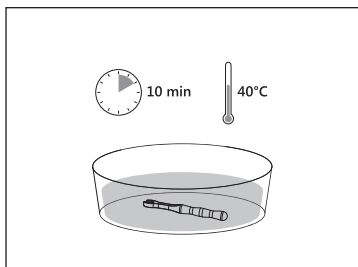
## K9 WRENCH

EN



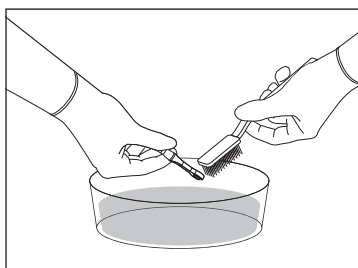
33

Place the K9 wrench in a clean container and add enzymatic detergent solution until the K9 wrench is covered completely;



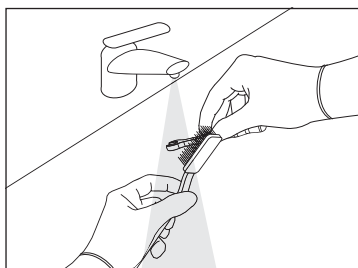
34

Let the wrench soak for 10 minutes at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . This procedure reduces the amount of blood, protein and mucous present on the K9 wrench;



35

During immersion in the enzymatic solution, delicately brush the surface of the K9 wrench using the brush with soft nylon bristles to eliminate all traces of visible dirt. Thoroughly clean the difficult areas such as edges and, in particular, the gaps;



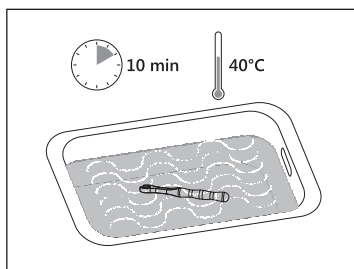
36

Delicately brush the surface of the K9 wrench under running water using the brush with soft nylon bristles;

## COMBI touch

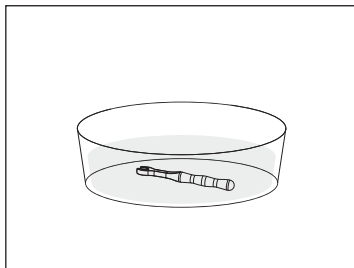
Place the K9 wrench in an ultrasonic tank in an enzymatic detergent solution at 40°C  $\pm 2^{\circ}\text{C}$ , for at least 10 minutes;

37



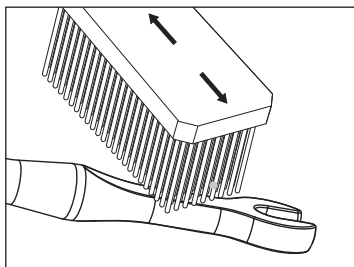
Remove the K9 wrench from the ultrasonic tank and rinse with demineralised water;

38



Delicately brush the surface of the K9 wrench again using the brush with soft nylon bristles;

39



## 08.4.2 → COMBINED MANUAL/AUTOMATIC CLEANING

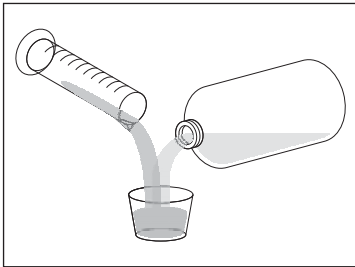
## MATERIALS NECESSARY

- Enzymatic detergent (Mectron ENZYMEC, 0.8% v/v);
- Ø 0,4 mm polishing needle;
- Water;
- Container for immersion in the enzymatic liquid;
- Brush with soft nylon bristles;
- Disposable syringe 20 ml;
- Demineralised water;
- Alkaline detergent: neodisher® FA (0.2 % v/v);
- Neutralising liquid: neodisher® FA (0.1 % v/v);
- Metal basket;
- Thermal disinfectant.

⚠ **CAUTION:** If you intend to disinfect the accessories, it is recommended to use water-based disinfectants with neutral pH (pH7). Alcohol-based disinfectant solutions and hydrogen peroxide are contraindicated, because they can fade the color and/or damage the plastic materials. This is also valid for chemical products such as acetone and alcohol. Always rinse with sterile water to maintain disinfection.

⚠ **CAUTION: Do not use hydrogen peroxide.** If you intend to disinfect the accessories, do not use hydrogen peroxide, but only disinfectants with neutral pH (pH7); always rinse with sterile water to preserve the disinfection.

## 08.4.2.1 → MANUAL PRE-WASH

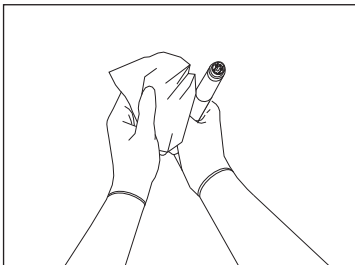


1

Prepare an enzymatic detergent\* solution with pH 6-9, as per the instructions of the manufacturer;

⚠ **CAUTION:** Once used, dispose of the enzymatic detergent correctly, do not recycle it.

## SCALER HANDPIECE



2

Clean the surface of the scaler handpiece and of its connector with a clean, soft cloth with low fiber-release, dampened with a detergent solution (pH 6-9);

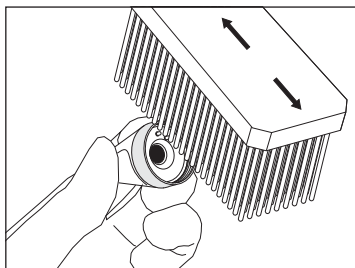
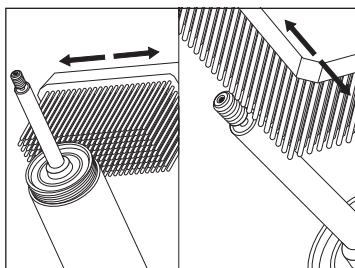


## COMBI touch

Delicately clean the surface of the handpiece using the enzymatic detergent solution with the aid of a brush with soft nylon bristles, placing special care to the following areas:

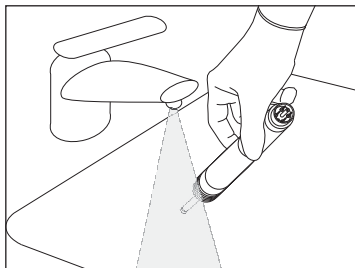
- threading of the handpiece
- titanium stem
- front terminal in its external and internal parts

3



4

Completely rinse with tap water to eliminate any detergent residues and perform the last rinse with distilled water;

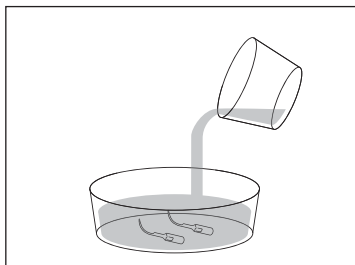


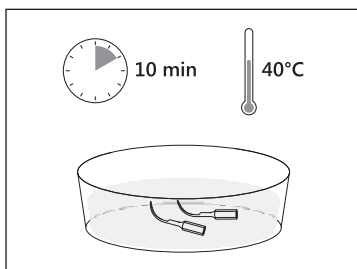
Process validated by independent bodies with enzymatic detergent Enzymec (Mectron).

## INSERTS

Place the insert horizontally in a clean container and add enzymatic detergent solution until the insert is covered completely;

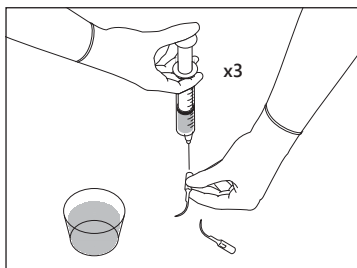
5





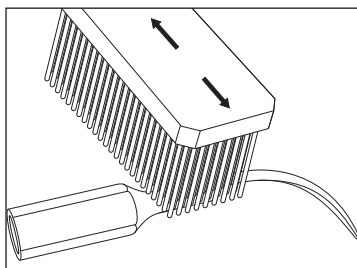
6

Let the insert soak for 10 minutes at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . This procedure reduces the amount of blood, protein and mucous present on the insert;



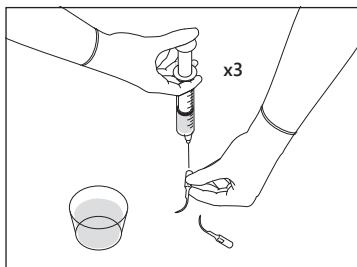
7

Using a 20 ml disposable syringe, inject 20 ml of enzymatic detergent solution 3 times inside the cavity of the insert;



8

Delicately brush the surface of the insert under running water (drinking water, temperature  $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ), in particular the parts that are difficult to access (cavities, structured surfaces, etc.) using a brush with soft nylon bristles;  
The insert must be brushed until no residues can be seen (at least 30 seconds);



9

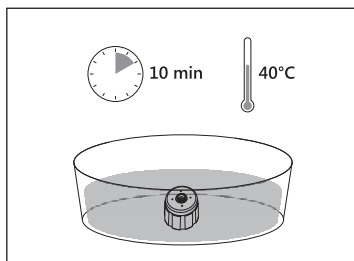
Using a 20 ml disposable syringe, inject 20 ml of cold demineralised water 3 times inside the cavity of the insert;

Process validated by independent bodies with enzymatic detergent Enzymec (Mectron).

## INSERTS TORQUE WRENCH

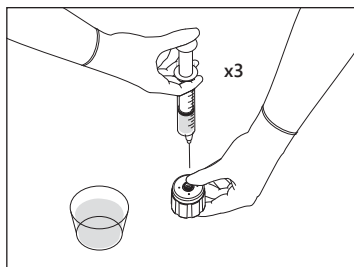
Soak the wrench in the enzymatic detergent solution for 10 minutes at 40°C  $\pm 2^\circ\text{C}$ ;

10



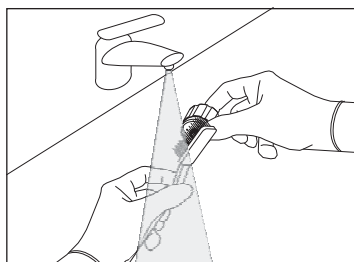
Using a 20 ml disposable syringe, flush the surface of the wrench three times with 20 ml of enzymatic detergent solution;

11



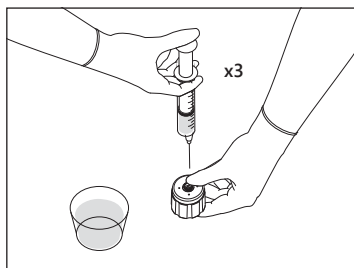
Delicately brush the surface of the wrench under running water (drinking water, temperature 20°C  $\pm 2^\circ\text{C}$ ), in particular the parts that are difficult to access (cavities, structured surfaces, etc.) using a brush with soft nylon bristles; The wrench must be brushed until no residues can be seen (at least 30 seconds);

12



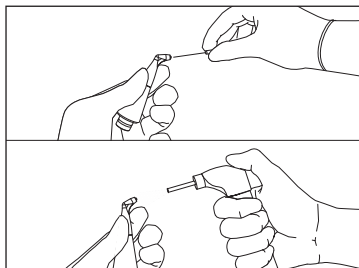
Using a 20 ml disposable syringe, flush the surface of the wrench 3 times with 20 ml of enzymatic detergent solution;

13



Process validated by independent bodies with enzymatic detergent Enzymec (Mectron).

## POLISHER TIPS

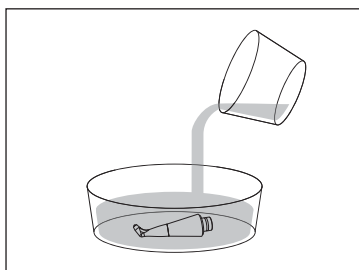


14

Free the channel of the polisher tip from residues of powder using the relevant Ø 0,4 mm cleaning needle supplied. Blow compressed air into the central hole in the tip, from both ends;

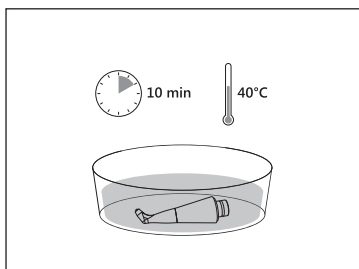
⚠ **CAUTION:** Clean the nozzle channel exclusively using the Ø 0,4 mm cleaning needle supplied with the device.

⚠ **CAUTION:** If the subgingival perio tip is present on the polisher tip, remove it and dispose of it.



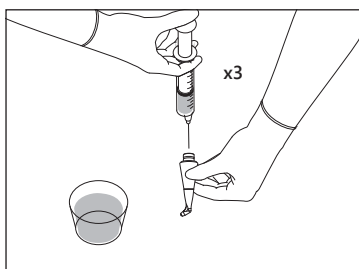
15

Place the polisher tip horizontally in a clean container and add enzymatic detergent solution until the polisher tip is covered completely;



16

Let the polisher tip soak for 10 minutes at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . This procedure reduces the amount of blood, protein and mucous present on the polisher tip;



17

Using a 20 ml disposable syringe, inject 20 ml of enzymatic detergent solution 3 times inside the cavity of the polisher tip;

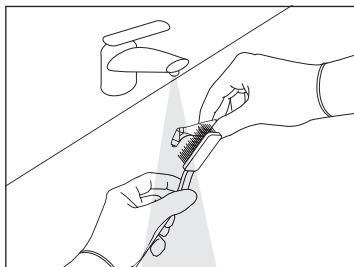
EN

## COMBI touch

Delicately brush the surface of the polisher tip under running water (drinking water, temperature 20°C +/- 2°C), in particular the parts that are difficult to access (cavities, structured surfaces, etc.) using a brush with soft nylon bristles;

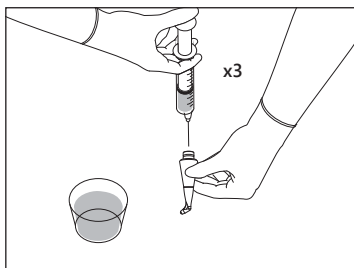
The polisher tip must be brushed until no residues can be seen (at least 30 seconds);

18

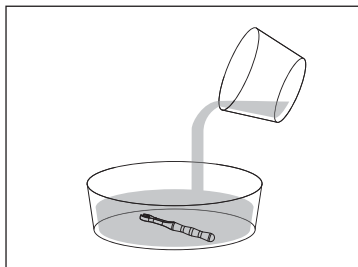


Using a 20 ml disposable syringe, inject 20 ml of cold demineralised water 3 times inside the cavity of the polisher tip;

19

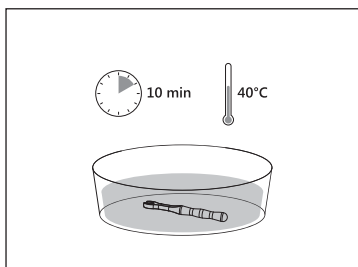


## K9 WRENCH



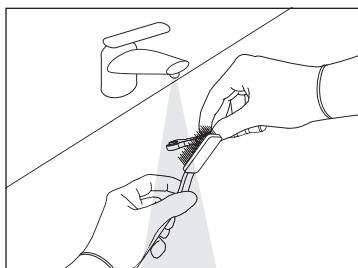
20

Place the K9 wrench in a clean container and add enzymatic detergent solution until the K9 wrench is covered completely;



21

Let the K9 wrench soak for 10 minutes at  $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . This procedure reduces the amount of blood, protein and mucous present on the K9 wrench;



22

Delicately brush the surface of the K9 wrench under running water (drinking water, temperature  $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ), in particular the parts that are difficult to access (joint) using a brush with soft nylon bristles;  
The K9 wrench must be brushed until no residues can be seen (at least 30 seconds);

EN

## 08.4.2.2 → MECHANICAL CLEANING

❗ **CAUTION:** The following mechanical cycle must always be preceded by the pre-washing phase with enzymatic detergent.

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

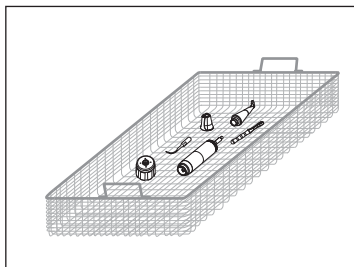
⚠ **CAUTION:** Avoid overloading the thermal disinfecter as this could compromise cleaning effectiveness.

⚠ **WARNING:** Upon completion of the cleaning cycle in the thermal disinfecter, the scaler handpiece remains at the heated washing temperature. Use appropriate precautions when extracting the scaler handpiece from the thermal disinfecter to prevent injury to the operator.

❗ **CAUTION:** Due to its shape, the scaler handpiece can rotate. When not in use, the scaler handpiece must always be placed on its support.

Place the accessories in a metal basket and place the basket in the thermal disinfecter;

1

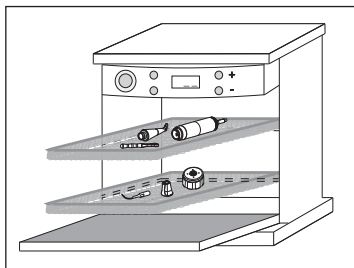


Sequence and parameters applicable to the cycle:

- 1 min, rinse with cold water;
- 5 min, wash with alkaline detergent at 55°C ±2°C;
- 1 min, neutralisation with suitable solution (1/3 cold water, 2/3 hot water);
- 1 min, rinse with water (1/3 cold water, 2/3 hot water);
- 5 min, thermal disinfection at 93°C with demineralised water.

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

2



Procedure validated with Miele PG8535 instrument washer/disinfecter.  
Miele DES-VAR-TD program.  
Alkaline detergent: neodisher® FA (0.2 % v/v);  
Neutralising liquid: neodisher® Z (0.1 % v/v);

## 08.4.3 → AUTOMATIC CLEANING

## MATERIALS NECESSARY

- Alkaline detergent: neodisher® FA (0.2 % v/v);
- Neutralising liquid: neodisher® FA (0.1 % v/v);
- Water;
- Metal basket;
- Adaptors;
- Thermal disinfectant.

⚠ **CAUTION:** Before starting to clean the thermal disinfectant, assess the entity of dirt and, if necessary, perform a pre-wash (paragraph 8.4.2.1) to avoid repeating the entire cleaning cycle.

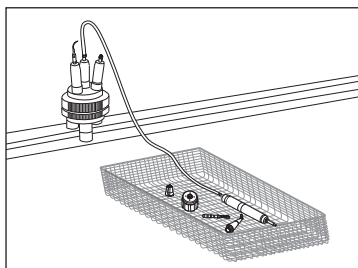
EN

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

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

⚠ **WARNING:** Upon completion of the cleaning cycle in the thermal disinfectant, the scaler handpiece remains at the heated washing temperature. Use appropriate precautions when extracting the scaler handpiece from the thermal disinfectant to prevent injury to the operator.

⚠ **CAUTION:** Due to its shape, the scaler handpiece can rotate. When not in use, the scaler handpiece must always be placed on its support.



1

Position the accessories in a metal basket. Connect the relevant adapter (supplied as an option) to the scaler handpiece connector and then to the water jet cleaning connections of the thermal disinfectant.

Repeat the same operation for the inserts and polisher tips, connecting them to the relevant adapters supplied as an optional.

2

Sequence and parameters applicable to the cycle:

- 1 min, rinse with cold water;
- 5 min, wash with alkaline detergent at  $55^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ;
- 1 min, neutralisation with suitable solution (1/3 cold water, 2/3 hot water);
- 1 min, rinse with water (1/3 cold water, 2/3 hot water);
- 5 min, thermal disinfection at  $93^{\circ}\text{C}$  with demineralised water.

Thermal disinfection has not been tested experimentally. In compliance with ISO 15883-1, Table B.1 [4] thermal disinfection at a temperature of  $90^{\circ}\text{C}$  for 5 min determines a value of A0 3000.



**08.5 → CLEANING VERIFICATION****MATERIALS NECESSARY**

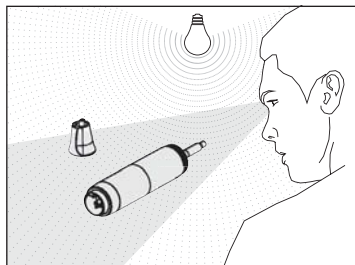
- Light source;
- Magnifying glass 2.5X.

EN

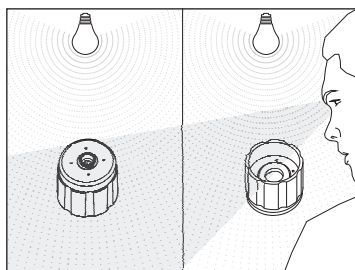
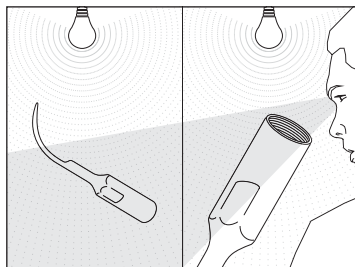
Once the cleaning operations have been completed, visually inspect the scaler handpiece and scaler front tip under an adequate source of light, if necessary using a magnifying glass 2.5X, paying attention to the details that could conceal dirt residue (threading, cavities, grooves) and, if necessary, repeat the cleaning cycle if dirt is still visible; Finally, check the integrity of those parts and those elements that could have deteriorated during use:

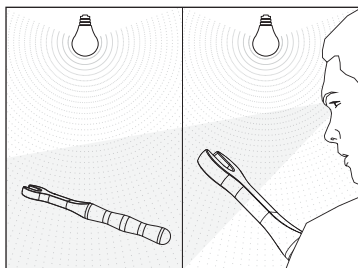
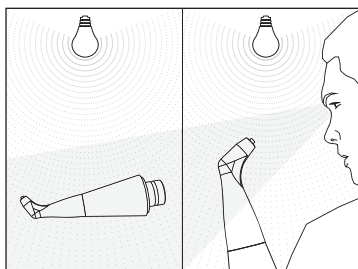
Repeat the checks on the other accessories (inserts, insert torque wrenches, polisher tips, K9 wrench), repeating the cleaning cycle if necessary.

1



2





### 08.6 → DRYING AND LUBRICATION

#### MATERIALS NECESSARY

- Compressed air;
- Soft cloth with low fibre release;
- Medical grade lubricant.

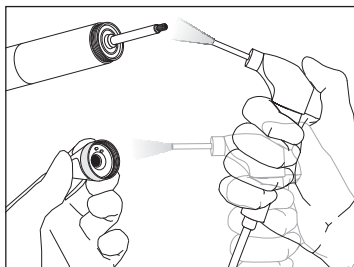
EN

Dry all parts of the scaler handpiece and the scaler front tip well, in particular the electric contacts, by blowing compressed air;

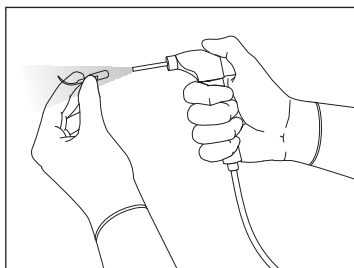
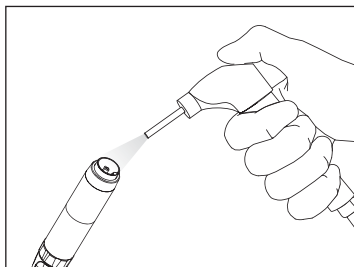
**⚠ CAUTION:** The scaler handpiece electric contacts must be dry before the end of the sterilization cycle, before connection of the device lead. Always make sure that the connector electric contacts are entirely dry; dry them by blowing compressed air if necessary.

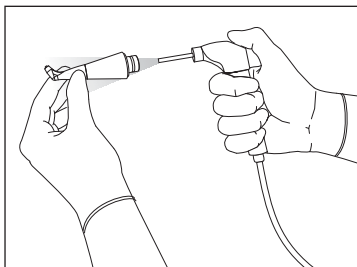
**⚠ CAUTION:** Before starting the sterilization cycle, make sure that the insert is thoroughly dry both internally and externally. To do this, blow compressed air both externally and through the internal passage hole. This will prevent the appearance of stains, streaks on the surface or oxidation inside the insert.

1



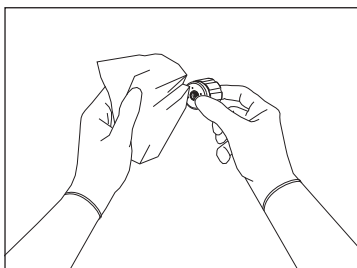
2





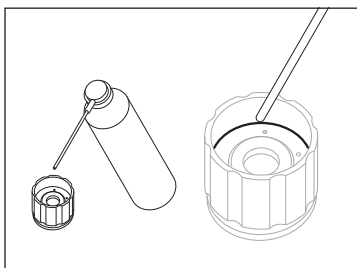
3

⚠ **CAUTION:** Before starting the sterilization cycle, make sure that the polisher tip is thoroughly dry both internally and externally. To do this, blow compressed air both externally and through the internal passage holes. This will prevent the appearance of stains, streaks on the surface or oxidation inside the polisher tip.



4

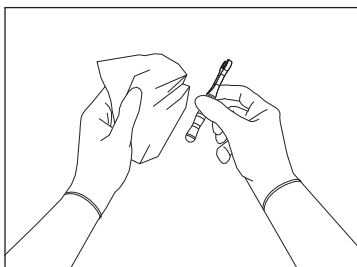
Dry the inserts torque wrench using a soft cloth with low fibre release



5

Lubricate the inserts torque wrench with medical-grade lubricants at the point indicated;

⚠ **CAUTION:** Do not use oil or silicone-based lubricants.



6

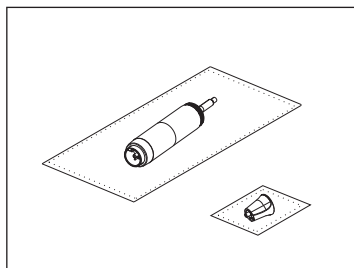
Dry the K9 wrench using a soft cloth with low fiber release.

## 08.7 → STERILIZATION

### PREPARATION

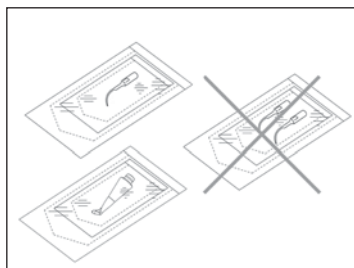
Seal the scaler handpiece (without inserts) and the scaler front tip individually, separately in disposable sterilization bags.

1



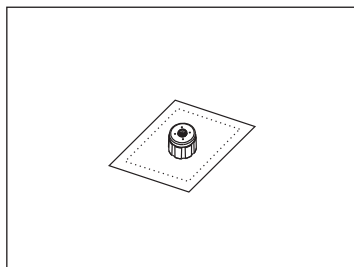
Seal the inserts individually inside a disposable bag for sterilization.  
Seal the polisher tips individually inside a disposable bag for sterilization.

2



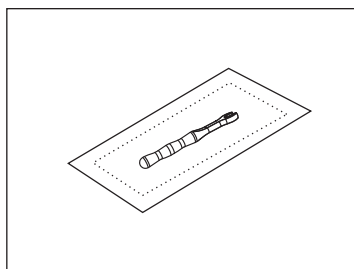
Seal the wrench individually inside a disposable bag for sterilization.

3



Seal the K9 wrench individually inside a disposable bag for sterilization.

4



## STERILIZATION METHOD

The scaler handpiece and the other accessories that can be sterilized are manufactured with materials that resist a maximum temperature of 135°C for a maximum time of 20 minutes.

Once the scaler handpiece and the other accessories that are able to be sterilized have been put into bags individually, perform the sterilization process in the steam autoclave.

The sterilization process validated by Mectron S.p.A., in a steam autoclave, guarantees SAL 10<sup>-6</sup> by setting the parameters indicated below:

**Type of cycle:** 3 times Pre-vacuum (min. pressure 60 mBar).

**Minimum sterilization temperature:**

132°C (interval 0°C ÷ +3°C).

**Minimum sterilization time:**

4 minutes.

**Minimum drying time:** 20 minutes.

All of the stages of sterilization must be performed by the operator in compliance with ISO 17665-1:2007, ISO 556-1:2002 and ANSI/AAMI ST 46:2002.

⚠ **CAUTION:** Do not sterilize the handpiece with the insert screwed onto it.

⚠ **WARNING: Infection control - Parts that can be sterilized** - Diligently remove all residues of organic dirt before the sterilization.

⚠ **CAUTION:** Perform the sterilization using a water steam autoclave only. Do not use any other sterilization procedure (dry heat, irradiation, ethylene oxide, gas, low temperature plasma, etc.).

⚠ **CAUTION:** Do not exceed the allowed load of the steam sterilizer.

⚠ **WARNING:** On completion of the sterilization cycle in autoclave, the scaler handpiece remains at the sterilization temperature for a long time.

Use appropriate precautions when extracting the scaler handpiece from the autoclave to prevent injury to the operator.

⚠ **CAUTION:** Wait for the scaler handpiece to cool down completely before use.

## 09 → MAINTENANCE

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

- 1 Empty the powder containers;
- 2 Perform a complete cleaning cycle of the irrigation circuit using the "flush" function (see chapter 06 - "flush" function) both on the ULTRASOUND side and the POLISHING side;
- 3 Empty the irrigation solution container irrigation circuits, removing the irrigation solution container and performing the "flush" cycle of the ULTRASOUND side;
- 4 Eliminate any condensation from the air filter (see paragraph 09.3);
- 5 Disconnect the device from the mains electricity and the water and air circuits;

- 6 Clean and dry the water filter (see paragraph 09.2);
- 7 Before using the device again, clean and sterilize the handpiece and the accessories, following the instructions given in chapter 08 - CLEANING AND STERILIZATION;
- 8 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 authentic Mectron spare part.

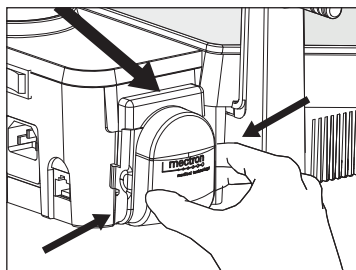
### 09.1 → REPLACEMENT OF THE PERISTALTIC PUMP

There is a plastic protection on the left side of the device, which covers the peristaltic pump housing. Remove this protection by pressing on the sides and pulling towards yourself;

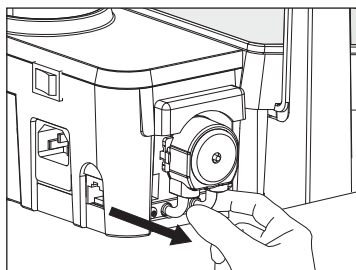
**⚠ CAUTION:** Before performing any kind of service on the peristaltic pump, make sure that the device is disconnected from the power outlet and that the liquid container is not connected.

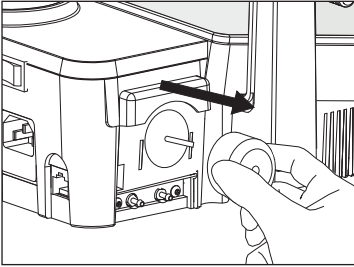
Disconnect the two silicon tubes of the peristaltic pump from their respective couplings, which are positioned beneath the pump;

1



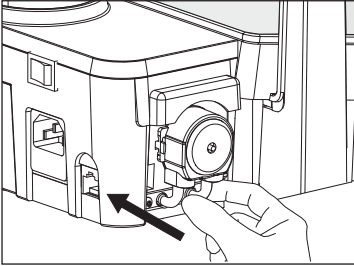
2





3

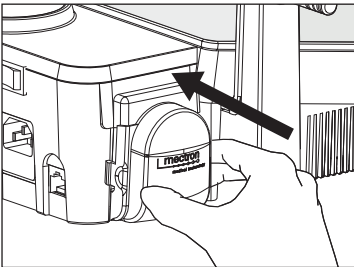
Extract the peristaltic pump from its base, pulling it towards yourself. Pay close attention, as pieces may detach;



4

Connect the new peristaltic pump to its seat until a "click" sound is heard and then connect the two pump tubings to their respective couplings positioned beneath the pump;

**⚠ WARNING:** Only use authentic Mectron parts.



5

Re-position the plastic cover on the peristaltic pump.



### 09.2 → CLEANING AND/OR REPLACING THE WATER FILTER

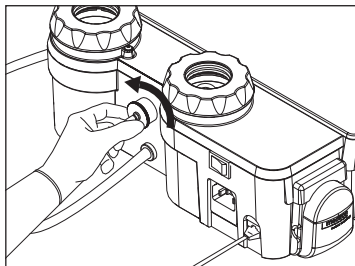
Check and clean the water filter monthly, performing the following operations:

Disconnect the water supply pipe from the male coupling.

Unscrew the knurled bush of the male coupling;

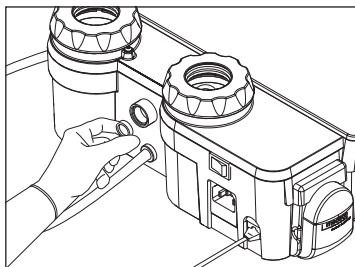
⚠ **CAUTION:** Before cleaning and/or replacing the water filter, make sure that the device is disconnected from the main electricity and that the liquid container is not connected.

1



Extract the filter and wash it under running water to eliminate the impurities that obstruct it.

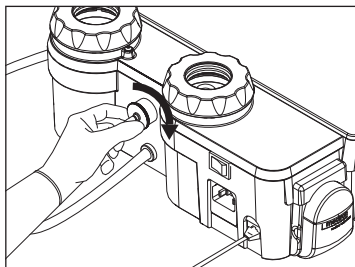
2



Re-introduce the filter into its seat and screw the knurled bush back into its housing tightly until it is fully in position.

3

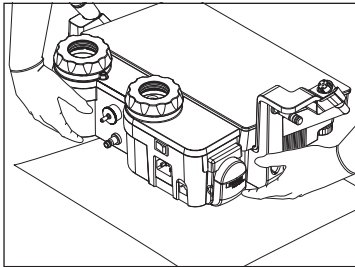
**NOTE:** Replace the filter with a new one if it is damaged or washing is not effective.



## 09.3 → ELIMINATING CONDENSATION

The device has an air filter, which intercepts any impurities and the condensate present in the pneumatic circuit.

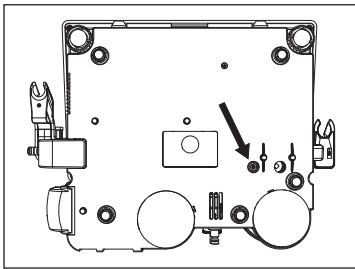
To prevent the condensation from entering into circulation in the device, check and empty the air filter weekly by performing the following operations:



1

Position an absorbent cloth underneath the device to collect the condensate;

⚠ **CAUTION:** This maintenance operation must be performed with the appliance on in order for the air circuit to be pressurised.



2

With the device on and in an exact horizontal position, press the air filter vent valve positioned on the bottom of the device, just until air escapes.

**NOTE:** However, it is recommended to use dry compressors and introduce a dehumidifier into the practice's pneumatic circuit.

EN

### 09.4 → CLEANING POWDER CONTAINERS AND CAPS

Check cleanliness of the powder container and, in particular, the cap as powder residues in the presence of moisture could solidify and make opening and closing operations difficult.

① **CAUTION:** Always switch the device off using the I/O switch and disconnect it from the mains electricity before cleaning the powder containers and the caps.

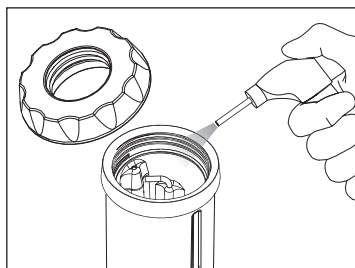
⚠ **WARNING:** Before blowing compressed air into the powder containers, make sure that they have been emptied.

Blow compressed air inside the container and on the threading of both the powder containers and the caps.

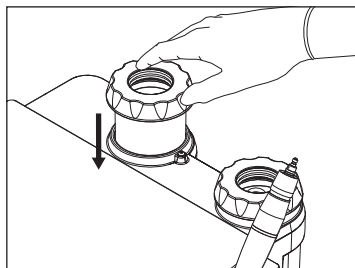
When the cleaning operation has been completed, re-position the containers on the device.

① **CAUTION:** Insert the powder containers in a way that the grooves on the bottom of the device are in line with the convexity of the powder containers.

1



2



## 10 → DISPOSAL MODES AND PRECAUTIONS

⚠ **WARNING: Hospital wastes.**

Treat the following items as hospital waste:

- Inserts: when they are worn out or broken;
- Torque wrench for inserts: when worn out or broken.
- Cleaner terminals, when worn or broken;
- Perio subgingival terminal, at the end of each treatment.

The use and disposal of materials, and materials that entail a biological risk, must be disposed of in accordance to the local regulations in force concerning hospital wastes.

The COMBI touch must be disposed of and treated as a waste for separate collection. Disregarding the previous points may entail a fine, pursuant to Directive 2012/19/UE. It is up to the purchaser to hand over the device for its disposal to the retailer who supplies them with new equipment; the instructions for proper disposal are available from Mectron.