

ROLENCE®

ULTRASONIC SCALER (Piezo)

ELITEDENT® PS-1/PS-1(LED)



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Section 1: Safety Precautions


Prior to installation and start-up of the ultrasonic scaler, carefully read the instructions provided herein!


1.1 Precautions for All Systems


 Do not place the ultrasonic scaler on or next to a radiator or other heat source. Excessive heat may damage the ultrasonic scaler's electronics. Place the ultrasonic scaler where air is free to circulate on all sides and beneath it. Do not cover vents on rear panel.


 **Always set the system's power adjustment to the lowest power setting for the application of a new or special Tips.**

 **Always flush your ultrasonic system for at least 30 seconds with highest flow after treatment.**


 **Do not operate the system in "Turbo" mode continuously for more than 20 minutes! Try to take a 10 minute break before re-use the system.**

 Equipment and dental water supply system maintenance are strongly recommended. See Section 11: System Maintenance And Care.

 Close the water shut-off valve in the dental water supply system every night before leaving the office.

 The use of an in-line water filter is recommended.

 Used for the intended purpose only. The ultrasonic scaler must be used by other than qualified and trained personnel, in medical facilities.

 Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked Hospital Only or Hospital Grade.

1.2 Precautions for Ultrasonic Prophylaxis Procedures

- Before first use, clean, disinfect and sterilize new or repaired handpieces and Tips you wish to use with the ultrasonic scaler.
- Always examine the unit and ultrasonic tips before commencing treatment. A damaged ultrasonic scaler or damaged tip must not be used.
- Ultrasonic tips that have been bent, damaged, or reshaped are susceptible to in-use breakage and should be discarded and replaced immediately.
- Retract the lips, cheeks and tongue to prevent contact with the ultrasonic tip whenever it is placed in the patient's mouth.

Section 2: Introduction

Rolence Enterprise Inc. is an ISO 9001, ISO 13485 certified manufacturer of Ultrasonic Scalers. All the products are FDA registered and compliant with EN standard (CE Marking).

2.1 Conformance to Standards:

ELITEDENT® PS-1/PS-1(LED) Ultrasonic Scaler conforms to IEC60601-1-2:2001 and IEC60601-1-1:2000.

The device is CE marked corresponding to European **Medical Device Directive (93/42/EEC)**

2.2 Supplies and Replacement Parts

Contact your local Rolence dealer to order supplies or replacement parts. There are no serviceable parts included in this device. Please contact your dealer to acquire all repairing service and technique supports.

CAUTION: EQUIPMENT NOT SUITABLE FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH NITROUS OXIDE.

CAUTION: U.S FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTAL PROFESSIONAL

Section 3: Application

The Ultrasonic Scaler is designed for use in dentistry for the following applications:

- General Scaling (G)

Removal of supragingival calculus
Removal of stains

- Endo (E)

Preparation, cleaning and irrigation of root canals
Retrograde preparation of root canals

- Perio (P)

Scaling and root planning
Periodontal treatments

Section 4: Specifications

ELITEDENT® PS-1/PS-1(LED) Ultrasonic Scaler

Voltage optional: 100V, 120V, 230V, 240V

4.1 Electric Voltage:

| VOLTAGE: | CURRENT |
|----------------|-----------|
| 100VAC 50/60Hz | 1.0A(MAX) |
| 120VAC 50/60Hz | 1.0A(MAX) |
| 230VAC 50/60Hz | 0.6A(MAX) |
| 240VAC 50/60Hz | 0.6A(MAX) |
| POWER INPUT: | 50VA |

WATER PRESSURE: 20-60 psi

4.2 Dimension:

| | |
|----------|---------|
| HEIGHT : | 6.5 CM |
| WIDTH : | 23.0 CM |
| DEPTH : | 22.0 CM |
| WEIGHT : | 2.2 KG |

4.3 Operation Environment:

| | |
|-----------------------|-------------------|
| AMBIENT TEMPERATURE | : +10°C ~ +40°C |
| RELATIVE HUMIDITY | : 30%~75% |
| ATOMOSPHERIC PRESSURE | : 700 hPa~1060hPa |

4.4 Transportation And Storage Environment:

| | |
|-----------------------|-------------------|
| AMBIENT TEMPERATURE | : -10°C~+70°C |
| RELATIVE HUMIDITY | : 10%~90% |
| ATOMOSPHERIC PRESSURE | : 500 hPa~1060hPa |

Section 5: Contraindications and Warnings

5.1 Contraindications

- Ultrasonic Systems should not be used for restorative dental procedures involving the condensation of amalgam or porcelain.
- This device is designed to work with ultrasonic tips compatible with EMS[®] system. For optimum performance please use only qualified ultrasonic tips supplied by EMS[®] or Rolence[®].
- Do not use this device if the patient or operator is wearing a pacemaker.

Remark: EMS[®] is the registered trademark of the Electro Medical Systems.

5.2 Warnings

- During using the unit, make sure that water is flowing continuously. If the handpiece overheats please check the water supply, and stop using the unit for a while.
- Do not operate the system in "Turbo" mode continuously for more than 20 minutes! Try to take a 10 minute break before re-use the system.

Section 6: Infection Control

6.1 General Infection Control Recommendations

- As with all dental procedures, the use of standard personal protection equipment (i.e., wearing a face mask, eyewear, or face shield, gloves and protective gown) is recommended.
- For maximal operator and patient safety, carefully follow section 11 system maintenance and care information detailed in the operating instruction accompanying your ultrasonic scaler.
- As with high speed handpieces, and other dental devices, the combination of water and ultrasonic vibration from your ELiTEDENT[®] Ultrasonic Scaler will create aerosols. With proper technique, much of the aerosol dispersion can be effectively controlled and minimized. Please carefully follow the procedural guide lines in this direction manual regarding the use of your ultrasonic scaler.

- Always flush your ELiTEDENT[®] Ultrasonic Scaler at least for 20 seconds with highest flow after treatment.
- Clean and disinfect the torque wrench after unscrewing it from the handpiece. The torque wrench can be autoclaved up to 135°C for at least 3 minutes.

6.2 Water Supply Recommendations

- It is highly recommended that all dental water supply systems conform to applicable CDC (Centers for Disease Control and Prevention) and ADA (American Dental Association) standards, and that all recommendations be followed in terms of flushing, chemical flushing, and general infection control procedures. See sections 6.1 and section 11.

Section 7: Installation Instructions

7.1 General Information

If the installation of your ELiTEDENT® ultrasonic scaler is performed by someone other than trained Rolence distributor personnel, care should be taken to observe the following requirements and recommendations.

7.2 Water Line Requirements

- The System's water supply line is factory installed. Do not disconnect from the ultrasonic scaler.
- Incoming water supply line pressure to the ultrasonic scaler must be 20 psi (138 kPa minimum) to 60 psi (414 kPa maximum). If your dental water system's supply line pressure is above 60 psi, install a water pressure regulator on the water supply line to your ultrasonic scaler.
- A manual shut-off valve on the dental water system supply line should be used so that the water can be completely shut-off when the office is unoccupied.
- A filter in the dental water system supply line is recommended so that any particles in the water supply will be trapped before reaching the ultrasonic scaler.
- After the above installations are completed on the dental water supply system, the dental office water line should be thoroughly flushed prior to connection to the System.
- After flushing system verify there are no leaks.

7.3 Electrical Requirements

Refer to Section 3: Specifications.

7.4 Unpacking the System

Carefully unpack your ELiTEDENT® ultrasonic scaler and verify that all components and accessories are included:

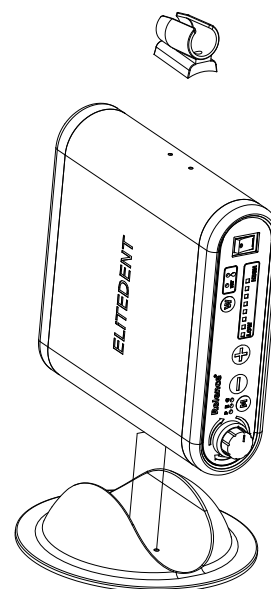
1. ELiTEDENT® Ultrasonic scaler main unit with factory installed water supply line and handpiece tubing with connector.
2. Detachable AC Power Cord.
3. Foot Control Switch.

4. Autoclavable Handpiece
5. Ultrasonic tips and torque wrench.
6. User Direction Manual.

7.5 System Installation

- ELiTEDENT® PS-1/PS-1(LED) is designed for both horizontal and vertical placement on a level surface. Refer to section 7.6 for more detail of vertical installation.
- Be sure unit is stable and resting on four feet.
- Placing unit in direct sunlight may discolor plastic housing.

7.6 Vertical Installation



7.7 Rear Panel Controls / Power Connection

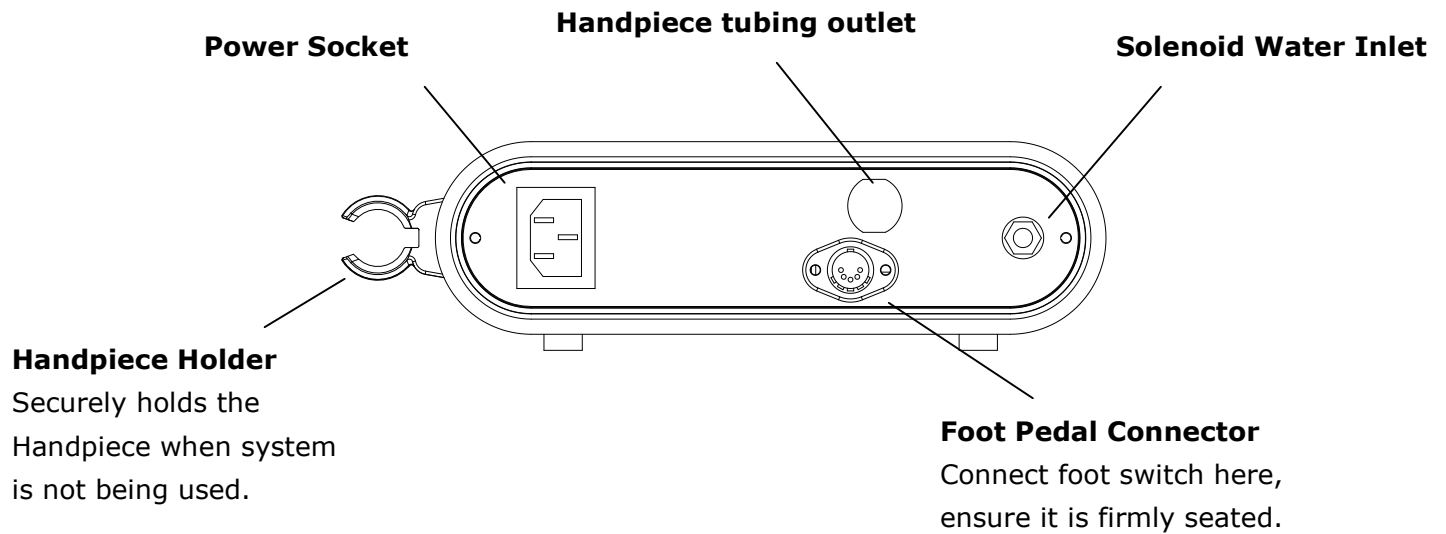
- The ON/OFF Control Switch and power indicator is located on the Front Panel of the ELiTEDENT® Ultrasonic Scaler. (See Section 8.1)
- Verify the ON/OFF Control Switch located on the front panel of the ELiTEDENT® ultrasonic scaler is in the OFF position before proceeding.
- Plug the detachable AC Cord into the back of the ultrasonic scaler and into an approved outlet.

7.8 Water Supply Line Connection

Connect the free end of the ultrasonic scaler's water supply line to the dental water supply line. Inspect all connections to make certain there are no leaks.

Section 8: ELITEDENT® Ultrasonic Scaler Description

8.1 System Controls – Rear Panel



Front Panel

Water Flow Adjustment
Turn knob to select Water Flow level for operation. Clockwise increases water flow, while counterclockwise decreases water flow. The rate of flow through the Hand piece determines the temperature of the water flow. Lower flow rate produces warmer temperature; higher flow rate produces cooler temperature.

Intensity Display

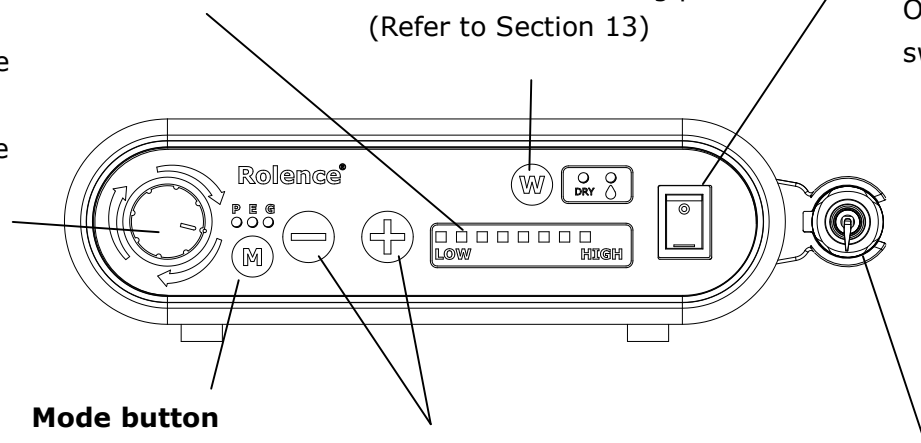
Indicates the power level, total 8 LEDs display.

Water Supply Mode & Auto Cleaning

- . Choose "DRY" mode with no water spray for some special tips or procedures.
- . Press the KEY for 3 seconds to activate Auto Cleaning process. (Refer to Section 13)

Power Switch / AC Power Indicator Light

Illuminates when POWER ON/OFF control switch is on.



Mode button

G: General scaling, Indicator flickers when "Turbo" mode is activated.
E: Endodontic procedures
P: Periodontal procedures

Intensity Control

Increase or decrease power level for operation: "+" increases power, "-" decreases power.

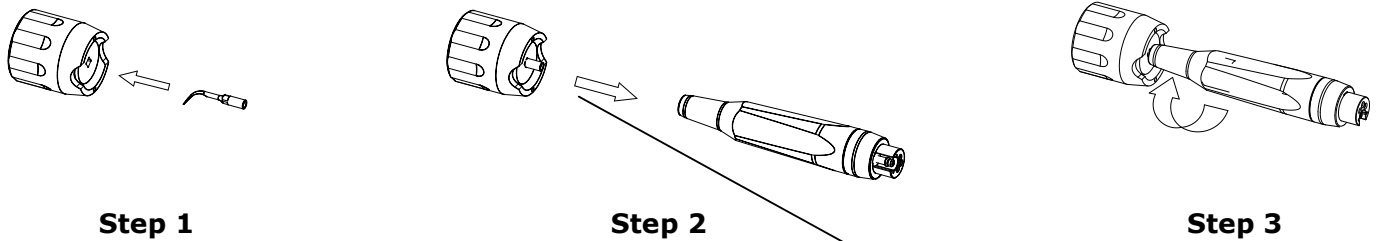
Handpiece

Operates EMS® Ultrasonic tips and transmits power and water flow from the scaler to the instrument.

8.2 Installation of Handpiece and ultrasonic Tips

The ultrasonic scaler is designed working with all EMS® tips. The system will automatically track the working frequency by microcomputer inside, no need to switch any button.

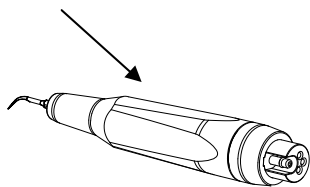
Use torque wrench to mount ultrasonic Tips onto the appropriate handpiece gently. Note: The tip must be screwed and moderately tightened. See below:



For more oral hygiene care, the handpiece can be detached and autoclaved separately. See below:

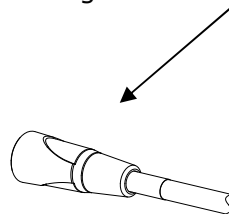
Handpiece

Enable to detach and autoclave



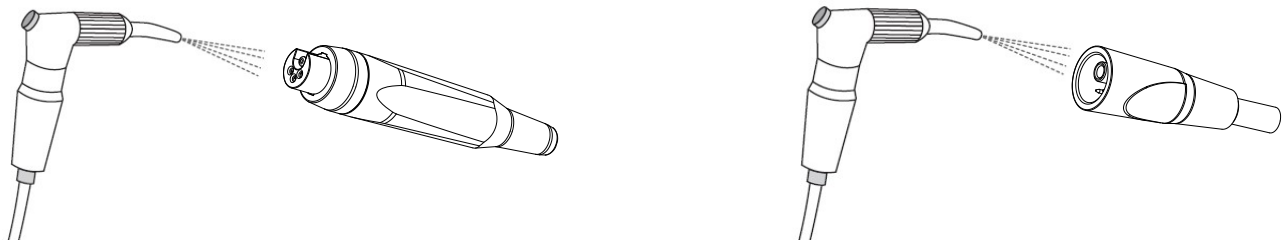
Handpiece Connector assembly

Include handpiece connector and tubing.



Note : Please **DO NOT** use other brands torque wrench. We disclaim the liability for warranty if using another brand of torque wrench and cause damage to the handpiece.

Before connecting the handpiece, blow dry the connections to remove eventual presence of liquid to ensure a proper electrical contact.



9.3 Foot Pedal Controls and Operation

The Foot Pedal is a two-position momentary switch, which activates both Ultrasonic energy and water flow at tip. Turbo function is only available in "G" mode.

| | | |
|--|---|--|
| | | |
| <p>Foot Pedal Released... Both ultrasonic activation and irrigating flow stop.</p> | <p>Foot Pedal Depressed Half Way (1st position)The ultrasonic insert tip is activated and irrigating water flow under normal function.</p> | <p>Foot Pedal fully depressed (2nd position). Indicator flickers. Only available in "G" mode. This activates the "Turbo" mode increasing extra power.</p> |


8.4 Use of Tips


The ultrasonic Tips is for use in dentistry with Rolence® ELITEDENT® Ultrasonic scaler.


Rolence offers 5 different kinds of ultrasonic Tips. The longer and thinner Tips is, the better becomes its access to periodontal pockets and inter-proximal areas. Also, at a constant power setting on the unit, a longer and thinner Tips delivers less clinical power. This means slower concernment removal and less pain for the patient. For gentle treatment, choose a very long and very thin Tips. Only switch to a shorter Tips if a particular treatment situation requires more power than the longer Tips can deliver.

The standard package of ELITEDENT® PS-1/PS-1(LED) ultrasonic scaler includes few tips only. To afford extra tips, please contact Rolence authorized dealer to order.

Before use of the ultrasonic Tips, please read following instruction carefully.

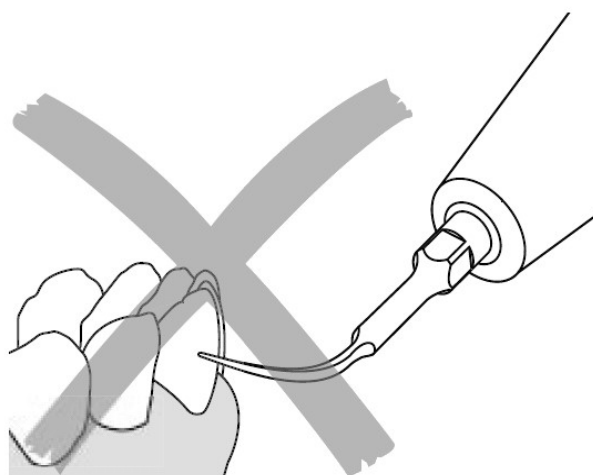
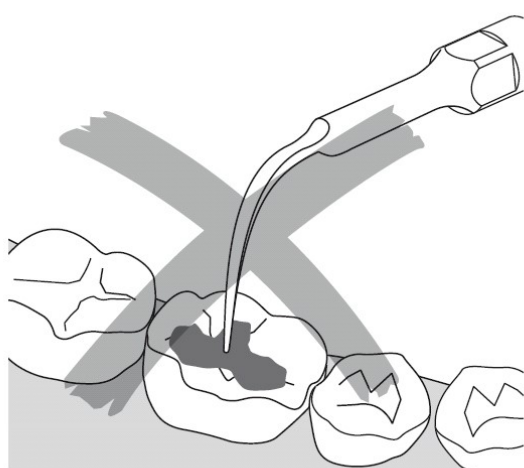
 Before use, always disinfect, clean and sterilize handpieces and Tips. Non-sterile handpieces and Tips may cause bacterial or viral infections.

 To avoid heat damage on the tooth or handpiece, be careful with working dry. The end of the Tips immediately heats up when used dry.

 Always examine your ultrasonic system and Tips for damage before commencing treatment. Damaged accessories or a damaged product must not be used and must be replaced.

Note: Never use the Tips of this system on metal or porcelain restorations. The high frequency ultrasonic oscillations may loosen the restoration.

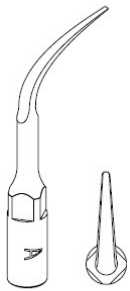
Note: Do not hold the Tips head-on to the enamel. Never direct the end of the Tips vertically or almost vertically to the tooth.



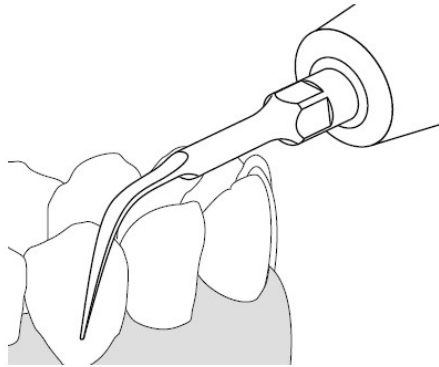
Tips A

Tips A is used for general supragingival deposit removal on all tooth surfaces in all quadrants.

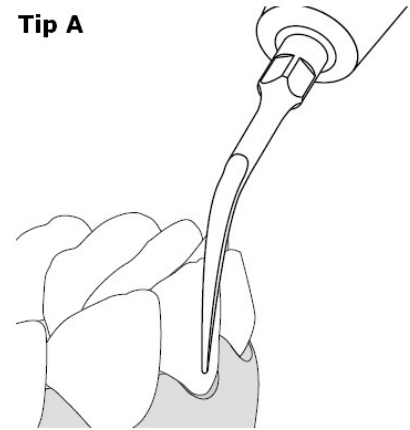
Tip A



Tip A



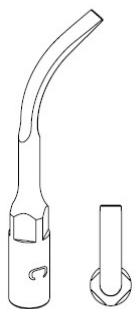
Tip A



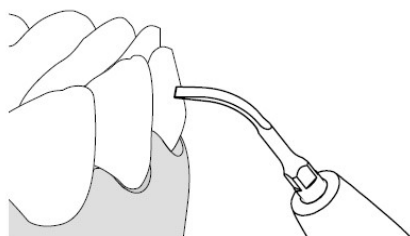
Tips C

Tips C is designed for the removal of heavy deposits on anterior teeth. It can also be used for the removal of orthodontic cements. Unlike other Tips, Tips C may be directed vertically to the tooth surface for optimum efficiency.

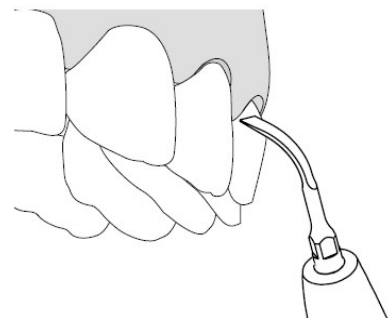
Tip C



Tip C

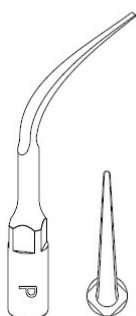


Tip C

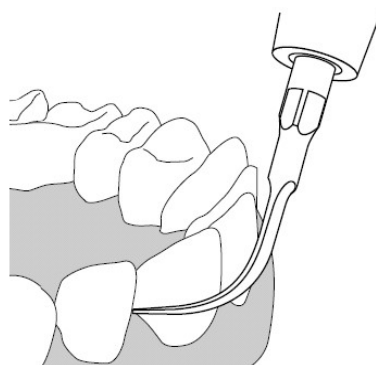


Tips P

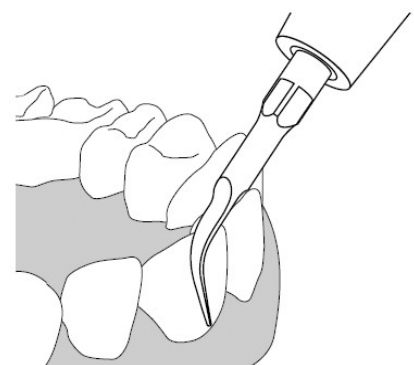
Tips P is designed for general supragingival deposit removal on all tooth surface in all quadrants, including the inter-proximal and sulcus areas.



Tip P



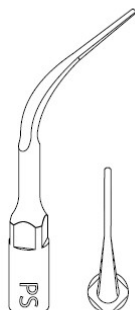
Tip P



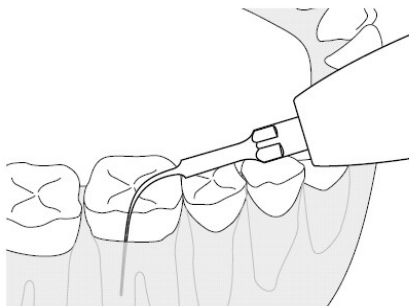
Tips PS

Tips PS is for general subgingival de-deposit removal on all root surfaces and can also be used for supragingival maintenance therapy. It is suitable as well for periodontal pocket irrigation with antimicrobial delivery.

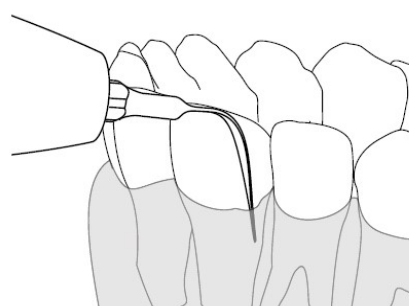
Tip PS



Tip PS



Tip PS



8.5 Scaling tip worn out

When is a scaling tip worn out?

The shape and mass of the individual tips are determining characteristics for achieving maximum ultrasonic generator efficiency. Both characteristics should be monitored in order to maintain the best possible performance of the unit.

Therefore, it is strongly advised not to alter the structure of a scaling tip by filing or bending.

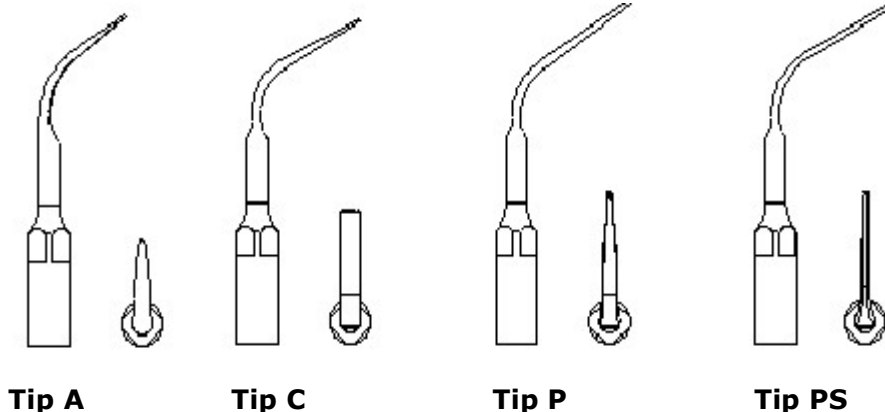
Use the **TIP CARD** coming with tip package to check the wear condition of scaling tips.

Similarly, the ageing of tips due to normal wear results in a change in their characteristics.

Tips damaged as a consequence of wear or accidental impacts (fall, etc.) must be systematically replaced.

Section 9: Accessories

1. PS Sterilizable Handpiece
2. External Power Supply (AC-AC)
3. Foot pedal
4. Water Line Assembly with quick disconnect
5. Torque wrench
6. Ultrasonic tips (Optional): Tip A, C, P, and PS.



Section 10: Techniques For Use

10.1 Patient Positioning

- For optimal access to both the upper and lower arches, the backrest of the chair should be adjusted to a 45° degree angle. This assures patient comfort and Clinician visibility.
- Have the patient turn his/her head to the right or left. Also position chin up or down depending upon the quadrant and surface being treated. Evacuate irrigate using either a saliva ejector or High Volume Evacuator (HVE).

10.2 Performing ultrasonic scaling procedures

- Note: Refer to section 11 for general procedures to be followed at the beginning of each day and between patients.
- The edges of scaling tips are intentionally rounded so there is little danger of tissue laceration with proper ultrasonic scaling technique. Whenever the tip is placed in the patient's mouth, the lips, check and tongue should be retracted to prevent accidental prolonged contact with the activated tip.
- Choose your preferred mode setting and prepare relevant ultrasonic Tips for your practice.
- Autoclave ultrasonic tip and handpiece before use. Fix ultrasonic tip onto handpiece gently. DO NOT FORCE IT INTO PLACE.

- In general, it is suggested a "feather-light-touch" be used both supra and subgingivally. The motion of the activated tip and acoustic effects of the irrigating fluid, in most cases, is adequate to remove even the most tenacious calculus.
- Periodically check the ultrasonic tips for wear with the tip card coming in tip package.
- The use of a saliva ejector or High Volume Evacuator (HVE) is recommended during all procedures.
- If water leakage found in handpiece, check the handpiece and handpiece connector to eliminate.

10.3 Patient Comfort Considerations

Reasons for sensitivity

- Incorrect tip placement. Point should be directed away from root surfaces.
- Not keeping tip in motion on tooth. Do not allow the tip to remain in a static position on any one area of the tooth. Change the tip's path of motion.
- Applying pressure. Use extremely light grasp and pressure, especially on exposed cementum.
- If sensitivity persists, decrease power setting and/or move from the sensitive tooth to another and then return.

Section 11: System Maintenance and Care

Daily Maintenance

It is recommended that you perform the following maintenance procedures to help minimize bio-film formation in the water path of your ELITEDENT® ultrasonic scaler which could affect the water flow to the ultrasonic tips, and scaling performance.

Start-Up Procedures at the beginning of the day:

1. Open the manual shut-off valve on the dental office water supply system.
2. Turn the System ON using the Power ON/OFF switch. (see illustration on page 7) Verify the Power Indicator Light is on.
3. Set the Power Control knob to minimum setting.
4. Set the Water Control knob to maximum.
5. Hold the Handpiece (without Tips installed) upright over a sink or drain. Activate the Foot Pedal and flush the water line for at least 2 minutes.
6. Install a sterilized tip into the Handpiece and set the water control knob to your preferred operating position.

Between Patients:

1. Remove ultrasonic tip and dismantle handpiece used, clean and sterilize.
2. Clean and disinfect the surfaces of the cabinet, Power Cord, Handpiece cable assembly, control knobs, Foot Control and cable assembly by applying an approved non-immersion type disinfectant solution* carefully following the instructions provided by the disinfectant solution manufacturer. To clean system, generously spray disinfectant solution on a clean towel and wipe all surfaces. Discard used towel. To disinfect system, generously spray disinfectant on a clean towel and wipe all surfaces. Allow disinfectant solution to air dry. Do not spray disinfectant solution directly on the ultrasonic scaler.
3. Install a newly sterilized handpiece. Set power to minimum. Hold the handpiece over a sink or drain and flush the water line at maximum water flow

for 30 seconds.

4. When ready, place a sterilized Tips into the handpiece.
5. The handpiece can be autoclaved up to 135°C..

Shut-Down Procedures at the end of the day:

1. Remove ultrasonic Tips and handpiece used, clean and sterilize.
2. Turn the System OFF.
3. Clean and disinfect the surfaces of the cabinet, Power Cord, Handpiece cable assembly, control knobs, Foot Control cable assembly by applying an approved non-immersion type disinfectant solution* carefully following the instructions provided by the disinfectant solution manufacturer. To clean system, generously spray disinfectant solution on a clean towel and wipe all surfaces. Discard used towel. To disinfect system, generously spray disinfectant on a clean towel and wipe all surfaces. Allow disinfectant solution to air dry. Do not spray disinfectant solution directly on the ultrasonic scaler.
4. Close the manual shut-off valve on the dental water supply system.

Sterilizing:

1. Place the handpiece and pouched ultrasonic tips into steam autoclave. After warm-up is completed, operate at a sterilizing temperature and pressure of 273° F/31 psi (134°C/216 kPa) for 12 minutes, followed by a 20-30 minute drying time.
2. Carefully dry the electrical contact of handpiece and cable connector before connecting them.

DO NOT USE Cold sterilization solution.

***Note:** Those water-based disinfection solutions are preferred, due some alcohol-based disinfectant solutions may be harmful and may discolor plastic materials.

Section 12: Trouble shooting

Although service and repair of the ELITEDENT® PS-1/PS-1(LED) Ultrasonic Scaler should be performed by ROLENCE dealer personnel, the following are some basic trouble shooting procedures that will help avoid unnecessary service calls. Generally, check all lines and connections to and from the System, a loose plug or connection will often create problems. Check the settings on the System's knobs.

12.1 Troubleshooting Guide

Problem: System will not operate: (Power Indicator Light is not lit.)

Check that the Power switch is in the ON position, and that the detachable Power Cord is fully seated in the receptacle on back of System.

1. Check that the System's plug is fully seated in an appropriate AC receptacle, and that AC current is present.

(Power Indicator Light is lit.)

1. Check that the Foot Pedal Connector is fully seated in the Foot Pedal Receptacle on the back of the System.

System operates:

(No water flow to the tip.)


1. Assure that water control is properly adjusted.
2. Check that water indicator on front panel is properly chosen.
3. Check that water supply control valve(s) (dental office water supply) are open.


(Tips stops vibrating)


1. Deactivate foot control.
2. Verify ultrasonic Tips is properly installed.
3. Depress foot control to try again.


Section 13: Auto-Cleaning Function

- 1) To activate the Auto-Cleaning procedure, keep pressing the "Water Supply Mode & Auto-Cleaning" KEY for more than 3 seconds. The LED above the "Water Supply Mode & Auto-Cleaning" KEY will start to blink and the water will flush through the main unit to the handpiece. The flushing continues 30 seconds.
- 2) When the Auto-Cleaning is finished, the Main Unit returns to the settings prior to cleaning.
- 3) For emergency cancellation of Auto-Cleaning procedure, you can keep pressing the "Water Supply Mode & Auto-Cleaning" KEY for 3 seconds. The LED blinking and water flushing will stop and return to the setting prior to Auto-Cleaning.

 We suggest users conduct Auto-Cleaning at the beginning of daily start-up procedure, between the patients and at the end of daily operation.

 Prior to conducting the Auto-Cleaning procedure, be sure to remove the tips from the handpiece, turn the water flow adjustment dial to maximum, and put the handpiece into a cup or over a sink because the water will come out from the handpiece.

 Activate Auto-Cleaning without tips and make sure the handpiece and cord are firmly attached.

 The LED above the "Water Supply Mode & Auto-Cleaning" KEY will keep blinking during the flushing procedure.

Section 14: Disposal of Unit

- Keep original packaging until the ELiTEDENT® Ultrasonic Scaler is to be disposed of permanently. You can use it for shipping or storing your ELiTEDENT® Ultrasonic Scaler at any time.
- Dispose of the ELiTEDENT® Ultrasonic Scaler in accordance with local and national laws.

Section 15: Disclaimer

ROLENCE considers itself responsible for the effects on safety, reliability and performance of this product only if:

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by ROLENCE.
- The electrical installation of the relevant room complies with the requirements.
- The equipment is used in accordance with these instructions for use.

Section 16: Warranty

16.1 Malfunction

Rolence hereby warrants that for a period of one year from the delivery date, this device shall be free from defects in material and workmanship. In case the machine is found malfunctioned under normal use, Rolence will offer service of free maintenance and parts for replacement.

16.2 Repair

Repairs must be only carried out by an authorized Rolence engineer/dealer. If repairs during warranty period are not carried out by an authorized engineer/dealer, warranty will expire immediately.










16.3 Warranty Exception

The warranty stated herein is the sole warranty applicable to Rolence products. Rolence expressly disclaims the liability for warranty even within warranty period, if

- (1) Damages caused by natural disaster.
- (2) Operator's fault or wrong operation.
- (3) Application use other than field specified in this instruction.
- (4) A malfunction or damage caused by repair, adjustment, modification which is not carried out by Rolence authorized technicians/dealers.
- (5) A malfunction caused by abnormal power source or voltage.
- (6) It is a consumption part.

(This instruction subjects to change without pre-notice.)

Section 17: Glossary of Symbols

| | |
|---|---|
|  | Attention, Consult accompanying Documents |
|  | Alternating Current |
|  | Power off |
|  | Power on |
|  | Manufacturer |
|  | Type BF Applied Part; Type BF Equipment - Protection against electric shock |
|  | Equipment class: Class II (IEC601-1) - double insulated |
|  | The equipment complies with the requirements in the Medical Device Directive 93/42 EEC. |
|  | Icon to identify electric and electronic devices. The unit must be collected and disposed of separately. |

EU authorized representative name and address



CMC Medical Devices & Drugs S.L
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