Dentsply Sirona

SmartLite Pro EndoActivator™

Endodontic Activation System

Endodontisches Aktivierungssystem
Système d'activation pour traitement endodontique
Sistema di attivazione endodontico
Sistema de Activación de Endodoncia
Endodontisk aktiveringssystem
Endodontisk aktiveringssystem
Endodontisk aktiveringssystem
Endodonttinen aktivointijärjestelmä
Endodontický aktivační systém
Endodontiline aktiveerimissüsteem
Σύστημα Ενδοδοντικής Ενεργοποίησης
Gyökérkezelő aktiváló rendszer
Endodontiskā aktivizācijas sistēma
Endoaktyvatoriaus sistema
Sistema de ativação dos irrigantes endodônticos
Sistema de Ativação Endodôntica
Sistem de activare endodontică
Endodontický aktivačný systém
Endodontik Aktivasyon Sistemi

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SmartLite Pro EndoActivator™

Endodontic Activation System

Sonic activation for cleaning and disinfection during endodontic treatment

CAUTION: For dental use only.
USA RX Only.

CONTENT

1. PRODUCT DESCRIPTION

The SmartLite Pro EndoActivator™ Endodontic Activation System is used in endodontic treatment by application of sonic energy. The SmartLite Pro EndoActivator™ Activator Tips tips are used in conjunction with the SmartLite Pro EndoActivator™ Attachment mounted on the SmartLite Pro EndoActivator™ handpiece to provide the energy for tip oscillation and vibration. Evidence-based endodontics has shown that cavitation and acoustic streaming improve debridement and the disruption of the smear layer and biofilm.
Activated fluids promote deep cleaning and disinfection into lateral canals, fins, webs and anastomoses. A cleaned root canal system facilitates 3-D obturation and long-term success. The EndoActivator Attachment mounted on the SmartLite Pro EndoActivator™ handpiece is a cordless pen-style, oscillating energy device for use by dental professionals in dental offices or dental laboratories.

SmartLite Pro EndoActivator™ system is characterized by:

- Small size and lightweight ergonomic design.
- Compact cordless design with convenient handling features and exchangeable batteries.
- Individually adjustable EndoActivator Attachment, rotatable by 360°.
- EndoActivator Attachment design providing excellent intra-oral access.
- Up to 5 minutes of oscillation time per activation with audible signals at start and every 30 seconds of use.

1.1 Indications

Intracanal activation of irrigating fluids used for cleaning and disinfecting root canals.

1.2 Contraindications

None Known.

1.3 Delivery Forms Some delivery forms may not be available in all countries.
PRODUCT CONTENTS LIST (Note: See catalog for detailed Kit contents)
- 1x SmartLite Pro® handpiece
- 1x EndoActivator Attachment
- 2x Batteries
- 1x Charging Base
- 1x Accessories Box containing:
  Power Connector
  AU, EU, US, UK Plug Adapters
  USB Cable
- 1x IFU
- 1x Technique Guide
- 1x SmartLite Pro EndoActivator™ Barrier Sleeves (100/pack)
- 1x Activator Tips (25/pack) - Small (15/02) 22mm
- 1x Activator Tips (25/pack) - Medium (25/04) 22mm
- 1x Activator Tips (25/pack) - Medium Long (25/04) 28mm

1.4 Compatible Materials
The SmartLite Pro EndoActivator™ System is designed to be used in conjunction with endodontic irrigation solutions such as sodium hypochlorite and EDTA.

2. SAFETY NOTES
Be aware of the following general safety notes and the special safety notes in other chapters of these Instructions for Use.

Safety alert symbol
This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings
Never modify any component of the SmartLite Pro EndoActivator™ System. Any modification may compromise safety and effectiveness.

2.1.1 SmartLite Pro® Handpiece

WARNING: This product can expose you to chemicals including Di-isononylphthalate (DINP), which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.
- Do not use a damaged device.
- Do not autoclave.
- Do not submerge in any liquid or chemical.
- Only authorized technicians should repair the handpiece or battery pack.
- Persons fitted with cardiac pacemakers, defibrillators and other active implanted medical devices, have been cautioned that some types of electronic equipment might interfere with the operation of the device. Although no instance of interference has ever been reported to Dentsply Sirona, we recommend that the handpiece and cables be kept at least 6 to 9 inches (15 to 23cm) away from any device and their leads during use.
- There are a variety of pacemakers and other medically implanted devices on the market. Clinicians should contact the device manufacturer or the patient's physician for specific recommendations. This unit complies with IEC 60601 Medical Device Standards.

2.1.2 Charging Base

WARNING: This product can expose you to chemicals including Bisphenol-A (BPA), which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.
- Low voltages are present inside the charging base (5 V DC). Use only under dry conditions. Do not use if the charging base or handpiece is wet. Avoid short circuit between contact pads on the charging base. Only authorized technicians should repair the charging base.
- Do not use for voltages different from the range indicated on the charging base and power adapter.

- Note: Unplug power connector from power source before disconnecting power connector from the charging base.
- Always make sure the charging base is placed offside the dental unit and only touched with clean/disinfected gloves to prevent from exposure to spatter or spray of body fluids.
- Always make sure handpiece, attachment, and battery pack are completely reprocessed and thoroughly dry before inserting it into the charging base or attaching the attachment to the handpiece.

2.1.3 Battery Pack

- Prevent battery from short circuit during use and storage.
- Keep electrical contacts clean and dry.
- Do not remove battery pack from hand piece during operation.

2.1.4 EndoActivator Attachment

- Do not autoclave.
- Do not submerge in any liquid or chemical.
- Do not attempt to use EndoActivator Attachment with any instrument other than designated EndoActivator Activator Tips. Instability and tip dislodgement may occur. Detached parts may be aspirated, ingested or cause soft tissue injury. To reduce risk, use of a rubber dam is strongly recommended.
- Aspiration: Seek appropriate medical attention.
- Ingestion: If accidental swallowing occurs, drink lots of water. If nausea or illness develop, seek medical attention immediately.
- Do not use the device as a tissue retractor or apply lateral force as this may damage the connection between attachment and handpiece.

2.1.5 EndoActivator Activator Tips

- Product is required to be disinfected prior to use. See detailed Instructions.
- Use only new, clean unused activator tips, removed from their original packaging at time of use. To reduce risk of infection, do not use activator tips if packaging is damaged or compromised.
- Ensure activator tip is fully inserted onto EndoActivator Attachment over barrier sleeve. Use of activator tip incompletely attached or with excessive lateral pressure may dislodge the tip from the attachment. Tip may be aspirated, ingested or cause soft tissue injury. To reduce risk, use of a rubber dam is strongly recommended.
  - Aspiration: Seek appropriate medical attention.
  - Ingestion: If accidental swallowing occurs, drink lots of water. If nausea or illness develop, seek medical attention immediately.
- Avoid operating activator tip within 2mm of apex or if incomplete or open apex is suspected to prevent tissue damage from irrigant. If accidental extrusion occurs, follow irrigant manufacturer's instructions for use. If symptoms persist, seek medical attention.
- Avoid operating activator tip without irrigant to prevent debris accumulation and possible infection. Re-instrument and re-irrigate to ensure complete debridement. If symptoms develop, provide remedial treatment.
- Avoid allowing tip to extend beyond apex to prevent bacterial contamination to periradicular tissue. If accidental placement occurs, thoroughly irrigate and reconfirm working length. If symptoms develop, provide remedial treatment.
- Care should be taken to have good control on any rotary or oscillating instrument to protect patients from injury. Contact with soft tissues (skin, gingiva, mucosa) may result in injury to the tissue. If contact occurs, thoroughly wash the affected area with water and seek appropriate medical attention.
- Used activator tips are contaminated. Follow proper exposure control plans. In the event of an accidental exposure, follow recommended post-exposure procedures. Following use of the activator tip, proper handling and disposal techniques are required. Used activator tips are contaminated and sharp. When handling or disposing, use precautions as when handling or disposing other contaminated sharps.
- Do not autoclave activator tips. Autoclaving may increase risk of tip fracture.

2.1.6 Transport

- Intact devices can be transported by land freight or air freight in the original packaging. The applicable requirements must be met (see table below).
- Defective devices can also be transported by air freight or land freight in the original packaging. If the battery is defective, the device must not be transported by air freight under any circumstances.
- Leaking liquid can be an indicator of a defective battery.

Standards and regulations that apply to the transport of SmartLite Pro® system

- For international shipping of lithium-ion batteries, refer to the International Air Transport Association (IATA) guidelines, located at http://www.iata.org/lithiumbatteries.
- For shipping of lithium-ion batteries within the United States, refer to the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) site at http://www.phmsa.dot.gov/hazmat/ guidance.

	Air Freight	Land Freight
Intact device or defective device with intact battery	• UN 3481 Lithium batteries in equipment • IATA Packing instruction 967 Part II • Special regulations issued by airlines and national regulations must be complied with	• UN 3481 Lithium batteries in equipment • ADR Special provisions 188 f) and g)
Device with defective battery	Not possible	• International, multilateral agreements M 228 and M 259 • ADR SV 661 (international, road) • Regulations issued by GRS (German Joint Battery Takeback System Foundation) for the transport of waste lithium batteries (FRG, road)

2.2 Precautions

This product is intended to be used only as specifically outlined in these Instructions for Use. Any use of this product inconsistent with these Instructions for Use is at the discretion and sole responsibility of the dental practitioner.

- Do not use a handpiece and attachment which has not been properly processed. Protect the handpiece and attachment from gross contamination by applying the single-use, FDA-cleared SmartLite Pro EndoActivator™ Barrier Sleeve. Barrier sleeves are non-sterile and intended for single-use only. Discard after use. Do not reuse sleeves in other patients in order to prevent cross-contamination.
- Do not attempt to negotiate or force tip into strongly curved canals to their full working length. Tip fracture may occur. Do not bend the tip excessively to avoid motor stalling or obstructing tip oscillation.
- Do not remove the tip from the root canal while still oscillating to avoid splashing of liquid.
- Do not apply the barrier sleeve too tightly over the attachment head to avoid motor stalling or obstructing tip oscillation. Briefly check proper tip operation outside the patient`s mouth before intraoral use.
- Use only Dentsply Sirona supplied power supply, power cord, charging base and battery. Use of any accessories other than specified in this Instructions for Use may result in damage to the handpiece and its components as well as unpredictable performance.
- Do not use adjacent to or stacked on other equipment. If adjacent or stacked use is necessary, closely watch system and its components to verify normal operation in this configuration.
- Do not autoclave the handpiece, attachment or activator tips. Sterilizing will cause component damage and may cause bodily injury.
- Barrier sleeves and activator tips are designed for single use only. The barrier sleeves are ready for use. Do not attempt to reprocess for reuse.
- Stabilize attachment head when attaching or removing activator tip to limit lateral force applied to handpiece connection. Excessive force may damage the connection between attachment and handpiece.
- Do not remove the attachment from handpiece by pulling from the top. Remove the attachment from the handpiece by grasping firmly at the base and pulling.

- It is the responsibility of the Healthcare Professional to determine the appropriate uses of this product and to understand:
  - The health of each patient
  - The dental procedures being undertaken
  - Applicable industry and governmental agency recommendations for infection control in dental healthcare settings
  - Requirements and regulations for safe practice of dentistry
  - These Instructions for Use in their entirety.
- Failure to follow recommendations for environmental operating conditions (see section 6.3) could result in injury to patients or users.
- Inspect equipment before each use for worn, loose or damaged parts.
- There are no user serviceable parts except the O-ring attached to the coupling end of the attachment. Opening any of the components may result in unsafe operation and will void the warranty.
- According to IEC60601-1, this device must not be used in the presence of a flammable anesthetic gas mixed with air, oxygen or nitrous oxide. (Note: nitrous oxide by itself is not a flammable anesthetic gas).
- User should not touch the patient and accessible charging base contacts or USB contact simultaneously.
- Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
- Devices marked "single-use" on the labeling are intended for single-use only. Discard after use. Do not reuse in other patients in order to prevent cross contamination.
- As a precautionary measure the handpiece and attachment may be protected from gross debris, but not all contamination, by applying a protective barrier sleeve. Reprocess reusable components after each use according to instructions.
- Do not spray disinfectant or other fluid directly onto the handpiece, attachment, battery, charging base, power supply or cord. The user should spray solution onto a cloth or use a wipe to disinfect items per instructions in Section 4.
- Prevent liquids from entering the handpiece, battery pack, and charging base.
- Ensure the battery contacts are fully dry before charging batteries or attaching batteries into the handpiece to prevent corrosion. Similarly, ensure that the contacts on the attachment are fully dry before attaching to the handpiece body.
- Do not place the system on or next to a radiator or other heat source. Excessive heat may damage the system's electronics.

Interactions
None Known.

2.3 Adverse Reactions
None Known.

2.4 Storage Conditions
Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.
- Store at temperatures between -5°C/35°C (23°F/95°F).
- Use the product at room temperature.
- Protect from moisture.
- Store at relative humidity range <75% (non-condensing).
- Do not use after expiration date.

3. STEP-BY-STEP INSTRUCTIONS

SmartLite Pro EndoActivator™ – Operation at a glance

ON/OFF button
First Button Press – Turns the unit On and starts the activation of the activator tip
Second Button Press – Reduces the speed of the activator tip
Third Button Press – Turns the unit Off.

Indicator lights

ON/OFF button light

- **Slowly flashing orange** handpiece battery has low power and must be exchanged soon
- **Fast flashing orange** handpiece battery is empty and must be exchanged to continue to operate
- **Solid orange** unit is in an overheating protection state and can't be operated until light turns off.

Light adjacent charging port (NOTE: no light with battery on top indicates missing contact)

- **Solid orange** battery is charging
- **Solid green** battery is fully charged.

Audible signals

- **One short beep:** battery or attachment insertion into handpiece
- **One beep:** start of cycle, interrupt, every 30 seconds of usage, or end of cycle
- **Two beeps:** warning (i.e. attachment is not connected)
- **Four beeps:** overheating protection.

Signal Condition	EndoActivator Attachment	
	Beep	Signal LED
Battery Insertion	1x	-
Start Cycle	1x	-
Second power level	1x	-
Stop cycle manually	1x	-
End of cycle	1x	-
Warnings (i.e. attachment not connected)	2x	-
Low battery	-	blinking
Empty battery	-	blinking fast
Overheating protection	4x	continuous

3.1 Installation and charging

1. Insert battery pack into handpiece. Battery pack is pre-charged however, it may be necessary to charge the battery before first use.
2. To recharge the battery:
   - Connect charging base to USB mini connector.
   - Make sure power socket used for power connector is accessible at all times in case of necessary emergency disconnection.
   - Insert the battery onto the charging base. The battery light will illuminate solid orange, indicating battery is recharging and will show constant green when fully charged.

Note, the SmartLite Pro EndoActivator™ Complete Kit comes with two batteries. It is recommended that the battery not being used is stored on the charging base so that it is fully charged when needed.

3.2 Operation – EndoActivator Attachment Assembly

1. Attach the EndoActivator Attachment to the SmartLite Pro® handpiece by firmly pressing attachment into handpiece opening while slightly rotating at the same moment.
2. Protect assembled handpiece and attachment from gross debris by applying a single-use barrier sleeve.

To reduce the risk of cross-contamination

- Ensure the disposable polyethylene barrier protection sleeve has been correctly applied over the entirety of the attachment and handpiece before beginning a procedure.
- The polyethylene barrier sleeve does not replace cleaning and disinfection of the dental instruments. Please clean and reprocess dental instruments after each patient as described in Section 4, Hygiene and Disposal.
- Do not apply the SmartLite Pro EndoActivator™ barrier sleeve too tightly over the attachment head to avoid motor stalling or obstructing tip oscillation. Briefly check proper tip operation outside the patient`s mouth before intraoral use.

3.3 Operation – Activator Tip Selection

1. Prepare canal to produce a fully tapered shape.
2. Select the activator tip that manually fits loosely within 2mm of working length. See size chart below.

To reduce risk of tissue damage due to extrusion of irrigant

- Only operate the tip 2mm or more from working length or apex.
- Small and Medium (22mm) tips are marked with depth gauge rings at 18, 19 and 20mm.
- Medium Long (28mm) tip is marked with depth gauge rings at 18, 19, 20, 24, 25 and 26mm.
- Avoid use when apex is incomplete or open.

Tip Size	Length	Tip Diameter	Taper
Small	22mm	0.15mm	15.02
Medium	22mm	0.25mm	25.04
Medium Long	28mm	0.25mm	25.04

3. With clean/disinfected gloves, select a new, unused activator tip. Ensure tip is in the original, undamaged packaging. If packaging is damaged or unsealed, do not use the contaminated activator tip.

To reduce the risk of cross-contamination

- Ensure the activator tip is in the original, undamaged packaging.
- If packaging is damaged, dispose of activator tip and damaged packaging according to local regulations.
- Dispensing materials with clean/disinfected gloves in a separate room, bringing only what will be used into the operatory is strongly recommended.
- Prior to use, process tips as described in Section 4, Hygiene and Disposal.

4. Completely peel off the seal from the blister back. Use sterile college pliers or adequate forceps to grab the activator tip at the colored shaft and remove from its packaging away from the patient field. Prior to use, follow the Processing Instructions for activator tips.
5. While holding the handpiece in one hand and stabilizing the head of the attachment with the thumb, attach the activator tip over the barrier sleeve in place protecting the assembled attachment and handpiece. The activator should snap on firmly, promoting a secure connection with the attachment.

Small parts - To reduce the risk of inhalation or aspiration

- Ensure activator tip is firmly attached.
- Do not use with lateral pressure.
- Do not use with instruments other than designated activator tips.
- Rubber dam isolation is strongly recommended.

6 Adjust the EndoActivator Attachment: The attachment is rotatable by 360°, thus the position of activator tip may be individually adjusted.

3.4 Operation – Activation

1. Fill pulp chamber with NaOCl, EDTA, or other irrigant solution.

To reduce risk of infection

- Only operate the tip no closer than 2mm of working length or apex.
- Small and Medium (22mm) tips are marked with depth gauge rings at 18, 19 and 20mm.
- Medium Long (28mm) tip is marked with depth gauge rings at 18, 19, 20, 24, 25 and 26mm.
- Avoid use without irrigation solution.

2. Place the attached activator tip into the prepared root canal.

To reduce risk of tissue damage due to extrusion of irrigant

- To avoid motor stalling, place the activator tip freely in the coronal third of the canal before activation.
- Only operate the tip no closer than 2mm of working length or apex.
- Small and Medium (22mm) tips are marked with depth gauge rings at 18, 19 and 20mm.
- Medium Long (28mm) tip is marked with depth gauge rings at 18, 19, 20, 24, 25 and 26mm.
- Avoid use when apex is incomplete or open.

3. Depress the ON/OFF button to activate. Note: button defaults to high speed upon activation. Depress the ON/OFF button again to switch to low speed.
4. Use a pumping action to move the activator tip in short 2-3mm vertical strokes.
5. Hydrodynamically agitate the intracanal solution for 30-60 seconds.
6. Depress the ON/OFF button either twice (at high speed level) or once (at low speed level) to switch off before retracting from root canal.
7. Irrigate, then use intracanal suction to eliminate loose debris.
8. Repeat the above steps for each intracanal irrigant used.
9. Do not remove the activator tip from the root canal while still oscillating to avoid splashing of liquid.
10. When the clinical procedure has been completed, remove the attached activator tip by grasping the large circular clean guard portion of the attached activator tip with fingers and snap off while securely holding the attachment close to the head to avoid bending forces towards the handpiece connecting area.
    Activator tips are intended for single-patient use only. Dispose of according to local regulations.
11. Clean, disinfect, and prepare contaminated handpiece and attachment for reuse according to section 4, Hygiene and Disposal.
    Barrier sleeves are intended for single-patient use only. Dispose of according to local regulations.

4. HYGIENE AND DISPOSAL

To reduce the risk of cross-contamination infection

- Do not reuse single-use products. Dispose of in accordance with local regulations.
- The barrier sleeve is designed for single-use and must be disposed of after each use in accordance with local regulations. The barrier sleeve is not a replacement for cleaning, disinfection, and sterilization.
- The activator tip is designed for single-use and must be disposed of with contaminated sharps after each use in accordance with local regulations.
- Reprocess reusable products as described below.

4.1 Activator Tip

Processing Instructions for Activator Tip	
Warnings	• Follow proper infection prevention activities, such as proper hand washing and donning new gloves at pertinent steps. • Use only the recommended validated processing procedure. • Do not autoclave prior use. Autoclaving may increase risk of activator tip fracture.
Limitations on reprocessing	• Activator Tips are not validated for use in automated washer disinfectors. • Intended for single-use only. • Use of the device beyond its useful life may cause damage to the device and increases the risk of patient cross-contamination. • Use of autoclave or steam sterilization is not recommended. • Chemical vapor sterilization and dry heat sterilization methods have not been tested or validated for efficacy and are not recommended for use.
Initial treatment at the point of use	Imediately after use, it is recommended that the activator tips be removed from the attachment and discarded according to local regulations.
Preparation before cleaning/ disinfection	Wear clean gloves prior to handling and disinfecting.
Cleaning: Mechanical	Activator tips are not validated for ultrasonic cleaning.
Cleaning and Disinfection: Manual	Cleaning • Cleaning is not needed prior use. Disinfection by Immersion and Wiping • The recommended disinfectant solution is 5.25% Sodium Hypochlorite solution (bleach) and wiping with 70% Isopropyl Alcohol (IPA). • Disinfect the activator tips by fully immersing in a bath of 5.25% Sodium Hypochlorite solution for one minute. Gently wipe the activator tips with a sterile gauze moistened by 70% Isopropyl Alcohol. Air dry the activator tips until completely free from moisture. Do not use disinfecting solutions containing Phenol or any products which are not compatible with the treated filling material.
Cleaning and Disinfection: Automated	Activator tips are not validated for automated immersion disinfection.
Drying	The drying instructions are incorporated in the disinfection section above.
Maintenance, Inspection and Testing	Visually inspect the device for any damage prior processing. If the device is fractured, cracked, distorted, etc., discard and do not use.
Packaging	Ensure that the blister packaging for the individual activator tips is not damaged before use.
Sterilization / Steam autoclaving	Do not subject to steam sterilization. Material cannot tolerate autoclaving and may result in degradation.
Storage	• Store at room temperature, away from moisture or excessive humidity. • Keep away from sunlight and heat. • Use the product at room temperature. • To prevent contamination, store processed device in covered storage such as a drawer or cabinet until use.
Additional Information	Prior to use, inspect the device. Discard any device which has become damaged or compromised.
Manufacturer Contact	Within the United States, call Dentsply Sirona at 1-844-848-0137. For areas outside the United States, contact your local Dentsply Sirona representative.

4.2 Handpiece, Attachment, Charging Base

To reduce the risk of Electrical short-circuit or dangerous malfunction
Injury
- Safeguard handpiece against liquid penetration during cleaning and disinfection.

NOTICE
Wrong cleaning or disinfection method
To reduce the risk of damage to components
- Follow Instructions Below.

Instructions for Cleaning and Disinfecting Handpiece, Attachment, Charging Base	
Warnings	• The handpiece, attachment and charging base are not sterilizable by autoclave. • The system components cannot tolerate high-level disinfection procedures. Intermediate-level disinfection is appropriate for the handpiece, attachment and charging base. • Do not autoclave in steam autoclave. • Do not clean/disinfect in automated washer/disinfector. • Do not immerse in liquid. • Do not clean or disinfect with chlorine bleach/sodium hypochlorite (corrosion of contacts) or Lysol® Brand I.C.™ Disinfectant Spray (cracking of charging base). • Disconnect the power supply plug from the power outlet and charging base unit prior to cleaning/disinfection.
Limitations on reprocessing	• Repeated reprocessing has minimum effect on these instruments. End of life is normally determined by wear and damage due to use. • Cold liquid immersion disinfection/sterilization, chemical vapor sterilization and dry heat sterilization methods have not been tested or validated for efficacy and are not recommended for use.
Initial treatment at the point of use	• Remove barrier sleeve and discard according to local regulations. • Use a new, clean pair of examination gloves. • Do not disassemble attachment from handpiece at point of use. • Wipe vigorously with disposable cloth / paper wipe in combination with an alcohol-based, tuberculocidal, quaternary ammonium solution with a label claim for cleaning. • Remove all visible soil, ensuring fluid penetrates all crevices. Use fresh wipes to rub fluid into the crevices. Do not allow solution to penetrate the casing. Discard used wipes. Additional wipes may be used. • Do not remove battery pack from handpiece. Do not attempt disassembly of charging base. • It is recommended that the device be reprocessed as soon as is reasonably practical following use. • Start reprocessing within 1 hour after use. • Charging base should be reprocessed as soon as reasonably practical after being exposed to spatter or spray of body fluids or touched by contaminated hands or contaminated handpiece.
Preparation before cleaning	Always disassemble attachment from handpiece before processing. Use moderate force to pull the attachment from the handpiece.
Cleaning and Disinfection: Automated	Do not use automated washer/disinfectors for reprocessing system components. Component damage will occur.
Cleaning: Mechanical	Cleaning by Immersion N/A – No validated processes. Do not subject components to immersion. Component damage will occur.

Cleaning and Disinfection: Manual	**Cleaning** The handpiece, attachment and charging base have to be manually cleaned. 1. Discard used gloves according to local regulations. 2. Disinfect hands with an appropriate bactericidal, virucidal and fungicidal hand disinfectant solution according to local regulations. Use according to disinfectant solution manufacturer's Instructions for Use. 3. Use a new clean pair of examination gloves. 4. Disassemble attachment from handpiece. Use separate wipes for attachment and handpiece. 5. Scrub handpiece, attachment and charging base with an impregnated wipe or disposable towel soaked with an alcohol-based, tuberculocidal, quaternary ammonium solution with a label claim for cleaning, approved according to local regulations and use according to cleaning solution manufacturer's Instructions for Use until it is free of visible residues. 6. Special Note: Use care when cleaning the mating surfaces of the attachment and handpiece. Use only a moist impregnated towel. • For the attachment: Vigorously scrub the area near the o-ring with a fresh wipe. Ensure fluid covers o-ring and surrounding crevices. When cleaning the mating surface, ensure that cleaning agent only contacts the sides that fit within the handpiece (with o-ring). Avoid applying cleaning agent to the electrical contacts on the bottom of the attachment. • For the handpiece mating cavity: Use a fresh wipe to clean mating groove directly below the surface. Use care to ensure cleaning agent is applied only to the top of the cavity interior. Ensure only minimal cleaning agent enters the cavity that houses the electrical pins. Do not allow fluid to pool in the cavity around the contact pins. Immediately absorb excess fluid with a dry disposable towel. • For the battery and handpiece mating seam: Use a fresh wipe to clean mating groove. • Remove all visible soil, ensuring fluid penetrates all crevices. Use fresh wipes to rub fluid into the crevices. Do not allow solution to penetrate the casing. Discard used wipes. Additional wipes may be used. 7. Remove cleaning solution residue with a damp cloth. Use tap water to dampen cloth. 8. Allow the devices to air dry for at least 5 minutes.
Cleaning and Disinfection: Manual	**Disinfection** 1. After cleaning, wipe all device surfaces with a new single-use cloth in combination with an alcohol-based, tuberculocidal, quaternary ammonium solution, approved according to local regulations and use according to disinfectant solution manufacturer`s Instruction for Use. Use a separate wipe for attachment and handpiece. Ensure direct contact of device and disinfectant by pressing the wet wipes on the device after half of the required contact time. 2. Ensure that the device stays wet for the entire contact time specified by wrapping wipes around device. Use additional wipes as needed. 3. Pay special attention to seams, areas around buttons, window and crevices. 4. Use fresh wipes to disinfect the attachment o-ring area, handpiece mating cavity and battery/handpiece mating seam for the entire contact time. Use care to ensure cleaning agent is applied only to the top of the cavity interior. Ensure only minimal cleaning agent enters the cavity that houses the electrical pins. Immediately absorb excess fluid with a dry disposable towel. 5. Wipe the devices with a sterile, clean, lint-free cloth that is well dampened with deionized water for 30 seconds to remove all disinfecting agent. Pay special attention to all seams, especially around the attachment/handpiece junction. Ensure cloth is damp with deionized water for the entire 30 seconds. Discard used cloth and repeat rinsing with a new, second dampened cloth for 30 seconds. Discard second cloth and rinse with a new, third dampened cloth for a final 30 seconds. 6. Wipe device with a fourth dry, sterile lint-free cloth to remove all fluid. 7. Allow the devices to air dry for at least 5 minutes.
Drying	Wipe the devices dry with a sterile, clean, lint-free cloth. Allow the components to fully air dry before storage.
Maintenance, Inspection and Testing	• Visually inspect to ensure that all contamination has been removed. • Visually inspect power supply and cord for damage. • Components that are damaged, worn, or distorted such as the o-rings should be discarded and replaced. • See maintenance section below for additional recommended maintenance and testing.

Packaging	No particular requirements.
Sterilization	• N/A Sterilization is not allowed. No methods have been validated. Do not subject components to steam autoclaving or liquid chemical sterilant immersion. Component damage will occur.
Storage	Store the handpiece, attachment and charging base at room temperature, away from moisture or excessive humidity.
Additional Information	Reassemble for use as described above in step-by-step instructions.
Manufacturer Contact	Within the United States, call Dentsply Sirona at 1-844-848-0137. For areas outside the United States, contact your local Dentsply Sirona representative.
The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.	

Incidental surface contact of the power supply and cord with water, soap or a water-based hospital-level disinfection solution will not damage the material of construction. Do not allow any solution to penetrate the casing.

4.3 Disposal of Unit

This device is provided with a lithium-ion phosphate battery. Device and battery must not be disposed of in normal domestic waste. For environmental reasons, dispose of device and battery according to local environmental guidelines or regulations.

5. MAINTENANCE

5.1 Battery

- Batteries are equipped with low self-discharge technology resulting in a long operating life.
- Batteries are pre-charged and ready to use upon purchase, however, charging before the first use is recommended.
- When the battery light shows **solid orange** the battery is charging. Upon complete recharging, the battery light remains permanently **green**. The battery needs approximately 2 hours to be fully recharged.
- When the ON-OFF button light **slowly flashes orange** the battery needs to be recharged. At first occurrence approximately 10-20 cycles remain. Sonic activation energy is not reduced during this period.
- If the battery pack needs to be replaced, simply pull the battery pack by pulling it from the main housing along its longitudinal axis.

5.2 General maintenance

- A thin coating of petroleum jelly may be applied to attachment o-rings and charging base battery post as needed to facilitate insertion and removal.
- Inspect and replace worn or damaged o-rings as needed to maintain optimal performance.

6. REORDER INFORMATION, TECHNICAL DATA, WARRANTY TERMS, CORRESPONDENCE

6.1 Accessories

Accessory	Reorder no.
SmartLite Pro EndoActivator™ Barrier Sleeves	644434
SmartLite Pro EndoActivator™ Activator Tips - Small (25/pack)	644435
SmartLite Pro EndoActivator™ Activator Tips - Medium (25/pack)	644436
SmartLite Pro EndoActivator™ Activator Tips - Medium Long (25/pack)	644437
SmartLite Pro EndoActivator™ Attachment	644438
SmartLite Pro® Battery	644401
SmartLite Pro® O-Rings (3/pack)	644408

6.2 Serial number

The handpiece, battery packs, charging base and attachment have different serial numbers.

The serial number ([SN]) should be quoted in all correspondence which requires identification of the product. XXXXX = 00001 through 99999 as marked on the component.

Serial number format SmartLite Pro EndoActivator™ Complete Kit	HXXXXX
Serial number format SmartLite Pro® Charging Base	CXXXXX
Serial number format SmartLite Pro EndoActivator™	AXXXXX

6.3 Technical Specifications

AC supply connection:	100V – 240V / - 50 - 60Hz
Charging Base Power input:	5V, 1A
Operation:	Ambient temperature: Between 0°C and +45°C (32°F and 113°F) Relative humidity: Between 20% and 90%
Storage:	Ambient temperature: Between -5°C and +35°C (23°F and 95°F) Relative humidity: <75% (non-condensing)
Transport:	Ambient temperature: Between -10°C and +50°C (14°F and 122°F)
Battery performance:	• Battery is pre-charged however, charging is recommended prior to first use • Time for battery recharge: Approximately 2 hours • 3.2V, 600 mAh
Battery over current/ temperature protection:	Resettable fuse
Average oscillation frequency:	*EndoActivator Attachment:* Approximate frequency X cps
Unit handpiece dimensions (with battery and EndoActivator Attachment):	EndoActivator Attachment Length: 19cm Width: 1.5cm
Unit weight:	SmartLite Pro® handpiece with EndoActivator Attachment and battery pack: 91 grams Charging base with power connector: 375 grams
Applied Parts	Attachment, Activator Tips, Barrier Sleeve

6.4 Classifications

Type of protection against electric shock	Class II
Degree of protection against electric shock	Type B Applied Part
Mode of operation for handpiece	Operating high speed, low speed, off
Settings for Handpiece	1 (On/Off)
According to medical device directive:	I (Rule 12) (IEC 60601) UL 60601-1
Pollution Degree Classification	Pollution Degree 2
Overvoltage Category	Category II (connected to wall outlet)

6.5 Symbol Identification

REF	Reference number / Catalogue number
LOT	Lot number / Batch code
SN	Serial number
	Expiration date

	Country of origin: China
	Country of origin: Switzerland
	Manufacturer
	Date of manufacture
	Authorized Representative
	UDI barcode carrier
	Medical equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1CAN/CSA-C22.2 No. 601.1, ANSI/AAMI ES60601-1 (2005, 3rd ed.) CAN/CSA-C22.2 No. 60601-1 (2008), 13VA
	CE indicator of European technical conformity
	CE and notified body number indicating European technical conformity
	Medical device
	RX
	Class II equipment
 5V-1A	Direct current / Power supply rating
	IP code / Protection class IPX4 (Handpiece)
	Type B applied part (Tips, Barrier sleeve)
	Consult electronic instructions for use (see adjacent URL)
	Packaging unit / Contains 25 parts
	Packaging unit / Contains 100 parts
	Do not use if package is damaged
	Opened packages are not replaced
	Dispose of in accordance with Waste Electrical and Electronic Equipment Directive 2012/19/EU of the European Parliament and the Council of the European Union
	Fragile, handle with care

	Keep dry
	Keep away from sunlight
	Atmospheric pressure limitation
	Temperature limitation
	Non-sterile
	Do not sterilize
	Caution
	Do not re-use
	Plastic material

6.6 Electromagnetic Compatibility Precaution

This information is required by the 4th edition of IEC 60601-1-2.

- The SmartLite Pro® System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
- Portable and mobile RF communications equipment can affect the SmartLite Pro® System.
- The use of accessories, transducers and cables other than those specified by Dentsply Sirona, may result in increased emissions or decreased immunity of the SmartLite Pro® System.
- The SmartLite Pro® System should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the SmartLite Pro® System should be observed to verify normal operation in the configuration in which it will be used.
- Per IEC 60601-1-2, no additional environmental operating conditions are required for normal use.

Guidance and manufacturer's declaration – electromagnetic emissions		
The SmartLite Pro® System is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartLite Pro® System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The SmartLite Pro® System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The SmartLite Pro® System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A - Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The SmartLite Pro® System is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartLite Pro® System should assure that it is used in such an environment.			
IMMUNITY Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5, + 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV Line(s) to earth	± 0.5, + 1 kV line(s) to line(s) ± 0.5, ± 1, ± 2 kV Line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0,5 cycle 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T for 250/300 cycles	0% U_T for 0,5 cycle 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartLite Pro® System requires continued operation during power mains interruptions, it is recommended that the SmartLite Pro® System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The SmartLite Pro® System is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartLite Pro® System should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the SmartLite Pro® System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{3}] \sqrt{P}$ $d = [\frac{3,5}{3}] \sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{3}] \sqrt{P}$ 800 MHz to 2,7 GHz Where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	

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

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

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Complies with the following Directives/Standards:	
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended by directive 2007/47/EC, annex 1
2002/95/EC	Restriction of the use of hazardous substances in electrical and electronic equipment
IEC 60601-1 ed. 3.1	2012 – Medical Electrical Equipment (General requirements for basic safety and essential performance)
IEC 60601-1-2	2005 – Medical electrical equipment - Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-57	2011 - Medical electrical equipment - Part 2-57: Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic use
EN 980	2008 – Symbols for use in labeling of medical devices
EN 1041	2008 – Information supplied by the manufacturer of medical devices
EN 1639	2009 – Dentistry – Medical devices for dentistry - Instruments
EN ISO 10993-1	2009 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 17664	2017- Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
IEC 80601-2-60	2012 – applies to the basic safety and essential performance of Dental Units, Dental Patient Chairs, Dental Handpieces and Dental Operating Lights
IEC 62366	2015 – Application of usability engineering to medical devices

The SmartLite Pro EndoActivator™ System complies with:

UL 60601-1
CSA C22.2 No. 601.1
E113604

6.7 Warranty terms

Dentsply Sirona grants a 2-year warranty on all components of the SmartLite Pro EndoActivator™ System except the battery and activator tips. The battery is covered by a 1-year warranty. There is no warranty on the activator tips. The warranty commences on the date of purchase. Within the warranty period, Dentsply Sirona will eliminate free of charge any defects in the appliance resulting from faults in material or workmanship either by repairing or exchanging parts or exchanging the whole device at Dentsply Sirona's discretion.

Not covered by this warranty: Damage arising from improper use (operation with incorrect current/voltage, unsuitable power point, breakage, cleaning by other than the recommended methods), normal wear and defects which have a negligible effect on the value or operation of the appliance.

This warranty becomes void if repairs are undertaken by unauthorized persons.

This warranty extends to every country where this device is supplied by Dentsply Sirona or its appointed distributor and where no import restrictions or legal regulations hinder or prevent service being given under warranty.

Service under this warranty does not affect the expiration date of the warranty. The warranty on parts or entire devices which are exchanged ends when the warranty on this device expires.

In the event of a claim of this device, return the complete device (charging base attachment and the handpiece) together with the invoice to your dealer or send it to your nearest Dentsply Sirona Service Center.

All other claims including those for damages resulting from this warranty are excluded unless our liability is legally mandatory.

6.8 Lot Number, Expiration Date and Correspondence

1. The following numbers should be quoted in all correspondence:
   - Reorder number
   - Serial Number
   - Expiration date
2. Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.

Dentsply LLC
1301 Smile Way
York, PA 17404 USA
www.dentsplysirona.com

EC REP DENTSPLY DeTrey GmbH
De-Trey-Straße 1
D-78467 Konstanz
Germany

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