

### ENDOACTIVATOR™ SYSTEM

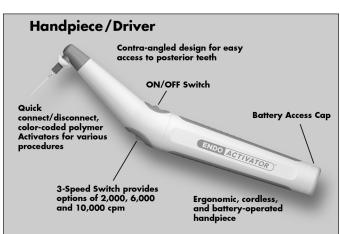
Sonic handpiece Driver and Activator tips for use in endodontic treatment.

Advanced Endodontics Clifford J. Ruddle, DDS 227 Las Alturas Road Santa Barbara, CA 93103 1 800 753 3636 1 805 964 8838 Fax 1 805 965 8253 www.endoruddle.com Manufactured in China









#### CAUTION:

U.S. federal law restricts this material to the sale by, or on the order of a dentist.

#### INDICATIONS FOR USE:

The EndoActivator System is used in endodontic treatment by application of sonic energy. The Activator tips are used in conjunction with the handpiece Driver 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.

# CONTRAINDICATIONS:

None known.

#### PRECAUTIONS:

- The EndoActivator System is comprised of the handpiece Driver and Activator tips of various sizes. The system functions as intended when the component parts (sold separately or as a complete system) are used together. Any other manufactured "tip" or "handpiece" is not interchangeable or compatible with this system.
- All endodontic procedures should be performed with an EndoActivator™ protective barrier sleeve (sold separately) placed over the handpiece Driver. The Activator tips are for singlepatient use only and should be discarded following treatment.
- The handpiece Driver provides 3-speed sonic motor options of 2,000, 6,000 and 10,000 cpm (based on fully charged battery). The power settings used are ultimately determined by the procedure to be performed, the clinician's experience, and the power needed to efficiently complete the clinical task.
- The handpiece Driver requires 1-AA battery for operation. The handpiece Driver has a micro-CPU circuit board to power its electrical system.
- The circuit board takes a very small amount of electric power from the battery when the Driver is in the OFF position. Periodically change the battery to ensure optimal clinical performance.

#### CLINICAL APPLICATIONS: · Debridement and disruption of the smear layer and biofilm

- Placement of calcium hydroxide and MTA around root curvatures
- · Removal of residual obturation materials during retreatment procedures

## INSTRUCTIONS FOR USE:

- Prepare canal to produce a fully tapered shape
- Fill pulp chamber with NaOCI, EDTA, or other final rinse solution
- · Select the Activator that manually fits loosely within 2 mm of working length
- · Place the barrier sleeve over the Driver to protect the entire handpiece · Attach the Activator over the barrier-protected Driver. The Activator should snap on firmly,
- promoting a secure connection with the handpiece Driver.
- ce the attached Activator tip into the prepared root canal
- Depress the ON/OFF switch to activate. Note: Switch defaults to 10,000 cpm upon activation. Depress the 3-speed switch to select 6,000 cpm or 2,000 cpm.
- Use a pumping action to move the handpiece Driver/Activator in short 2-3 mm vertical strokes
- · Hydrodynamically agitate the intracanal solution for 30-60 seconds
- Irrigate, then use intracanal suction to eliminate loose debris Repeat the above steps for each intracanal irrigant used

In general, to maximize clinical performance, use 10,000 cpm to encourage debridement and promote the disruption of the smear layer and biofilm. Select either 2,000 cpm of 6,000 cpm to effectively deliver intracanal materials, such as calcium hydroxide or MTA. The power selected is based on the length, diameter, and curvature of any given root,

and the energy required to effectively accomplish the clinical task. When the clinical procedure has been completed, remove the attached tip by grasping the large circular clean guard portion of the connected Activator with fingers and snap off. Pull the Activator off the Driver by firmly supporting the contra-angled neck of the handpiece. Next, remove the barrier sleeve and discard. Activator tips and protective barrier sleeves

# are intended for single-patient use only.

BATTERY REPLACEMENT:

- The EndoActivator handpiece Driver comes with one (1) "AA" batterv. To install a new battery:
- counterclockwise to disengage, push off, and remove the battery housing Remove the battery by gently pulling it out of the battery compartment
- For longer life and optimal clinical performance, insert a premium quality "AA" alkaline or lithium battery. Orient the positive end of the battery toward the ON/OFF and 3-way

• Firmly hold the handpiece Driver and rotate the proximal, non-removable screw cap

switches.

IMPORTANTLY, the Activator tips are intended for single-patient use only.

· Re-insert the housing, line-up female/male orientational guides and gently turn the proximal screw cap clockwise until housing is snug. DISINFECTION:

For infection control, select the appropriately sized EndoActivator tip and remove it from the plastic package. The Activator tip should be cleaned and disinfected with a 2x2 gauze moistened with a disinfecting solution such as alcohol or sodium hypochlorite.

Use a barrier sleeve over the entire handpiece Driver. Upon removing the barrier sleeve, the outer surface of the handpiece Driver may be wiped down with a mild detergent or disinfecting

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