DENTAL USE ONLY

DIRECTIONS FOR USE - ENDOACTIVATOR® SYSTEM
SONIC HANDPIECE DRIVER AND ACTIVATOR TIPS FOR USE IN ENDODONTIC TREATMENT.

1) 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.

2) CONTRAINDICATIONS
None known.

3) WARNINGS
- Do not submerge unit in water.
- Do not autoclave unit.
4) PRECAUTIONS

1) The EndoActivator® System is only to be used by dental professionals.

2) The EndoActivator® System is comprised of the handpiece and Activator tips of various sizes. The system functions as intended when the original component parts are used together. With the use of non-original components, serious consequences may result. The original components include the EndoActivator® handpiece, the Activator tip and protective barrier.

<table>
<thead>
<tr>
<th>The Dentsply Sirona reference number of the handpiece is</th>
<th>A0912</th>
</tr>
</thead>
<tbody>
<tr>
<td>The reference numbers of the Activator tips include</td>
<td></td>
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<tr>
<td></td>
<td>A0913 022-015 (Small)</td>
</tr>
<tr>
<td></td>
<td>A0913 022-025 (Medium)</td>
</tr>
<tr>
<td></td>
<td>A0913 022-035 (Large)</td>
</tr>
<tr>
<td>The reference number of the protective barrier is</td>
<td>A0914</td>
</tr>
</tbody>
</table>

3) The handpiece provides 3-speed sonic motor options (High, Med, Low). 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.

4) The EndoActivator® handpiece does not require calibration for normal use.

5) All endodontic procedures should be performed with an EndoActivator® protective barrier sleeve placed over the handpiece.

6) The Activator tip should be disinfected before use, or contamination of the root canal may result.

7) Proper use of the EndoActivator® System is required to prevent harm or hazard to the patient.

8) Improper handling of the EndoActivator® handpiece may result in breaking the distal or proximal ends of the rocker arm.

9) Activator tips and protective barriers are intended for single-patient use only. Cross contamination may occur to the patient if tips and barriers are re-used.

10) Proper disposal of Activator tips and protective barriers is required in accordance with local laws and regulations.

11) Proper disposal of the battery when the battery is depleted is required in accordance with local laws and regulations.

12) The handpiece must be repaired as necessary under the direction of the manufacturer.

13) Proper disposal of the handpiece when the handpiece is deemed non-functional is required in accordance with local laws and regulations.

14) Removal of the battery is recommended when the handpiece is not to be used for an extended period of time.

15) The acceptable temperature range for utilizing, storing and/or transporting the EndoActivator® System is -20°C to 45°C.

16) The handpiece should be stored away from strong electromagnetic equipment as it may affect handpiece performance.

17) The handpiece should be stored away from portable and mobile RF communications equipment as it may affect handpiece performance.

18) The handpiece should not be used adjacent to or stacked with other equipment. Additionally, it should be checked for normal operating functions on a regular basis.

5) ADVERSE REACTIONS

None known.
6) **STEP BY STEP INSTRUCTIONS**

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

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 handpiece 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.

6.1) **ACTIVATOR TIP REMOVAL**

Firmly support the head of the handpiece with your thumb while grasping the white, circular, flange portion of the Activator tip with opposite thumb and forefinger.

Use your thumb to maintain support of the handpiece and pull the Activator tip STRAIGHT off. Keep the handpiece head and Activator tip aligned during the removal process.

The Activator tip snaps ON/OFF in exactly the same alignment. NEVER use a clockwise or counterclockwise motion to remove a Tip. NEVER twist, turn or torque the tip when removing.
6.2) BATTERY REPLACEMENT

The EndoActivator® handpiece comes with one (1) “AA” alkaline battery.

To remove the battery housing, firmly grasp the contra-angled portion of the handpiece with one hand and begin turning the non-removable, screw knob counterclockwise with your other hand.

Rotate the screw knob counterclockwise to progressively disengage the battery housing and remove it from the handpiece. Replace with a high quality lithium battery.

To close compartment, slide housing over the new battery and position the EndoActivator® logo as pictured above. ALIGN the orientational tracks within the grooves, and turn the screw knob clockwise until snug.

6.3) Replacement parts

Battery Housing Replacement Part
In case of failure on the removable battery housing, you can order a replacement part ref.: A0915

Rocker arm replacement kit
In case of broken distal end of the rocker arm, you can order a replacement part ref.: A0916

6.4) 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 gauze moistened with a disinfecting solution such as sodium hypochlorite.

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

Use a barrier sleeve over the entire handpiece. Upon removing the barrier sleeve, the outer surface of the handpiece may be wiped down with a mild detergent or disinfecting solution. DO NOT submerge the handpiece in any disinfecting solution or autoclave. Never over-saturate the handpiece with any disinfecting solution.

7) ENDOACTIVATOR® WARRANTY INFORMATION

Implied Warranties
Endo Inventions guarantees its product for a period of one year after the date of purchase. If any defect due to faulty materials and workmanship occurs within this one-year period, Endo Inventions will repair or replace the product at its expense.
The warranty does not cover product and/or product parts that are subject to wear and that can be considered as consumable parts by their nature or that are made of silicone. The warranty is not valid if a defect is due to damage caused by incorrect use, poor maintenance, or if alterations or repairs have been carried out by persons not authorized by Endo Inventions.

**Limitation of Remedies**
In no event shall Endo Inventions or any of its affiliated parties be liable for any special, incidental or consequential damages based upon breach of warranty, breach of contract, negligence, tort, or any other legal theory. Such damages include, without limitation, loss of savings or revenue; loss of profit; loss of use; the claims of third parties; and cost of any substitute equipment or services.

**Warranty Restrictions**
What is not covered under warranty?
- Activator tips
- Protective barrier sleeves
- Damage caused by misuse, abuse, neglect or alterations
- Normal wear and tear, including chips, scratches, abrasions, cracking, discoloration or fading
- Replacement batteries*

* Special note: If the product is not going to be used for an extended period of time (two weeks or longer), the battery should be removed. The battery must also be removed during transport, for example when being sent for After Sales Service.

**8) GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC EMISSIONS**

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

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The handpiece 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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations /flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>RF emissions CISPR 14-1</td>
<td>Complies</td>
<td>The handpiece is not suitable for interconnection with other equipment.</td>
</tr>
</tbody>
</table>
The handpiece is intended for use in the electromagnetic environment specified below. The Customer or the user of the handpiece should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment –guidance</th>
</tr>
</thead>
</table>
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | ±2, ±4, ±6kV Contact ±2, ±4, ±8kV 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 ±1kV for input/ output lines | Not applicable | Mains power quality should be that of a typical commercial or hospital environment.
| Surge IEC 61000-4-5 | ±1 kV differential mode ±2 kV common mode | Not applicable | 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 | <5 % UT for 0.5 cycle (>95 % dip in UT) 40 % UT for 5 cycles (60 % dip in UT) 70 % UT or 25 cycles (30 % dip in UT) <5 % UT for 5 sec (>95 % dip in UT) | Not applicable | Mains power quality should be that of a typical commercial or hospital environment. If the user of the handpiece requires continued operation during power mains interruptions, it is recommended that the handpiece be powered from an uninterruptible power supply or a battery.

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.

Portable and mobile RF communications equipment should be used no closer to any part of the handpiece, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

\[ d = \left[ \frac{3.5}{V_1} \right] \sqrt{P} \]

\[ d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz} \]

\[ d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz} \]

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, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: ⚠️
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 handpiece is used exceeds the applicable RF compliance level above, the handpiece should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the handpiece.

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

Recommended separation distances between portable and mobile RF communications equipment and the handpiece

The handpiece is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the handpiece can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the handpiece as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>Separation distance according to frequency of transmitter m</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td></td>
<td>(d = \frac{0.015}{P^{1/2}})</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.70</td>
</tr>
<tr>
<td>100</td>
<td>11.7</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance \(d\) in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where \(P\) is The maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.
<table>
<thead>
<tr>
<th>Symbols</th>
<th>EN</th>
</tr>
</thead>
<tbody>
<tr>
<td>🚫</td>
<td>Do not throw away</td>
</tr>
<tr>
<td>📅</td>
<td>Manufacture date</td>
</tr>
<tr>
<td>🏠</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🚨</td>
<td>See directions for use</td>
</tr>
<tr>
<td>☓️</td>
<td>Non sterilizable</td>
</tr>
<tr>
<td>⚙️</td>
<td>One use only</td>
</tr>
<tr>
<td>↔️</td>
<td>Opened packages are not replaced</td>
</tr>
<tr>
<td>⚡️</td>
<td>Batch number</td>
</tr>
<tr>
<td>🔍️</td>
<td>Article reference</td>
</tr>
<tr>
<td>☔️</td>
<td>Keep away from rain</td>
</tr>
<tr>
<td>📄</td>
<td>Green dot</td>
</tr>
<tr>
<td>⬇️</td>
<td>The upper and lower limits of temperature of use, storage and transportation</td>
</tr>
<tr>
<td>👤</td>
<td>Type B applied part</td>
</tr>
</tbody>
</table>

PATENT NO. 7,261,561 AND OTHER PATENTS PENDING

**Manufacturer**

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**EC | REP**

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