




## BRASSELER USA ABRASIVE and POLISHING INSTRUMENTS

BRASSELER USA ABRASIVES and POLISHERS are available in non-sterile models under various trade names with numerous applications and shapes, head diameters and working lengths. The devices are most often reusable and are sterilized using steam sterilization in a gravity or prevacuum cycle. Some devices are single use and are labeled with a graphical symbol .

### Description

BRASSELER USA's ABRASIVES and POLISHER family includes both intra-oral and extra-oral devices for such materials as porcelain, acrylic, semi-precious and high noble metals and composites. An ABRASIVE is a rotary dental device that can adjust various materials, and is designed to fit into a dental handpiece. A POLISHER is a rotary dental device that can adjust and polish various materials, and is designed to fit into a dental handpiece. Some Polishers and Abrasives are supplied pre-mounted, while others require the use of a Mandrel. BRASSELER USA devices are reusable unless otherwise labeled as single use only.

### Intended Use

BRASSELER USA devices fit into a dental handpiece, which provides the rotation, allowing the user to adjust or polish materials both intra-orally and extra-orally, e.g., crowns, composite restorations, bridges, amalgam fillings, etc.


### Warnings and Precautions

**WARNING:**

**PROVI PRO AND ET COMPOSITE DISCS CANNOT BE STERILIZED. THEY ARE FOR SINGLE USE ONLY.**

Warning: Attention should be paid to the speed of work (RPM)

- Always refer to the product packaging for the Maximum RPM
- Operating a polisher or abrasive with too high of an RPM may generate undesirable heat
- Operating a polisher or abrasive with too high of an RPM may cause the polisher to fail

- Thoroughly clean and steam sterilize the device prior to the first use and each subsequent reuse
- Devices labeled Single Use  CANNOT be cleaned or steam sterilized prior to use and must be discarded after use
- Do not use chemical or dry heat to sterilize BRASSELER USA devices, as these processes have not been validated for use
- Do not use worn-out or dull devices
- Do not apply excessive pressure on the device as this could cause undesirable heat or may cause the device to fail
- Avoid removing the device at too sharp an angle to avoid leverage and breakage
- Carefully read package labels to ensure use of the appropriate device
- Ensure the device is fully seated and securely gripped in the handpiece collet prior to use
- Ensure that Abrasive and Polishing Wheels are properly assembled to the Mandrel before operation of the device
- Move the device continuously when in use to avoid localized heating and/or damage to the device
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device
- Use a rubber dental dam while using devices to avoid possible aspiration or swallowing
- Always wear gloves when handling contaminated instruments



- Eye protection must be worn to protect against eject particles
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated
- BRASSELER USA Bur Blocks are used to hold the devices for storage and steam sterilization, but are not intended to maintain sterility of the device

**General Instructions**

1. The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
2. Clean and sterilize Polishers and Abrasives in accordance with the directions provided below prior to first use and prior to each reuse using the procedures provided below.
3. Do not force devices into the handpiece. In case of difficult access, check both handpiece turbine and device and refer to handpiece instructions for troubleshooting.

**Cleaning and Sterilization Instructions**

Scope	These instructions are applicable to all BRASSELER USA Dental Polishers and Abrasives. They are applicable before initial use and after each subsequent use. Devices are provided mechanically clean, but are not sterile. Therefore, they should be sterilized before first use.
Warnings	<ol style="list-style-type: none"> <li>1. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Cleaning agents with neutral pH are recommended.</li> <li>2. Do not use cleaning agents or disinfectants containing alcohol.</li> <li>3. Do not use Cold Sterilizing Methods for the sterilization of devices. These agents often contain strong oxidizing chemicals that may dull or weaken devices.</li> </ol>
Reprocessing Limitations	The end of life is determined by wear and damage and the devices should be inspected for defects (i.e. broken tips, device deterioration, etc.) during the cleaning process.
Point of Use	Delay in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.
Containment/Transportation	Devices can be transported wet or dry and should be protected from damage. If transported wet there is an increased chance of staining or deterioration. Prolonged storage in disinfectant solutions may result in degradation of the product and must be avoided.
Manual Cleaning Procedure	<p>If hand cleaning is the only available option, devices should be cleaned in a sink reserved for cleaning instruments.</p> <p>Rinse the device (and dedicated instrument block, if applicable) under cool running water for at least one (1) minute.</p> <p>Prepare a fresh bath of neutral-pH cleaning solution. Follow the agent’s manufacturer’s instructions. Immerse the device (and instrument block) and, keeping it immersed, brush thoroughly away from the body using the neutral cleaning agent. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process.</p> <p>Special care should be taken to clean crevices and other hard-to-reach areas thoroughly. Visually inspect to confirm the removal of debris. Repeat the cycle if needed.</p> <p>Thoroughly rinse the device (and instrument block) under running warm water for at least one (1) minute and until visibly clean.</p> <p>Dry the device using a non-shedding wipe or clean compressed air.</p>

## Brasseler USA Abrasives and Polishing Instruments - Instructions for Use



Automated Cleaning Procedure	<p>Prepare a fresh pH-neutral cleaning solution; place the device in the dedicated instrument block (if applicable) and then place in a sonication unit. Follow the agent manufacturers' instructions for correct concentration, exposure time, temperature and water quality. Completely submerge the device in the cleaning solution and sonicate for at least fifteen (15) minutes.</p>												
	<p>Perform a final thorough rinse of the device and instrument block (if applicable) under running warm tap water for at least (1) minute. Visually inspect to confirm the removal of debris. Repeat the cycle if needed.</p>												
	<p>Dry the device using a non-shedding wipe or clean compressed air.</p>												
Inspection Testing	<ol style="list-style-type: none"> <li>1. Carefully inspect each device to ensure that all debris has been removed.</li> <li>2. Visually inspect the device for damage/wear that would prevent proper operation.             <ol style="list-style-type: none"> <li>a. Do not use if the tip is broken.</li> <li>b. Do not use if there is deterioration in the material.</li> <li>c. Do not use if there is evidence of corrosion.</li> </ol> </li> </ol>												
Packaging	<p>Singly: Pack the device in pouches validated for sterilization</p> <p>In Sets: Place the device in the dedicated instrument block.</p>												
Sterilization	<p>Use the following cycle for steam sterilization</p>												
	<table border="1"> <thead> <tr> <th>Cycle Type</th> <th>Sterilization Exposure Time (minutes)</th> <th>Sterilization Exposure Temperature</th> <th>Dry Time (minutes)</th> </tr> </thead> <tbody> <tr> <td>Gravity</td> <td>10</td> <td>135°C (275°F)</td> <td>30</td> </tr> <tr> <td>Pre-vacuum (4 Pulses)</td> <td>5</td> <td>134°C (273°F)</td> <td>30</td> </tr> </tbody> </table>	Cycle Type	Sterilization Exposure Time (minutes)	Sterilization Exposure Temperature	Dry Time (minutes)	Gravity	10	135°C (275°F)	30	Pre-vacuum (4 Pulses)	5	134°C (273°F)	30
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	<p>Ensure that the sterilizer manufacturer's maximum load is not exceeded.</p>												
Storage	<p>The device should be stored in the sterilization pouch (or instrument block) until required.</p>												
Additional Information	<p>These processes have been validated as being capable of preparing devices for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.</p>												

Brasseler USA Dental, L.L.C.  
 One Brasseler Blvd.  
 Savannah, GA 31419 USA  
 Telephone 912-925-8525