

## BRASSELER USA ABRASIVE and POLISHING INSTRUMENTS

BRASSELER USA ABRASIVES and POLISHERS are available in Sterile and 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.

### Contraindications

- Polishers and Abrasives contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.
- This product contains nickel, a chemical known to the state of California to cause cancer, birth defects or other reproductive harm.



### Warnings and Precautions

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

- The device is to be used on the instruction of, or by a dentist or other licensed practitioner.
- Attention should be paid to the speed of work (RPM):
  - Always refer to the product packaging for the Maximum RPM. Use of the device beyond the RPM range may cause the device to break and result in patient or user harm.
  - Operating a polisher or abrasive with too high of an RPM may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Proper irrigation is required while using the device. Inadequate use of irrigation may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Do not apply excessive pressure on the device as this could cause undesirable heat or may cause the device to fail and cause patient or user injury.
-  Devices marked as single use are not intended to be used on more than one patient. Use on more than one patient may lead to decreased cutting efficiency which could result in device failure or generation of undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Polishers and Abrasives must be thoroughly cleaned and steam sterilized prior to the first use and each subsequent reuse to prevent the risk of infection or cross-contamination.
- Devices labeled Single Use  CANNOT be cleaned or steam sterilized prior to use and must be discarded after use. Sterilization of these devices could cause device damage which may lead to patient or user injury.
- Polishers and Abrasives labeled "Sterile" require no further action prior to first use but must be thoroughly cleaned and steam sterilized prior to each subsequent reuse to prevent the risk of infection or cross-contamination.

- If the packaging for “Sterile” labeled devices is opened or damaged or is past its expiration date, the device must be thoroughly cleaned and steam sterilized prior to use and each subsequent reuse to prevent the risk of infection or cross-contamination.
- Do not use chemical or dry heat to sterilize BRASSELER USA devices, as these processes have not been validated for use. Use of these processes may be corrosive to the device and could result in premature device failure.
- Proper cleaning is required after use of the device to prevent cross-contamination. Failure to properly remove the accumulated debris may cause the device to break causing patient or user harm or may generate undesirable heat and cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Use a rubber dental dam while using devices to avoid possible aspiration or swallowing of the device.
- Always wear gloves when handling contaminated instruments to avoid possible infection/cross-contamination.
- Eye protection must be worn to protect against eject particles which could cause user injury.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated that could cause possible infection/cross-contamination.
- Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause procedural delays or patient or user injury.
- Animal hair brushes, buffs or felts are not intended to be used intra-orally and could cause patient infection or cross-contamination. Properly clean and sterilize any prostheses used with these devices to prevent patient infection or cross-contamination.
- Failure to follow these instructions may cause the following: preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the device.
- Always inspect the devices before use:
  - Use of worn-out or dull devices could cause undesirable heat or may cause the device to fail.
  - Use of bent devices could cause vibration that may cause patient discomfort or damage to the preparation site.
- Move the device continuously when in use to avoid localized heating and/or damage to the device. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Avoid removing the device at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
- Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays or injury of the patient or user, aspiration or swallowing of the device or damage to the preparation site due to vibration of a worn chuck or turbine.
- Ensure the device is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the device to “walk out” of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the device.
- Never force a device into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- Ensure that Abrasive and Polishing Wheels are properly assembled to the Mandrel before operation of the device. Failure to do so may lead to injury of the patient or user or aspiration or swallowing of the device.
- BRASSELER USA Bur Blocks used to hold the devices for storage and steam sterilization are not intended to maintain sterility of the device. Devices should be stored in the sterilization pouch to prevent cross-contamination.
- Do not force devices into Bur Blocks as this could cause damage to the device or cause it to become lodged in the Bur Block.

### General Instructions

1. Clean and sterilize Polishers and Abrasives in accordance with the validated procedures provided below prior to first use and prior to each reuse.
2. 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 (unless labeled "STERILE"). Therefore, the devices 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 these devices. These agents often contain strong oxidizing chemicals that may dull or weaken the devices.</li> </ol>
Reprocessing Limitations	The end of life is determined by wear and damage in use. 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 (such as Enzol). Follow the cleaning agent 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>
Automated Cleaning Procedure	<p>Prepare a fresh pH-neutral cleaning solution (such as Enzol); place the device in the dedicated instrument block (if applicable) and then place in a sonication unit. Follow the cleaning 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" data-bbox="402 390 1273 600"> <thead> <tr> <th>Cycle Type</th> <th>Minimum Sterilization Exposure Time (minutes)</th> <th>Minimum Sterilization Exposure Temperature</th> <th>Minimum 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> <p>Ensure that the sterilizer manufacturer's maximum load is not exceeded.            The minimum dry time has been validated to ensure that the devices will not be left wet. Failure to achieve the minimum dry time may cause moisture to remain on the devices that could result in corrosion.</p>	Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)	Gravity	10	135°C (275°F)	30	Pre-vacuum (4 Pulses)	5	134°C (273°F)	30
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Storage	The device (or instrument block) should be stored in the sterilization pouch until required.												
Additional Information	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.												

### Glossary of Symbols

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Quantity	N/A
	Revolution (RPM)	ISO 21531
	Consult instructions for use	ISO 15223-1
	Caution	ISO 15223-1
	Non-sterile	ISO 15223-1
	Do not re-use	ISO 15223-1
<i>Rx Only</i>	Caution: Federal law restricts this device to sale by or on the order of a "dentist/physician" licensed by the law of the State in which he/she practices to use or order the use of the device.	FDA 21 CFR Part 801.109 (b)(1)
<i>Made in</i>	Made in	N/A
	Manufacturer/Legal Manufacturer	ISO 15223-1



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