

BRASSELER USA Aluminum Bur Blocks

BRASSELER USA Aluminum Bur Blocks (also known as instrument blocks) are available in assorted sizes with various drilled-hole configurations to accommodate select rotary dental instruments. The devices are non-sterile, reusable and can be sterilized using steam sterilization in a gravity or prevacuum cycle.

Description

BRASSELER USA Aluminum Bur Blocks are made of perforated anodized aluminum in a variety of colors, with drilled holes designed to fit select rotary dental instruments such as dental burs, discs, polishers, abrasives and mandrels of assorted sizes.

With the exception of one device, all of the BRASSELER USA Aluminum Bur Blocks are a two-piece construction comprised of a perforated or open Bur Block bottom and a Bur Block top, which is attached at the rear corners allowing the top to be flipped open. The remaining Bur Block (also known as a Strip Tube) is a perforated two-piece, closed-end tube construction, which screws together using internal threads. Bur Blocks are non-sterile and reusable.

Intended Use

BRASSELER USA Aluminum Bur Blocks are intended for the organization and storage of rotary dental instruments. The blocks can also be used to hold rotary dental instruments during steam sterilization. Bur Blocks are not intended to maintain the sterility of the contained devices.

Warnings and Precautions

- BRASSELER USA Bur Block catalog number A101 must be sterilized using a prevacuum autoclave cycle only
- BRASSELER USA Aluminum Bur Blocks used to hold rotary dental instruments for storage and steam sterilization are not intended to maintain sterility of the contained devices
- Use neutral pH cleaning agents following manufacturer's directions
- Cleaning agents with chlorine or chloride as the active ingredient are corrosive to aluminum and must not be used. Use of agents with harsh cleansers or cleansers with high or low pH, may dissolve the anodized coloring from the Aluminum Bur Block reducing the useful lifetime of the device.

- Bur Blocks must be thoroughly cleaned prior to the first use and prior to each subsequent reuse
- Do not use chemical or dry heat to sterilize BRASSELER USA Aluminum Bur Blocks, as these processes have not been validated for use
- Do not use if etched markings are illegible
- Do not use if drilled holes are obstructed, chipped or otherwise damaged in any manner
- Do not use if the device exhibits signs of corrosion or damage
- Do not use if the device has a loose lid or if the lid does not open or close properly
- Do not use if the device is missing parts or is broken in any manner
- Do not force rotary dental instruments into drilled holes as this may impede sterilization
- Do not leave device in wet condition as this may lead to corrosion or interaction with stored devices
- Carefully read package labels to ensure use of the appropriate device
- Always wear gloves when handling contaminated instruments used in the Bur Bloc

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 the device in accordance with the validated procedures provided below prior to first use and each subsequent reuse.
3. Do not store the Aluminum Bur Block when wet as this may cause corrosion of the aluminum or interaction with stored rotary dental instruments.

Cleaning and Sterilization Instructions

Scope	<p>These instructions are applicable to all BRASSELER USA Aluminum Bur Blocks. They are applicable before initial use and after each subsequent use. Bur Blocks are provided mechanically clean, but are not sterile. Therefore, Bur Blocks should be cleaned and sterilized before first use and subsequent reuses.</p>
Warnings	<ol style="list-style-type: none"> 1. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to aluminum and must not be used. Use of agents with harsh cleansers or cleaners with high or low pH may dissolve the anodized coloring from the Aluminum Bur Block and reduce the useful lifetime of the device. Cleaning agents with neutral pH are recommended. 2. Do not use Cold Sterilizing Methods for the sterilization of Aluminum Bur Blocks. These agents often contain strong oxidizing chemicals that may strip the anodized color from the Aluminum Bur Block and reduce the useful lifetime of the device.
Reprocessing Limitations	<p>The end of life is determined by wear and damage during cleaning and sterilization. Bur Blocks should be inspected for defects (i.e. missing pins, chipped holes, faded etching, broken lid etc.) during the cleaning process.</p>
Point of Use	<p>Delay in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.</p>
Containment/ Transportation	<p>Aluminum Bur Blocks can be transported wet or dry and should be protected from damage. If transported wet there is an increased chance of staining or corrosion of the aluminum. Prolonged storage in disinfectant solutions may result in degradation of the product or dissolution of the anodized coating and must be avoided.</p>
Manual Cleaning Procedure	<p>If hand cleaning is the only available option, Bur Blocks should be cleaned in a sink reserved for cleaning instruments.</p> <p>Rinse the device under cool running water for at least one (1) minute.</p> <p>Prepare a fresh bath of neutral-pH cleaning solution (such as Enzol) following the manufacturer's directions. Immerse the device and soak for at least ten (10) minutes.</p> <p>After soaking, and keeping it immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. Use wire brushes with caution as brass particles may result in galvanic corrosion, which may cause discoloration of aluminum.</p> <p>Special care should be taken to thoroughly clean drilled holes, lid hinges, crevices and other hard-to-reach areas using a pH neutral cleanser. Visually inspect to confirm the removal of gross debris. Repeat the cycle if needed.</p> <p>Thoroughly rinse the device 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>

Ultrasonic Cleaning Procedure	<p>Prepare a fresh pH-neutral cleaning solution following the manufacturer’s instructions for correct concentration, exposure time, water temperature and quality. Place the Bur Block in a sonication unit ensuring the device is completely submerged, and sonicate for at least fifteen (15) minutes.</p> <p>Perform a final thorough rinse of the device under running warm tap water for at least (1) minute.</p> <p>Visually inspect to confirm the removal of gross debris from drilled holes, lid hinges, crevices and other hard to reach areas. Repeat the cycle if needed until visibly clean.</p> <p>Dry the device using a non-shedding wipe or clean compressed air.</p>												
Inspection Testing	<ol style="list-style-type: none"> 1. Carefully inspect each device to ensure that all debris has been removed. 2. Visually inspect the device for damage/ wear that would prevent proper operation. <ol style="list-style-type: none"> a. Do not use if drilled holes are obstructed. b. Do not use if the lid is broken or loose. c. Do not use if the anodized coating has faded or disappeared as the interior etchings identifying bur location may be obscured or lost. d. Do not use if there is evidence of corrosion, rotary instrument interaction or other signs of damage. 												
Packaging	<p>Singly: Pack Bur Blocks in pouches validated for sterilization</p> <p>In Sets: Pack select rotary dental instruments into the Bur Block for steam sterilization</p>												
Sterilization	<p>Use the following cycle for steam sterilization</p> <table border="1" data-bbox="402 1026 1273 1205"> <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>3</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.</p>	Cycle Type	Sterilization Exposure Time (minutes)	Sterilization Exposure Temperature	Dry Time (minutes)	Gravity	10	135°C (275°F)	30	Pre-vacuum (4 Pulses)	3	134°C (273°F)	30
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Gravity	10	135°C (275°F)	30										
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Storage	<p>The Bur Block should be stored in the sterilization pouch until required. The Bur Block is not intended to maintain the sterility of the contained devices.</p>												
Additional Information	<p>These processes have been validated as being capable of preparing Aluminum Bur Blocks for reuse. Any deviation from these instructions should be properly validated for effectiveness and potential adverse results.</p>												

Glossary of Symbols

Symbol	Meaning	Standard
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Quantity	N/A
	Consult instructions for use	ISO 15223-1
	Caution	ISO 15223-1
	Non-sterile	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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