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Instructions for Use for Munce® Aluminum Bur Blocks

Instructions for use. The Munce® Aluminum Bur Blocks are designed to accommodate the Munce Discovery Burs®. The bur blocks are non-sterile and require sterilization prior to use and after each use. They are reusable.

Indications/Intended Use:

Munce® Bur Blocks (“Bur Blocks”) are intended to facilitate the organization and storage of the Munce Discovery Bur® rotary dental instruments.

General Instructions and Precautions:

1. The device is to be used on the instruction of, or by a dentist or other licensed practitioner. It is the sole responsibility of the dentist to determine the appropriate use in clinical circumstance.
2. Bur Blocks must be thoroughly cleaned and sterilized prior to the first use and prior to each subsequent reuse (see Cleaning Instructions below).
3. Do not store the Bur Block when wet as this may cause corrosion of the aluminum or interaction with stored rotary dental instruments.
4. Do not use chemical or dry heat to sterilize the Bur Blocks, as these processes have not been validated for use.
5. Do not use if etched markings are illegible.
6. Do not use if drilled holes are obstructed, chipped or otherwise damaged in any manner.
7. Do not use if the device exhibits signs of corrosion or damage.
8. Do not use if the device has a loose lid or if the lid does not open or close properly.
9. Do not use if the device is missing parts or is broken in any manner.
10. Do not force rotary dental instruments into drilled holes as this may impede sterilization.
11. Carefully read package labels to ensure use of the appropriate device.
12. Always wear gloves when handling contaminated instruments used in conjunction with the Bur Block.



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Cleaning and Sterilization Instructions for Munce® Aluminum Bur Blocks

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Scope	These instructions are applicable to all Munce® 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.
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 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 Bur Blocks. These agents often contain strong oxidizing chemicals that may strip the anodized color from the Bur Block and reduce the useful lifetime of the device.
Reprocessing Limitations	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.
Point of Use	Delay in reprocessing must be kept to a minimum to avoid contaminants drying thereby making cleaning more difficult.
Containment/Transportation	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.
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. Dry the device using a non-shedding wipe or clean compressed air.</p>

Ultrasonic
Cleaning

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.

Perform a final thorough rinse of the device under running warm tap water for at least (1) minute.

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.

Dry the device using a non-shedding wipe or clean compressed air.

Inspection
Testing

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.
 - 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 on Bur Blocks with laser etched hole labelling.
 - d. Do not use if there is evidence of corrosion or other signs of damage.

Packaging

Singly: Pack Bur Blocks in pouches validated for sterilization.

In Sets: Pack select rotary dental instruments into the Bur Block for steam sterilization.

Sterilization

Use the following cycle for steam sterilization

Cycle Type	Sterilization Expos (minutes)	Sterilization Exposure Temperature	Dry Time (minutes)
Gravity	10	135°C (275°F)	30
Pre-vacuum (4 Pulses)	3	134°C (273°F)	30

Ensure that the sterilizer manufacturer’s maximum load is not exceeded.

Storage

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.

Additional
Information

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.