

Cybercut

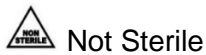
Diamond Dental Burs

Instructions for Use



Manufactured for Lares Research

295 Lockheed Ave,
Chico, CA 95973, USA



Not Sterile

INDICATIONS FOR USE

⚠ Caution: This product is to be used on the instruction of, or by a licensed dentist or other licensed practitioner. **Diamond burs** are single use invasive devices to be used sterile and indicated for treatment of patients with dental disease such as caries, or hard tissue damage. Lares **Diamond burs** are ISO standard 1797 compatible, available with numerous head diameters and working lengths.

INTENDED USE

Lares **Diamond burs** are intended to fit into a dental handpiece, which provides the rotation, allowing the user to abrade hard structures in the mouth, e.g., teeth or bone. Lares **Diamond burs** can also be used to cut hard metals, plastics, porcelains and similar materials.

COMPOSITION

A **Diamond bur** is a rotary abrading device made of stainless steel which is coated with diamond particles on the working end.

CONTRA-INDICATIONS

This product may contain Nickel, a chemical known to the state of California to cause cancer, birth defects or other reproductive harm. Do not use on individuals with a known allergic sensitivity to this metal.

GENERAL DESCRIPTION

- A **Diamond bur** is a rotary abrading device made of stainless steel which is coated with diamond particles on the working end, and which is designed to fit into a dental handpiece allowing the user to safely shape and debride tooth and restorative structures.
- The devices provided as non-sterile can be sterilized using steam sterilization in an autoclave.

OPERATING RECOMMENDATIONS

- Prior to use, sterilize the burs supplied in accordance with the validated procedure provided prior to first use.
- Select the correct handpiece matching the shank of the bur being used.
- Release the chuck and fully insert the bur into the handpiece.
- Ensure that the bur is secure before use.
- Do not force a bur into the handpiece. In case of difficult access, check both handpiece turbine and bur and refer to handpiece instructions for troubleshooting.

⚠ WARNINGS

- Although Lares **Diamond burs** are single use devices, risk of reuse can include cross contamination and failure due to fatigue
 - Devices are marked as single use and 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.
 - 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 bur as this could cause undesirable heat or may cause the bur to fail and cause patient or user injury.
 - **Diamond burs** must be steam sterilized prior to the first use 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 prevent the risk of infection or cross-contamination.
- Do not use chemical or dry heat to sterilize Lares **Diamond burs**, 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 during use of the device. 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 **Diamond burs** 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.
- 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 **Diamond burs**.

Caution:

- Carefully read package labels and instructions to ensure safe use of the appropriate device.
- Always inspect the burs before use
- Use a rubber dental dam while using burs to avoid possible aspiration or swallowing of debris.
- Use of worn-out or dull burs could cause undesirable heat or may cause the bur to fail.
- Use of bent burs could cause vibration that may cause patient discomfort or damage to the preparation site.
- Move the bur continuously when in use to avoid localized heating and/or damage to the bur. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- Avoid removing the bur 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 bur or damage to the preparation site due to vibration of a worn chuck or turbine.
- Ensure the bur is fully seated and securely gripped in the handpiece chuck 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 bur.
- Never force a bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- Bur blocks can be used to hold the devices for storage and steam sterilization but are not intended to maintain sterility of the device. Burs should be stored in the sterilization pouch to prevent cross-contamination.
- Do not force burs into bur blocks as this could cause damage to the bur or cause it to become lodged in the bur block.

PERSONAL PROTECTION EQUIPMENT

- Always wear STERILE gloves when handling STERILE and/or contaminated instruments.
- Eye protection must be worn to protect against potentially ejected particles.
- Surgical masks must be worn to avoid inhalation of any aerosol or dust generated.

UNDESIRABLE SIDE-EFFECTS

- Bur fracture/breakage.
- Infection – Do not use product if package is damaged or open due to risk of infection occurring.
- Complications usually associated with dental procedures include: Pain, bur fracture/breakage, soft tissue damage/bleeding.

DISPOSAL OF USED PRODUCT

After use, products should be disposed appropriately by user as biohazard material per local regulations.

STORAGE CONDITIONS

- **Diamond burs** should be stored in an ambient operatory temperature/environment, away from sunlight and corrosive chemicals, in a clean, dry location.
- **Diamond burs** should be stored in the sterilization pouch (or instrument block) until required.

STERILIZATION INSTRUCTIONS

Lares **Diamond burs** are provided mechanically clean, but not sterile.

Diamond burs are single use and are to be sterilized in accordance with the validated procedures provided prior to use and then properly discarded.

To clean the burs before sterilization

Rinse the bur (and dedicated bur block, if applicable) under cool running water for at least one (1) minute.

Prepare a fresh bath of neutral-pH cleaning solution. Follow the cleaning agent's manufacturer's instructions. Immerse the bur (and bur block) and soak for at least ten (10) minutes.

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 and steel particles may cause discoloration of stainless steel. Thoroughly rinse the bur (and bur block) under running warm water for at least one (1) minute and until visibly clean.

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

Inspect burs to be sterilized

Carefully inspect each bur to ensure that all debris has been removed.

Visually inspect the bur for damage/ wear that would prevent proper operation.

Do not use if the tip is broken.

Do not use if there is a broken section of a flute.

Do not use if there is evidence of corrosion.

Pack the burs for sterilization

Single: Pack the burs in pouches validated for sterilization

In Sets: Place the burs in the dedicated instrument block.

Sterilize the burs

Cycle Type	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Dry Time (minutes)
Gravity	30	121°C (250°F)	30
Pre-Vacuum	4	132°C (269°F)	30
Pre-Vacuum	3	134°C (273°F)	30

Store the burs

After sterilization, store burs in a dry, clean, and ambient temperature environment in the sterilization pouch or bur block until required.

Caution:


Ensure the sterilizer manufacturer's maximum load is not exceeded.


- 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.
- Do not use Cold Sterilizing Methods for the sterilization of rotary dental instruments. These agents often contain strong oxidizing chemicals that may dull or weaken rotary dental instruments.
- Used rotary instruments, damaged sterile packaging and unintentional open packaging shall be considered contaminated. Follow appropriate pre-cautions by utilizing this recommended sterilization guideline.


Sterilized **Diamond burs** MUST be stored in their sealed, sterile barrier pouch to maintain sterility until use.


 Batch Code

 Operating Instructions

 Autoclave at specific temperature

 Use by Date

 Do not use if package is damaged

 Do not re-use

Toll Free Ordering & Technical Assistance:

(888) 333-8440, EXT 1

Non Toll-Free Worldwide: (530) 345-1767

Internet & Online Ordering: www.laresdental.com

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