

1. IDENTIFICATION OF THE COMPANY

Company Name

American Orthodontics
 3524 Washington Avenue
 Sheboygan, WI 53081

24 HR EMERGENCY TELEPHONE NUMBER

(920) 457-5051
 Telephone for Information
(920) 457-5051

2. IDENTIFICATION OF THE PRODUCT

Product Name: Orthodontic Burs
 Product Description: Carbide Bur, Diamond Bur
 Product Part Numbers: Various

3. SCOPE & SUMMARY

The bur pattern selected will be chosen to cut a specific material in a specific application. The following table gives guidance:

Application	Bur Type		Material	Size (mm)	Speed (RPM)
Cavity Preparation	Carbide	Standard	Enamel/Dentine	010 to 023	< 450,000
Removal of Fillings	Carbide	Standard	Amalgam/Composite	010 to 018	60,000 to 120,000
Excavation	Carbide	Standard	Enamel/Dentine/Bone	010 to 023	< 2,000
Finishing Margins	Carbide	Finishing	Enamel	010 to 016	10,000 to 20,000
Finishing Restorations	Carbide	Finishing	Amalgam	012 to 023	18,000 to 30,000
Finishing Restorations	Carbide	Finishing	Composite	012 to 023	10,000 to 20,000
Finishing Restorations	Carbide	Finishing	Glass Ionomer	012 to 023	10,000 to 20,000
Cutting Bone	Carbide	Standard	Bone	018 to 027	500 to 3,000
Crown & Bridge Finishing	Carbide	Finishing	C&B Polymer	010 to 016	40,000 to 80,000
Crown & Bridge Metal Finishing	Carbide	Standard	Metals	018 to 027	< 30,000
Prosthetic Polymer Trimming	Carbide	Standard	Polymer	018 to 027	< 20,000
Cavity Preparation	Diamond		Enamel/Dentine	010 to 023	< 450,000
Finishing Margins	Diamond		Enamel	010 to 016	10,000 to 20,000
Finishing Restorations	Diamond		Composite	012 to 023	10,000 to 20,000
Finishing Restorations	Diamond		Glass Ionomer	012 to 023	10,000 to 20,000
Veneers	Diamond		Polymer	010 to 016	40,000 to 80,000
Veneers	Diamond		Ceramic	010 to 016	10,000 to 20,000
Crown & Bridge Finishing	Diamond		C&B Polymer	010 to 016	40,000 to 80,000
Crown & Bridge Metal Trimming	Diamond		Metals	018 to 027	<30,000
Prosthetic Polymer Trimming	Diamond		Polymer	018 to 027	<20,000
Endodontic Treatment & Crown Removal	Diamond		Zirconia	014 to 023	<450,000

4. INDICATIONS FOR USE, DOMAIN OF USAGE

Orthodontic burs can be used to cut or polish a wide variety of materials encountered in dentistry. These include tooth materials such as enamel and dentine, dental materials such as amalgam, composite, glass-ionomer cements, polymer and ceramic veneers and precious and non-precious alloys.

5. CONTRAINDICATIONS

It is the primary responsibility of the dental professional and/or orthodontist to identify any possible contraindications that may preclude the use of American Orthodontics' products.

6. SIDE EFFECTS

Orthodontic burs contain a small nickel content and should therefore not be used on individuals with a known sensitivity to this metal as in extreme cases it may cause hypersensitivity.

7. WARNINGS AND PRECAUTIONS

- Eye protection shall be worn to protect against ejected particles.
- Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- Ensure hand-pieces are maintained in good working order and remain correctly lubricated at all times.
- Move the bur continuously when in use so as to avoid localized heating.

- Never exceed the maximum speeds as shown in the above table as this may generate undesirable heat.
- Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to fail.
- Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken during re-processing and disposal. Suitable eye protection, gloves, and a mask should be worn when reprocessing.
- When removing burs from a blister pack, always utilize the Solo-Peel tab mechanism. Never use the burs to pierce the rear foil strip as this subjects the bur to adverse side loading and introduces undue stress.

8. PRE-STARTING PROCEDURES

Read all instructions and study details carefully before proceeding

- Prior to use inspect the bur for broken and/or damaged flutes, discard any potentially defective burs.
- Ensure the bur is fully seated and gripped in the hand-piece collet.
- Orthodontic burs are not supplied sterile. Clean and sterilize the burs before initial use and thereafter, prior to re-use in accordance with the below instructions.

For orthodontic burs, there are no special requirements for cleaning preparation unless infection control requires the use of a disinfectant, in which case a disinfectant agent validated for cleaning dental burs shall be used and the manufacturer's instructions followed.

9. STEP-BY-STEP INSTRUCTIONS

- a. **CLEANING:** Auto cleaning is the preferred process for cleaning. Use only validated washer disinfectors and appropriate agents validated for use on dental burs. When cleaning the burs follow the manufacturer's instructions.

If hand cleaning is the only available option, the burs shall be cleaned in a sink reserved specifically for this purpose. Rinse the burs under running cold water and keeping them immersed, brush thoroughly away from the body using a neutral cleaning or cleaning/disinfectant agent validated for use on dental burs. When brushing care shall be taken to avoid spreading contaminants by spraying or splashing. Use wire brushes with caution so as to safeguard against galvanic corrosion and discolouration.

Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided. Delays in re-processing must be kept to a minimum to avoid the risk of contaminant drying and thereby making cleaning more difficult.

After cleaning inspect the burs to ensure any traces of contamination have been removed. Repeat cleaning if required.

- b. **DRYING:** Dry the burs with paper towels or dry heat not exceeding 140°C.

- c. **STERILIZATION:** If using a vacuum autoclave, pack the burs into a dedicated instrument tray or pouch validated for sterilisation. If using a non-vacuum autoclave, the burs shall be contained in a dedicated bur stand with perforated lid.

Note: National legislation may require burs to be wrapped in pouches for processing in either type of autoclave system.

Autoclave the burs for a holding time of not less than 3 minutes at a temperature between 134 and 137°C. The holding time is the minimum time for which the minimum temperature is sustained.

The instructions from the autoclave manufacturer must be followed. In particular, care shall be taken not to exceed the maximum recommended load for the autoclave.

- d. **STORAGE:** The burs should be stored in the sterilisation container (bur stand or pouch) until required. Containers or pouches must be dry before opening to avoid recontamination of the contents from water. Storage should be in dry, clean conditions at ambient temperature.

10. DISCUSSION AND SUGGESTIONS

The above processes have been validated and found appropriate and effective for preparing debonding burs for reuse. It remains the responsibility of the re-processor to ensure that the equipment, materials and personnel used for such purposes, achieves the required results. This may require validation and monitoring of the process. Any deviation from these instructions shall be properly evaluated for effectiveness and any potentially adverse results.

The life of the bur is normally determined by wear and tear and NOT through re-processing. Burs should be routinely inspected following preliminary cleaning and again after re-processing.

15. STORAGE AND TRANSPORT CONDITIONS

There are no transport conditions that will negatively affect the product/medical device outside of harsh or rough handling, which could cause mechanical damage.

Store in a dry and clean environment at ambient temperature.

16. DISPOSAL CONSIDERATIONS

It is the primary responsibility of the dental professional and/or orthodontist to follow applicable laws relating to the disposal of used orthodontic medical devices.

17. WARRANTY LIABILITY

Buyer's remedies with respect to any claim arising out of any defect in any goods or services shall be limited exclusively to the right of repair or replacement of such goods (at the seller's option) or to repayment of the purchase price thereof. In no event shall seller be liable for any consequential or incidental damages including lost profits incurred by buyer with respect to any goods or services furnished by seller. Claims for damage or shortage must be made within 30 days of receipt of order.

In the event of burs being returned, please ensure any contaminated and/or potentially contaminated burs have been effectively cleaned, and are appropriately packaged for return

18. REGULATORY INFORMATION



American Orthodontics • 3524 Washington Avenue • Sheboygan, WI 53081 • www.americanortho.com



MT Promedt Consulting GmbH • Altenhofstrasse 80 • 66386 St. Ingbert, Germany



SEE INSTRUCTIONS
FOR USE



CONTAINS CHROMIUM
AND/OR NICKEL

CAUTION: Federal Law restricts this device to sale to or on the order of a dentist/orthodontist.
See www.americanortho.com for Symbol Glossary.

The information contained in the IFU is believed to be valid and accurate. American Orthodontics, however, makes no warranty, either expressed or implied, as to the completeness of information in all possible conditions. **Reasonable safety precautions must always be observed.**