

Diamond Rotary Dental Bur (Non-sterile)

Instructions for Use (IFU)



Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



1. SCOPE

These Instructions for Use (IFU) provide general instructions for the Diamond Rotary Dental Burs (Non-Sterile) and specific reprocessing instructions that are applicable to the cleaning and steam sterilisation of the multi-use Diamond Rotary Dental Burs prior to initial use, and there after every subsequent re-use.

These burs are supplied non-sterile for sterilisation before use and for use in combination with a rotary dental handpiece.

Prima Diamond Rotary Dental Burs (Non-sterile) are available with numerous head diameters, head shapes, shank sizes and working lengths.

The Predator Zirconia are further plated with a protective coating contributing to wear resistance. The range includes patterns designed to meet the needs of a wide range of applications.

Prima Diamond Rotary Dental Burs are manufactured from stainless steel with a nickel/diamond coating on the head of the bur.

2. DENTAL ROTARY BUR INDICATIONS FOR USE

These rotary burs are intended for a wide variety of restorative procedures including but not limited to removal of caries or old restorations, preparations of cavities for restorations, finishing of restorations, interproximal reduction (IPR), removal of crowns, orthodontic devices procedures and any other dental operation.

It can be used to cut, grind, or polish a wide variety of dental materials, including tooth material such as enamel, dentine, as well as dental materials such as amalgam, composite, zirconia, lithium di silicate, glass cements polymer and ceramic veneers and various alloys.

3. INTENDED PURPOSE

The rotary bur is intended for laboratory and dental applications in clinics and hospitals.

4. INTENDED USERS

Professional use – rotary burs are intended for dentistry and must only be used by dentists and other qualified professionals who are familiar with use of these burs based on their training and experience. Therefore, user training is not needed to ensure specified performance and safe use of the medical device.

For laboratory applications, the use of these burs must be by a licenced technician.

5. INTENDED POPULATION

All patients (human) in need of dental care as determined by a qualified professional.

6. CONTRAINDICATIONS AND WARNINGS

The use of Prima Dentals Diamond Rotary Dental Burs is contraindicated on any patient with known allergy to Nickel; nickel is listed within Proposition 65 - OEHHA (ca.gov) as having potential detrimental human impacts.

7. DEVICES IN COMBINATION WITH PRIMA DENTAL'S DIAMOND ROTARY DENTAL BURS

Prima Dental's Diamond Rotary Dental Burs are compatible with any approved handpiece that can be operated with FG shanks. The bur must always be positioned correctly within the handpiece before use. The security of the bur within the handpiece should be checked before use.

Maintain handpieces in good working conditions 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.

8. STORAGE (PRE-USE)

Store in a dry and clean environment at ambient temperature, within the original packaging.

9. SELECTION

The bur pattern selected will be chosen to cut a specific material in a specific application. The following table gives guidance and provides recommended RPM for the user.

The dental bur pattern and shape shall be selected at the physician's discretion and will be chosen according to the required application.

Table 1: Recommended operational speeds with respect to head diameter.

Head diameter 1/10mm	Maximum permissible speed (RPM)	Recommended operational speed (RPM)
007 - 010	450,000	100,000 - 220,000
011 - 014	450,000	70,000 - 220,000
015 - 018	450,000	55,000 - 160,000
019 - 023	300,000	40,000 - 120,000
024- 027	160,000	35,000 - 110,000
028 - 031	140,000	30,000 - 95,000
032 - 040	120,000	25,000 - 75,000
041 - 054	95,000	15,000 - 60,000
055 - 070	60,000	12,000 - 40,000
080 - 100	45,000	10,000 - 20,000

10. CLINICAL PRECAUTIONS AND WARNINGS

- The bur is to be used as per the following instructions by a dentists and other qualified professionals who are familiar with use of these burs based on their training and experience.
- Carefully read package labels to ensure appropriate use of the bur. Failure to do so may cause procedural delays or patient / user injury.
- Failure to follow this IFU may cause the following: possible damage to the tooth/restoration, injury to the patient or user, or possible aspiration or swallowing of the bur.
- Clean and sterilize the burs supplied in a non-sterile condition in accordance with the directions below before first use and before each reuse to avoid any risk of contamination.
- Gloves, eye protection and a mask should be worn when handling contaminated burs.
- Protect patient's eyes and vulnerable tissues when using these burs.
- Clinicians should wear eye protection and facemask when using these burs.
- Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- Ensure the bur is fully seated and gripped in the handpiece collet. Failure to follow these instructions may cause possible damage to the tooth, injury to the patient or user, or possible aspiration or swallowing of the bur.
- Do not use worn-out or dull burs as this may cause procedural delays or patient injury.
- Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to fail.
- 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 breakage which could cause patient or user injury.
- Never force a bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays or a badly seated bur.
- Do not exceed the maximum speeds as this may generate undesirable heat or bur damage/breakage.
- Paediatric diamonds burs should be used with mini handpiece intended for use with short shank burs and normal burs up to 20 mm in length.
- Observe the manufacturer's reprocessing materials/solutions information in order to ensure compatibility with bur materials for cleaning, disinfection and sterilization.
- The reprocessing materials/solutions exposure time and concentration specified by the manufacturer must be followed.
- Ultrasonic bath must not exceed temperatures of 42 °C because of the possible coagulation of protein.
- Burs that have not completely dried after cleaning and disinfection must be dried again (e.g. with compressed air) to avoid compromising the success of sterilization.
- Strong acids and strong bases may oxidize the stainless-steel shank.
- Avoid temperatures above 150°C.
- Never clean burs using metal brushes or steel wool.

11. REPROCESSING INSTRUCTIONS FOR DIAMOND ROTARY DENTAL BURS (MULTI-USE)

11.1. SCOPE

The reprocessing instructions detailed below apply only to reusable burs intended to be re-processed. Burs shall be reprocessed upon initial use and prior to being reused.

11.2. LIMITATIONS OF RE-USE

The end of life for the bur is determined by wear and damage in use for a maximum of six (6) re-uses (including re-processing cycles). The burs should be inspected for defects or damage during the cleaning process and prior to each re-use (up to maximum of 6 uses). If any defects or damage is observed OR following 6 re-uses, discard defective burs (refer to Section 11.11 for disposal).

Delay between use and reprocessing must be kept to a minimum to avoid contaminants drying, thereby making cleaning more difficult. The unclean dental burs can be immersed in the cleaning/disinfecting agent in accordance with manufacturer instructions. Prolonged/excessive storage should be avoided.

Caution: Do not leave burs immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the burs have been thoroughly cleaned first.

11.3. WARNINGS

Used bur should be considered as being contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient. Used burs are also considered as biohazard and need to be discarded as bio-hazard waste unless reprocessing procedures have been performed according to the instructions.

Due to the reduced effectiveness and reproducibility of manual cleaning, automated cleaning and steam sterilisation are the preferred processes for cleaning unused and soiled burs.

11.4. PRE-TREATMENT (FOR MANUAL AND AUTOMATED CLEANING)

Prior to use inspect the bur as per section 11.9 Inspection.

- 11.4.1. Rinse the burs for at least 1 min under running water (temperature < 35 °C/95 °F)
- 11.4.2. Soak the burs for the given soaking time (as per the cleaning material/solution instructions) in the cleaning solution and ensure the burs are fully submerged. The burs should be positioned with space between them to allow the surface area to be in contact with the solution.
- 11.4.3. During the soaking process the burs can be brushed with a soft brush to aid cleaning.
- 11.4.4. Subsequent ultrasonic treatment after soaking is recommended, for the minimum soaking time (as per recommendation in the instructions, but no less than 5 min). Ultrasonic bath must not exceed temperatures of 42 °C.
- 11.4.5. Check the burs for any visible remnants (e.g. bone or dentin particles), in case of visible contamination remaining repeat steps 1 to 3, if visible remnants cannot be removed discard the burs.

NOTE: For the purpose of the manual reprocessing validation performed, the cleaning agent gigazyme®, enzymatic cleaner, LOT: 1588793, Schülke & Mayr GmbH was used. Other equivalent reprocessing cleaning agents can be used upon local validation by the user.

Selection of cleaning solution/detergent should consider as a minimum the following:

- Selection based on suitability for cleaning of devices made of metallic materials contained in the device
- Consideration for relevant approvals e.g. VAH/DGHM, FDA/EPA clearance, CE marking).
- Aldehyde-free
- Suitability for ultrasonic cleaning
- Compatibility with the bur
- Further considerations related to cleaning solution/detergent:
- Pay special attention to the instructions with respect to concentration, temperature, soaking time and rinsing.
- Use only freshly prepared solution with sterile or low contaminated water (max. 10 germs/ml).
- Consider purified water with special attention for endotoxin levels (max. 0.25 units/ml).

11.5. MANUAL CLEANING

- 11.5.1. Clean with a suitable cleaning agent labelled for use on dental rotary burs or other types of reusable medical burs.
- 11.5.2. Prepare a fresh cleaning solution following the manufacturer's instructions for correct concentration, exposure time, water temperature and water quality (at least drinking water quality, consider purified water with special attention for endotoxin levels (max. 0.25 units/ml) and contamination (max. 10 germs/ml).
- 11.5.3. Disassemble the bur from the handpiece.
- 11.5.4. Only pre-cleaned burs should progress to the manual cleaning steps.
- 11.5.5. Soak the burs for the given soaking time (as per the cleaning material/solution instructions) in the cleaning solution and ensure the burs are fully submerged. The burs should be positioned with space between them to allow the surface area to be in contact with the solution.
- 11.5.6. During soaking process, the burs can be brushed with a soft brush to aid cleaning. Subsequent ultrasonic treatment after soaking is recommended, for the minimum soaking time (as per recommendation in the instructions, but no less than 5 min).
- 11.5.7. Remove the burs from the cleaning solution and rinse them at least three times intensively (for at least 1 min) with water. Consider water quality (at least drinking water quality or purified water with special attention for endotoxin levels (max. 0.25 units/ml) and contamination (max. 10 germs/ml)).
- 11.5.8. Inspect the burs (see section 11.9 Inspection).
- 11.5.9. Dry the bur using a non-shedding wipe or compressed air.

NOTE: For the purpose of the manual reprocessing validation performed, the cleaning agent gigazyme®, enzymatic cleaner, LOT: 1588793, Schülke & Mayr GmbH was used. Other equivalent reprocessing cleaning agents can be used upon local validation by the user.

11.6. DISINFECTION

- 11.6.1. Soak the disassembled burs for the given soaking time in the disinfectant solution so that the burs are sufficiently covered. and ensure the burs are fully submerged. The burs should be positioned with space between them to allow the surface area to be in contact with the solution.
- 11.6.2. Remove the burs from the disinfectant solution and rinse them at least five times intensively (at least 1 min) with water. Consider water quality (at least drinking water quality or purified water with special attention for endotoxin levels (max. 0.25 units/ml) and contamination (max. 10 germs/ml)).
- 11.6.3. Dry and pack the burs immediately after the removal.

NOTE: For the purpose of the manual disinfection validation performed, the disinfectant 3% Gigasept Instru AF (Schülke & Mayr GmbH, Norderstedt) was used with a 15 min exposure time. Other equivalent reprocessing disinfectants can be used upon local validation by the user.

11.7. AUTOMATED CLEANING AND DISINFECTION

Contamination must be removed prior to automatic reprocessing (see section 11.4 Pre-treatment).

- 11.7.1. Place the burs in the washer/disinfector in a suitable small parts tray or on the load carrier such that the burs do not touch one another.
- 11.7.2. Close the washer disinfector and start program.
- 11.7.3. Run the automatic wash cycle:
 - Step 1 Pre-wash cold tap water for 1 minute.
 - Step 2 Cleaning 0.5% cleaner 55°C for 5 minutes with demineralised water
 - Step 3 Rinsing with demineralised water for 1 minute
 - Step 4 Thermal disinfection with demineralised water >90°C for 5 minutes
- 11.7.4. After thermo-disinfection, a drying step can be added to the program of the washer/disinfector
- 11.7.5. After the program has completed, remove the burs from the disinfector.
- 11.7.6. Check the load is dry, if necessary, dry the burs using a non-shedding wipe or compressed air.
- 11.7.7. Visually inspect all the burs for cleanliness with the aid of magnification if necessary. If traces of contamination or residues are identified repeat the cleaning process.
- 11.7.8. Check all burs for signs of damage or deterioration (see section 11.9 Inspection). Any found with evidence of damage or deterioration should be disposed of immediately according to the disposal instructions (see section 11.11).

NOTE: For the purpose of the automated cleaning validation performed, the washer-disinfector type Miele Professional PG8581 was used with the cleaner **Neodisher® Mediclean Dental** (0.5%, from Dr. Weigert) in the Vario TD program. The validated program resembles an A0 value of >3000s. The burs were placed in an instrument basket Miele E473/2.

Please also consider local requirements including Health Technical Memorandum 01-05 – Decontamination in primary care dental practices, where applicable.

11.8. STERILISATION USING STEAM

For all burs labelled for re-use.

PACKAGING FOR STERILIZATION	<p>When using an autoclave with a pre-vacuum cycle, place the burs in appropriate bur trays or pack them in pouches validated for steam sterilization.</p> <p>NOTE: Local legislation for sterilization may require that dental burs are wrapped in pouches for processing in either type of autoclave.</p>								
STERILIZATION	<p>Follow the autoclave manufacturer's instructions to sterilize the burs. Care must be taken not to exceed the maximum recommended load for the autoclave.</p> <p>Steam sterilization has been validated in an autoclave for pre vacuum for holding times as follows: 3 minutes at a temperature of 132°C (3 x dynamic air-removal steam sterilization) and drying time of 15 minutes (under a separate drying validation).</p> <p>The holding time is the minimum time for which the minimum temperature is sustained.</p> <p>NOTE: For the purpose of the sterilisation validation performed, the burs were wrapped in Steriking® See-Through Heat Sealable Rolls (K953776), sterilisation packing acc. EN ISO 11607. Sterilisation was performed in a Tuttnauer ELARA 11-D (K090783).</p> <p>Bur blocks can be used for sterilization purposes for immediate use only.</p> <p>1) Place the packaged burs in the sterilization chamber.</p> <p>2) Start the program (the validated time was three (3) minutes as a minimum, longer time is also possible).</p> <table><tr><th>Sterilisation type</th><th>Cycle duration minutes minimum (minutes)</th><th>Cycle temperature (°C)</th><th>Drying time (minutes)</th></tr><tr><td>Pre-vacuum</td><td>3</td><td>134°C</td><td>15</td></tr></table> <p>3) Remove the burs at the end of the program and allow them to cool down.</p> <p>4) Check the packaging for possible damage and screening effects.</p> <p>5) Faulty/ damaged packaging must be considered as being non-sterile. The burs must be repacked and re-sterilized.</p>	Sterilisation type	Cycle duration minutes minimum (minutes)	Cycle temperature (°C)	Drying time (minutes)	Pre-vacuum	3	134°C	15
Sterilisation type	Cycle duration minutes minimum (minutes)	Cycle temperature (°C)	Drying time (minutes)						
Pre-vacuum	3	134°C	15						

STORAGE	The bur should be stored in the sterilization pouch until required. Storage should be in dry, clean conditions and at ambient temperature.
----------------	--

11.9. INSPECTION

Inspect the bur for any signs of damage or deterioration such as corrosion. Pay particular attention to the head of the bur for any loose material, coating abnormalities, wear, chips, flute damage, cracks or bending. Any burs found with any damage or deterioration which may cause concern should be discarded.

11.10. VALIDATION OF CLEANING AND STEAM STERILIZATION

The above detailed processes have been validated as being capable of preparing Prima's diamond rotary dental burs for reuse. It remains the responsibility of the re-processor to ensure that the reprocessing as actually performed, using the equipment, materials and personnel in the reprocessing facility, achieve the required results. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.










11.11. DISPOSAL

Used burs are considered as biohazard and need to be discarded as bio-hazard waste in accordance with local regulations.

11.12. TRACEABILITY

Each package includes lot number **LOT** on its label. This number must be quoted in any correspondence regarding to the bur.

12. EXPLANATION OF SYMBOLS

Symbol	Explanation	Symbol	Explanation
	Batch code		Catalogue number
	Manufacturer	Prima Dental Manufacturing Ltd. Gemba House, Stephenson Drive, Gloucester, GL2 2HA, United Kingdom	
	Non-Sterile Device		Consult instructions for use
	Date of Manufacture	Rx ONLY	Device for professional use only (US FDA)
	Caution		
	Do not use if packaging is damaged		Medical Device

13. CONTACT US

For further support, please contact us quoting the 7-digit LOT number printed on the device label:

Phone: +44 1452 729751

Email: sales@primadental.com

Revision A17 Issue Date: 18/08/2025