



INSTRUCTIONS FOR USE

# Solo Diamond®

Premium Diamond Burs

**CAUTION:** Federal law restricts this device for sale by or on order of a licensed dental practitioner.

**Product Description:** Premier’s Solo Diamond Premium Diamond Burs are rotary devices made of a stainless-steel shank with diamonds coated at the working end to produce efficient grinding of a tooth structure. The devices are available in several different shapes, head-diameters and working lengths. The Solo Diamonds are provided gamma sterilized with a validated 5-year pouch seal integrity to reduce cross-contamination.

**Intended Use:** Solo Diamond Premium Diamond Burs are sterile single-patient use diamonds used for restorative and prosthodontic dental procedures such as crown and bridge preparations, and cavity preparations. They are designed to fit into standard dental handpieces, which provides rotational force allowing the dental professional to grind hard structures in the mouth such as teeth and bones, as well as plastics, porcelains, metals, and other restorative materials.

**Sterility:**

- Solo Diamond Premium Diamond Burs are gamma sterilized with sterilization shelf life of 5 years printed on packaging.
- Do not re-sterilize. Single-patient use only.

**Storage and handling Conditions:**

- Always store the instruments in the original sterile protective packaging.
- Dental burs made of diamond, tungsten carbide and steel should be stored in a moisture free environment and protected against contaminants. This helps preventing the possibility of corrosion.

**Expiration:** Do not use after the sterilization shelf life date printed on the packaging.

**Contraindications:**

- Patient allergic to nickel and nickel alloys.
- The use of Solo Diamond Premium Diamond Burs with more than the recommended speed limits may result in a performance failure.
- Sterility cannot be guaranteed if package is opened or damaged prior to use.
- Should not be re-sterilized
- Intended for single-patient use only.

**Warnings:** This product may contain nickel and should not be used on patients with known allergic reactions to nickel or nickel alloys.

**Precautions:**

- Burs are sterile & single-patient use only. Do not use for more than one patient.
- Do not use if package is damaged/broken prior to use.
- Prior to use inspect the bur for breakage and/or damage, discard any defective burs.
- Patients, dentists and dental assistants should always wear eye protection, and other appropriate personal protective equipment (PPE) when using dental diamond burs to protect against particles ejected during use.
- Surgical masks shall be worn and high vacuum evacuation should be used to avoid inhalation of aerosol and/or dust generated during the procedure.
- Extremely tapered instruments will wear faster at the tip due to the smaller size. To maintain the longevity of these instruments, careful preparation with less contact pressure is important. Apply spiral instruments over their entire grinding surface.
- Do not apply excessive pressure on the operating bur as this could cause excessive heat and may cause the bur to fail.

**Instructions for Use (IFU):**

- Insert the diamond bur all the way into the chuck of the handpiece. Do not extend the bur from the chuck. Do not force diamond bur into the handpiece. In case of difficult access, check both handpiece turbine and diamond bur, and refer the handpiece instructions for troubleshooting.
- Securely tighten or latch the bur in the handpiece chuck. Loose and extended burs may be ejected from the handpiece, break or cause injury.
- Ensure the air pressure/electrical input to the handpiece does not exceed the manufacturer’s recommended settings.
- Ensure the bur is fully seated and securely gripped in the handpiece collet prior to use, and run the handpiece to ensure the bur is rotating prior to contact with the intended surface.
- The use of an adequate supply of water spray is recommended to ensure reliable cooling of the material being worked on to prevent unintended pulpal damage.
- Avoid tilting, levering, or applying excessive pressure to the bur during use that may result in slowing or “bogging” down. (Increased danger of breakage)
- Avoid using the diamond bur with a heavy transverse cutting pressure. Use light pressure and a brushing stroke.
- Observe permissible speeds and move the bur continuously when in use to avoid heating and/or damage to the bur. Use light pressure and a brushing stroke.

**Table indicating recommended and maximum allowable speed for varying head diameters:**

Solo Diamond Premium Diamond Burs – guidance for maximum RPM		
Instrument head diameter 01/10 (mm) - ISO	Maximum Permissible Speed (RPM)	Recommended Operational Speed (RPM)
007 - 010	450000	100000 - 220000
012 - 014	450000	70000 - 220000
016 - 018	450000	55000 - 160000
021 - 023	300000	40000 - 120000
025 - 027	160000	35000 - 110000
029 - 031	140000	30000 - 95000
033 - 040	120000	25000 - 75000
042 - 050	95000	15000 - 60000



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