



Solo Diamond®

Premium Diamond Burs

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.

Description of Device and Contents:

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.

Contraindications:

Dental diamond burs should not be used on patients who are allergic to any of the materials used in the bur, such as nickel or other metals.

Sterility cannot be guaranteed if package is opened or damaged prior to use.

PRECAUTIONS:

- Burs are sterile & single-patient use only. Do not use for more than one patient.
- Burs should be inspected before each use to ensure that they are not damaged or defective.
- Bur should be tested within the handpieces prior to use in patient's mouth.
- Do not apply excessive pressure on the operating bur as this could cause excessive heat and may cause the bur to fail.
- 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, 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.
- As a result of normal use, patients may experience discomfort, pain, or bleeding during or after the use of dental diamond.

Warnings:

Burs should be used at the recommended speed and with appropriate cooling to prevent overheating, damage to the burr and damage to the tooth or surrounding tissues. Do NOT surpass maximum speed recommendations especially when using burs with larger heads.

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

Do NOT reprocess or re-sterilize. Intended for single-patient use.

Some patients may be allergic to the materials used in the bur, which can cause a range of symptoms from mild itching and redness to severe allergic reactions.

Adverse Reactions:

Overheating or damage to tooth structure or surrounding tissue may occur if instructions are not followed.

If a serious incident has occurred in relation to the device, please report the incident to the Manufacturer and/or competent authority of the member state where the device was used.

Materials

Stainless steel electroplated with nickel.

Contents and Setup:

Each box shall contain 25 individually packed and sterile Solo Diamond Burs.

Directions for Use:

- 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

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 should be stored in a moisture free environment and protected against contaminants. This helps prevent the possibility of corrosion.

Disposal:

Dispose the instruments as biohazardous medical waste in accordance to facility or institutional guidelines/procedures after each use on a patient.

For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbols

A full explanation of symbols used on Premier Dental Packaging and literature is located at premierdentalco.com/symbol-glossary

Symbols	Symbol Meaning
	Single-use only
	Sterilized using irradiation (Gamma)
	Manufacturer
	Do not use if package is damaged
Rx ONLY	Federal law restricts this device for sale by or on order of a licensed dental practitioner.

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