

1 Scope and product description

These instructions apply to all BurDental rotary instruments for use on patients: diamond-coated burs (FG, RA, HP), tungsten carbide burs and cutters, sintered diamond instruments, diamond-impregnated and silicone rubber polishers, abrasive stones and wheels, and brushes. Instruments are supplied **non-sterile**. Instrument type, shank, ISO size and maximum permitted speed are printed on each pack.

Shank	ISO code	Ø / length	Handpiece
FG	314 (std) · 315 (long) · 316 (extra long)	1.60 mm · 19 / 21 / 25 mm	Air turbine, high-speed contra-angle
RA / CA	204	2.35 mm latch · 22 mm	Low-speed contra-angle
HP	104	2.35 mm · 44 mm	Straight handpiece, laboratory micromotor
CAD/CAM	–	3 / 4 / 6 mm as specified	Milling machine collet

2 Intended use and users

Intended use: removal, shaping, finishing and polishing of hard tooth substance, bone, and dental restorative materials (composite, amalgam, metal alloys, ceramics, zirconia, acrylics) in the dental practice and dental laboratory, and milling of CAD/CAM blanks.

Intended users: licensed dentists, dental surgeons, dental hygienists and dental technicians trained in rotary instrumentation. **Patient population:** all patients requiring restorative, prosthetic, surgical or preventive dental treatment.

Contraindications: none known when used as intended. Do not use an instrument for a material or indication for which it is not specified, and do not use damaged, bent or worn instruments.

3 Before each use

- Clean, disinfect and – for all invasive use – sterilise the instrument (section 7). New instruments are not sterile.
- Inspect under good light, ideally 6–8× magnification: reject instruments with bent shanks, chipped or missing diamond grit, broken or dull blades, cracked or hardened polisher heads, or corrosion.
- Use only clean, maintained handpieces that run true. Insert the shank fully and confirm it is locked.
- Bring the instrument to working speed **before** contact and check that it runs concentrically; discard any instrument that vibrates or wobbles.

4 Safe operation

- **Speed.** Never exceed the maximum speed printed on the pack (section 5). Larger heads, longer shanks and flexible instruments require lower speed.
- **Pressure.** Light, controlled pressure (guide value 0.3–2 N), instrument always moving. Excess pressure causes heat, blade fracture, grit loss and iatrogenic damage.
- **Cooling.** Water spray for all preparation on the patient: ≥ 50 ml/min directed at the working part. Long (≥ 25 mm) and large-head (> 2 mm) FG instruments and zirconia diamonds need particularly good cooling.
- **Working part.** Use the whole working length, not the tip only; end-cut only with end-cutting shapes.
- **No levering.** Never lever, jam or stop the instrument against the tooth.
- **Protection.** Eye protection, mask and gloves for the team; high-volume suction; protect the patient's eyes and soft tissue, rubber dam where indicated.
- **Polishers and brushes.** Low speed, no pressure, in the medium → fine → ultra-fine sequence on the pack; dry or with light water spray, never overheated.
- **Laboratory instruments (HP, CAD/CAM).** Dust extraction, eye protection and respiratory mask; never used on patients.

5 Maximum permitted speed

The binding value is the one printed on each pack. Where no value is printed, do not exceed the limits below.

Instrument group	Shank	Max. speed (min ⁻¹)	Typical working speed
Diamond burs, head ≤ 2.0 mm	FG	450 000	160 000 – 300 000
Diamond burs, head > 2.0 mm or long shank	FG	300 000	120 000 – 200 000
Zirconia diamond burs (fine grit)	FG	300 000	160 000 – 200 000
Carbide burs (cutting, finishing)	FG	450 000	160 000 – 300 000
Surgical carbide burs, 25–28 mm	FG / FGXL	200 000	100 000 – 160 000
Diamond and carbide burs	RA	40 000	10 000 – 30 000
Diamond and silicone polishers, Ø ≤ 6 mm	FG / RA	20 000	5 000 – 10 000
Polishers and wheels, Ø 10–14 mm	RA / HP	12 000	3 000 – 8 000
Abrasive stones (white / green), FG	FG	160 000	40 000 – 100 000
Abrasive stones, RA / HP	RA / HP	25 000	8 000 – 15 000
Carbide cutters, head ≤ 6 mm	HP	35 000	15 000 – 25 000
Diamond HP burs and sintered diamonds	HP	30 000	10 000 – 20 000
Brushes, felt and cloth wheels	HP	10 000	1 500 – 5 000
CAD/CAM milling burs	3 / 4 / 6 mm	per milling-machine manufacturer's strategy for the blank material	

Warning – exceeding the maximum speed can cause the instrument to fracture or fly out of the handpiece, with risk of injury to patient and operator, and produces heat that can damage pulp, bone and restorative materials.

6 Possible adverse effects and warnings

- **Thermal damage** to pulp or bone from insufficient cooling, blunt instruments or excess pressure (necrosis, heterotopic ossification after surgical use).
- **Mechanical injury** to soft tissue, adjacent teeth or the airway from slipping, fractured or dropped instruments; keep a firm finger rest, use a rubber dam or throat pack.
- **Instrument fracture** from levering, over-speed, re-use beyond its service life, or corrosion after incorrect reprocessing.
- **Cross-infection** if reprocessing is incomplete. Instruments that cannot be cleaned to a visually clean state must be discarded.
- **Aerosols and dust** of tooth substance, metal, ceramic or acrylic: suction, extraction and respiratory protection.
- **Material compatibility.** Diamond for enamel, ceramics and zirconia; carbide for dentine, metal, acrylic and composite. Diamond on metal or carbide on sintered zirconia shortens life and overheats the restoration.
- **Single-use items** (marked "do not reuse", e.g. prophylaxis brushes, disposable diamonds) are for one patient only and must not be reprocessed.

Report any serious incident related to a BurDental instrument to the manufacturer and to the competent authority of the country in which the user is established.

7 Reprocessing of reusable instruments

Instruments used on patients are **critical medical devices**: they must be cleaned, disinfected and steam-sterilised before first use and after every use. Reprocessing is carried out by trained staff using validated equipment. Where national requirements are stricter, they take precedence.

- 1 **At the point of use.** Remove from the handpiece and wipe off blood, tissue, composite and cement immediately with a lint-free cloth; keep in a covered tray and start cleaning within 1 hour.
- 2 **Pre-disinfection / soaking.** Immerse completely, free of air bubbles, in an aldehyde-free, alcohol-free alkaline or enzymatic instrument disinfectant with corrosion protection approved for rotary instruments; follow the agent's concentration and contact time (typically 3–4 %, 5–15 min). No hydrogen peroxide or chlorine agents; bath $\leq 45\text{ }^{\circ}\text{C}$.
- 3 **Cleaning – choose one method.**
 - a) **Automated (recommended):** washer-disinfector to ISO 15883 with thermal disinfection at $\geq 90\text{ }^{\circ}\text{C}$ for 5 min ($A_0 \geq 3000$).
Instruments in a bur stand or sieve tray, not touching; mildly alkaline CE-marked cleaner; neutralisation and drying phases observed.
 - b) **Ultrasonic:** 35–45 kHz, 5–10 min in fresh instrument cleaner, instruments held apart in a stand. Preferred for instruments with recesses (e.g. cross-cut carbides, spiral polishers).
 - c) **Manual:** stiff nylon brush (never metal) under running water until visually clean, then rinse. Manual cleaning must be followed by disinfection (step 2 agent) and does not replace thermal disinfection where a washer-disinfector is available.
- 4 **Rinse and dry.** Rinse with deionised or clean running water; dry with filtered compressed air or a clean lint-free cloth. Residual moisture causes corrosion and staining.
- 5 **Inspect.** Under 6–8 $\times$ magnification check for residual soil, corrosion, bent shanks, chipped or worn working parts; re-clean if soil remains, discard damaged or worn instruments.
- 6 **Package.** Place instruments in a bur stand or cassette and seal in a sterile-barrier pouch or container conforming to ISO 11607-1 / EN 868. Do not overload.
- 7 **Sterilise – steam (autoclave) only.** Fractionated pre-vacuum cycle, class B (or class S where the instrument has no recesses), validated to EN 13060 / ISO 17665:
 - **134 $^{\circ}\text{C}$, ≥ 3 min** holding time (5 min recommended), or
 - **121 $^{\circ}\text{C}$, ≥ 15 min** holding time.
 Drying ≥ 10 min; feed water to EN 13060. Unwrapped immediate-use sterilisation only in an emergency.
- 8 **Store.** Packaged, dry, dust-free, at room temperature, away from chemicals, in a closed cabinet; check pouch integrity and expiry before opening.

Material limitations

Instrument type	Steam 134 $^{\circ}\text{C}$	Steam 121 $^{\circ}\text{C}$	Dry heat 180 $^{\circ}\text{C}$	Ultrasonic	Washer-disinfector
Diamond burs, stainless steel shank	✓	✓	✓	✓	✓
Tungsten carbide burs and cutters	✓	✓	✓	✓	✓ ¹
Diamond-rubber and silicone polishers	✓ ²	✓	✗	✓	✓
Abrasive stones and wheels	✓	✓	✓	✓	✓
Brushes, felt and cloth wheels	✓ ²	✓	✗	✗	✗
Carbon-steel (non-stainless) burs	✗	✗	✓	✓ ³	✗
Single-use instruments	Do not reprocess – dispose after one patient				

¹ Carbide blades may discolour in alkaline washer-disinfector programmes; this does not affect function. ² Limit to 134 $^{\circ}\text{C}$ / 3–5 min; repeated long cycles harden the polisher head. ³ Only with a corrosion-inhibiting agent; dry immediately.

Service life and disposal

Instrument life depends on the material worked, pressure, speed and reprocessing, so a fixed number of cycles cannot be stated; the inspection in step 5 decides. As a guide: diamond burs after 5–10 preparations, carbide burs when cutting efficiency drops, polishers when the head is hardened, cracked or worn to the shank. Dispose of used instruments as contaminated sharps under local regulations.

8 Transport and storage of new instruments

- Original pack until first use; 5–40 $^{\circ}\text{C}$, $\leq 80\%$ RH, protected from dust, moisture, sunlight and chemicals.
- Keep the pack or label with lot number for traceability, also during use. Handle by the shank; do not drop.

9 Symbols used on labels and packaging

REF Catalogue number	LOT Batch / lot number	MD Medical device
MFR Manufacturer	DATE Date of manufacture	IFU Consult instructions for use
2 ϕ Do not reuse	NS Non-sterile	134$^{\circ}\text{C}$ Steam-sterilisable at stated temperature
min⁻¹ Maximum permitted speed	! Caution – read accompanying information	CE CE mark, notified body 0197

10 Manufacturer

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The current version of this document is available at www.burdental.com/ifu.html. Product-specific data (ISO number, head size, grit, maximum speed) are given on the product label and on the product page. It does not replace user training or the instructions of the handpiece, steriliser, cleaning-agent or milling-machine manufacturer.

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