

1 Scope and product description

These instructions apply to all BurDental hand-held abrasive strips: a flexible stainless-steel strip, electroplated with natural diamond grit on one side (WS, OS) or on both sides (SWS), with an uncoated centre section for insertion into the interproximal contact without abrading it, and uncoated ends for finger grip. The range comprises the WS37 and SWS37 finishing strips (medium, fine, extra-fine), the OS05 – OS40 orthodontic IPR strips and the OSK-50 IPR kit. Strips are reusable and are supplied **mechanically clean, non-sterile**, in tubes of 10. Grit size and strip thickness are identified by the colour-coded cap and printed on the pack.

Series	Coating	Grit / thickness	Size	Main use
WS37 · WS37F · WS37EF	Single-sided	Medium 45 µm (blue) · fine · extra-fine 15 µm (yellow)	148 × 3.75 mm, perforated; 0.13 mm (M) / 0.08 mm (EF)	Finishing and polishing of interproximal restorations and enamel
SWS37 · SWS37F · SWS37EF	Double-sided	Medium · fine · extra-fine	148 × 3.75 mm	As WS, both proximal surfaces in one pass
OS05 – OS40	Single- or double-sided	Per pack; stepped sequence OS40 → OS10	0.05 – 0.40 mm thick, for bow-type holder	Interproximal enamel reduction (IPR) in orthodontic and aligner treatment

2 Intended use and users

Intended use: manual contouring, finishing and polishing of interproximal surfaces of teeth and restorative materials (composite, glass ionomer, ceramic, metal), removal of interproximal excess material, and controlled interproximal enamel reduction (IPR) to create space in orthodontic and clear-aligner treatment.

Intended users: licensed dentists, orthodontists, dental hygienists and therapists within their scope of practice. No additional training beyond dental professional education is required. **Patient population:** patients requiring restorative finishing or orthodontic space creation; permanent and mixed dentition.

Contraindications: the strip base is stainless steel containing nickel – do not use on patients with a known nickel allergy. Do not use on teeth with enamel too thin for the planned reduction, on exposed dentine without the clinician's assessment, or where the strip cannot be passed through the contact without force.

3 Before each use

- Clean, disinfect and sterilise the strip before first use and after every patient (section 7). New strips are not sterile.
- Unpack carefully without bending or kinking the strip. Inspect under good light, ideally with magnification: discard strips with kinks, tears, cracks, missing diamond grit, corrosion or a dull surface.
- Select the thinnest strip or finest grit that will achieve the intended result and work up only if needed.
- Protective equipment for the team: gloves, mask, eye protection. Protect the patient's eyes; use high-volume suction and, where indicated, a rubber dam, as abrasion produces fine particles of enamel and restorative material.

4 Technique

- **Grip.** Hold the uncoated ends between thumb and index finger of each hand, or mount in a compatible strip holder, keeping the strip taut and flat.
- **Insertion.** Introduce the uncoated centre section through the contact point from the buccal side with a gentle rocking motion; never force the strip. Then slide the coated section into the area to be worked. For single-sided strips the coated side faces the tooth to be treated; the plain side protects the neighbouring tooth.
- **Motion.** Short, light buccal-lingual sawing strokes, following the contour of the proximal surface (cervical to occlusal as required). Light finger pressure only; the diamond does the work. Do not apply vertical force into the papilla and do not exert sideways or twisting force on the strip.
- **IPR.** Reduce in small increments, checking the space with a calibrated IPR gauge after each pass. Use water or air-water spray to cool and to clear debris. Finish with an extra-fine or polishing strip to leave a smooth enamel surface, then apply fluoride according to local protocol.
- **Removal.** Withdraw the strip in a straight line through the contact. If it jams, release the tension and work it free with the sawing motion; never twist or pull sharply.

Warning – strip fracture. Twisting, bending, kinking, excessive pressure or continued use of a worn or corroded strip can cause the strip to tear or break, with risk of injury to soft tissue and of aspiration or ingestion of the fragment. Stop at once if a strip tears, retrieve all fragments and discard the strip.

5 Possible adverse effects and warnings

- **Over-reduction** of enamel or restoration margins from coarse grit, excess pressure or omitting gauge checks; irreversible.
- **Thermal irritation and sensitivity** from prolonged dry abrasion of enamel; work intermittently with cooling.
- **Soft-tissue injury** to gingiva, papilla, lips or tongue from the strip edge or from slipping; keep a firm finger rest, retract soft tissue, protect the papilla.
- **Rough enamel surface** after IPR if not finished and polished, with increased plaque retention and caries risk.
- **Nickel sensitisation** on contact with the steel base in susceptible patients (see contraindications).
- **Cross-infection** if reprocessing is incomplete. The rough diamond surface retains tissue; strips that cannot be cleaned to a visually clean state under magnification must be discarded.
- **Particles and aerosol** of enamel and restorative material: suction, mask and eye protection for team and patient.
- Do not use strips in a rotary handpiece or at high speed; they are hand instruments only.

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

6 Service life and disposal

Strips are reusable medical devices in the **semi-critical / critical** category depending on use (contact with intact enamel, or with gingiva and blood). Their service life is limited by wear of the diamond coating, by fatigue of the steel and by the reprocessing cycle; a fixed number of uses cannot be stated. Discard a strip when the inspection in step 5 of section 7 shows a dull or bald coating, a kink, tear or crack, corrosion or discolouration with pitting. Mild grey discolouration after steam sterilisation without pitting is harmless. Dispose of used strips as contaminated sharps under local regulations.

7 Reprocessing (ISO 17664-1)

Before first use and after every patient. Carried out by trained staff with validated equipment; stricter national requirements take precedence. Not suitable: chemical (cold) sterilisation, dry-heat sterilisation, chemiclave, cleaning agents containing chlorine, chloride or hydrogen peroxide, strong acids or bases – all of these corrode the steel base or loosen the diamond coating.

- 1 **At the point of use.** Wipe off blood, enamel dust and restorative debris immediately with a damp lint-free cloth; keep strips flat in a covered tray, do not let them dry out, and start cleaning within 1 hour.
- 2 **Pre-disinfection / soaking.** Immerse fully, laid flat and not piled on each other, in an aldehyde-free, alcohol-free, pH-neutral to mildly alkaline enzymatic instrument cleaner with corrosion protection; follow the agent's concentration and contact time (typically 5–15 min). Bath ≤ 45 °C. Do not soak longer than the agent's stated time.
- 3 **Cleaning – choose one method.**
 - a) **Ultrasonic (recommended):** 35–45 kHz, 5–10 min in fresh instrument cleaner, strips held in a clamp, holder or mesh basket so that they lie flat and do not touch; bath ≤ 45 °C.
 - b) **Manual:** soft nylon brush (never metal or abrasive pads) under running water, brushing along the strip on both sides for at least 1 min until visually clean, then rinse 1 min. Follow with step 2 agent or ultrasonic cleaning.
 - c) **Washer-disinfector** to ISO 15883 (thermal disinfection ≥ 90 °C, 5 min, A₀ ≥ 3000) only in a fixed holder that keeps strips flat; mildly alkaline cleaner with neutralisation. Loose strips may be bent or lost in the chamber.
- 4 **Rinse and dry.** Rinse thoroughly with deionised or clean running water; dry at once with filtered compressed air or a clean lint-free cloth. Residual moisture causes corrosion.
- 5 **Inspect – critical control point.** Under 6–8× magnification check both sides of the coated section for residual soil trapped in the diamond grit, and the whole strip for kinks, tears, corrosion or bald areas. Re-clean if soil remains; discard damaged or worn strips.
- 6 **Package.** Lay strips flat, singly or in a strip holder, in a sterile-barrier pouch or container conforming to ISO 11607-1 / EN 868. Do not fold the strip to fit the pouch; do not overload.
- 7 **Sterilise – steam (autoclave) only.** Fractionated pre-vacuum cycle, class B (or class S), validated to EN 13060 / ISO 17665:
 - 134 °C, ≥ 3 min holding time (5 min recommended), or
 - 121 °C, ≥ 15 min holding time.
 Drying ≥ 10 min; feed water to EN 13060. Allow to cool before handling. Unwrapped immediate-use sterilisation only in an emergency.
- 8 **Store.** Packaged, flat, dry and dust-free at room temperature, away from chemicals, in a closed cabinet; check pouch integrity and expiry before opening.

Material limitations

Strip type	Steam 134 °C	Steam 121 °C	Dry heat	Chemical / cold sterilisation	Ultrasonic	Washer-disinfector
WS / SWS diamond finishing strips	✓	✓	✗	✗	✓ ¹	✓ ²
OS diamond IPR strips	✓	✓	✗	✗	✓ ¹	✓ ²
Strip holder / handle (stainless steel)	✓	✓	✓	✗	✓	✓

¹ Only clamped or in a holder, lying flat. ² Only in a fixed holder; manual or ultrasonic cleaning is preferred for strips.

The reprocessing steps above have been validated by the manufacturer as capable of preparing BurDental strips for reuse. The user remains responsible for ensuring that the reprocessing as actually performed, with the equipment, materials and personnel in the reprocessing facility, achieves the required result, and for routine monitoring and validation of that process.

8 Transport and storage of new strips

- Keep in the original tube until first use; 5–40 °C, ≤ 80 % RH, dry, protected from dust, sunlight and chemicals.
- Keep the tube label with catalogue and lot number for traceability, also during use. Remove strips from the tube one at a time without bending.

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
NS Non-sterile	134°C Steam-sterilisable at stated temperature	DRY Keep dry
! Caution – read accompanying information	Ni Contains nickel	UKCA UKCA mark (Class I, self-declared)

10 Manufacturer

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The current version of this document is available at www.burdental.com/ifu.html. Product-specific data (grit, thickness, width, coating sides) are given on the product label and on the product page. This document does not replace user training or the instructions of the steriliser, cleaning-agent or strip-holder manufacturer. Rotary instruments are covered by document BD-IFU-01.

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