



ROUND FLEX

RoundFlex Polishing Discs

Dental Finishing and Polishing Discs

GENERAL INFORMATION

Kagayaki RoundFlex is a family of dental finishing and polishing discs, offered as RoundFlex, RoundFlex T, RoundFlex M, and RoundFlex H, in coarse, medium, fine, and extrafine grit. Disc diameter, colour-coding, and mandrel supply vary between product lines; see "Technical Specifications" and "Package Contents" below and the article number on the product packaging (label).

RoundFlex, RoundFlex T, and RoundFlex M discs are mounted on a mandrel that connects the disc to a compatible dental handpiece and are supplied together with one or more mandrels, as indicated on the product packaging (label). RoundFlex H discs are supplied without a mandrel. All mandrels are made of stainless steel and are reusable.

The disc itself is intended for single use only and must not be reprocessed. The mandrel is reusable and must be cleaned, packaged, and steam sterilized before first use and after each patient use; see "Cleaning and Sterilization of the Mandrel" below.

The discs and mandrels are supplied non-sterile.

INTENDED PURPOSE AND INDICATIONS FOR USE

RoundFlex discs are intended for the step-by-step mechanical finishing of the surface of dental restorations: removal of excess restorative material, shaping of the final anatomical form, smoothing of roughness, and production of a smooth, glossy surface.

The discs are indicated for treating the oral, vestibular, contact (approximal), and side surfaces of restorations on anterior and posterior teeth. They are not intended for treatment of occlusal surfaces.

The product is intended to be used by dental professionals only, in dental clinics, hospitals, and dental laboratories, in accordance with applicable occupational safety regulations and these instructions for use.

TECHNICAL SPECIFICATIONS

- Available grits: coarse, medium, fine, and extrafine.
- RoundFlex discs: available in 9.6 mm and 12.6 mm diameters, colour-coded Coarse (dark brown), Medium (light brown), Fine (orange), and Extrafine (yellow).
- RoundFlex T and RoundFlex M discs: available in 9.5 mm and 12.7 mm diameters, colour-coded Coarse (dark brown), Medium (light brown), Fine (orange), and Extrafine (yellow).
- RoundFlex H discs: available in 10 mm, 12 mm, and 14 mm diameters, colour-coded Coarse (blue), Medium (green), Fine (yellow), and Extrafine (white).
- Disc materials: polyethylene terephthalate backing and aluminium oxide abrasive; central bushing material: polymer, brass, or chrome-plated brass.
- Mandrel material: stainless steel. RoundFlex discs are supplied with one long and one short mandrel; RoundFlex T and RoundFlex M discs are each supplied with one mandrel; RoundFlex H discs are supplied without a mandrel.
- Recommended speed: 10,000 rpm for coarse and medium discs; 20,000 rpm for fine and extrafine discs.
- Maximum speed: 20,000 rpm for all grits.
- Not intended for use with air-turbine handpieces.

Never exceed the maximum permissible rotation speed.

CONTRAINDICATIONS AND POSSIBLE SIDE EFFECTS

Do not use the product if the patient is known to be allergic or hypersensitive to any of the product materials: polyethylene terephthalate, aluminium oxide, polymer, brass, chrome-plated brass, or stainless steel.

No adverse reactions are expected when the product is used as intended.

Possible risks associated with improper use include overheating of the treated surface, soft-tissue burns, or separation of the disc from the mandrel, which may be followed by aspiration, swallowing, or injury to the eye or soft tissue.

WARNINGS AND PRECAUTIONS

- For professional dental use only, in accordance with applicable occupational safety regulations and these instructions for use.
- The disc is supplied non-sterile and is intended for single use only. Do not reuse or reprocess the disc.
- The mandrel is supplied non-sterile, is reusable, and must be reprocessed before first use and after each patient use.
- Not intended for treatment of occlusal surfaces.
- Not intended for use with air-turbine handpieces.
- Do not use the product if the packaging is damaged or has been opened before use.

- Do not use the disc if cracks, chips, burrs, coating delamination, or contamination are visible on its surface. Do not use the mandrel if it is damaged.
- Before starting work, make sure the mandrel is fixed firmly in the handpiece and that the disc rotates smoothly without run-out; only then is the instrument ready for safe use.
- Avoid touching the restoration surface with the mandrel or the disc bushing, as this may cause discoloration.
- Treat the restoration in one direction only, from the gingiva toward the restoration. Movement in the opposite direction, beyond the enamel margin, is not recommended.
- Apply light pressure and let the disc do the work.
- Using discs at high speed, with a long contact time, or with excessive pressure can cause overheating of the treated surface, soft-tissue burns, or separation of the disc from the mandrel, which may be followed by aspiration, swallowing, or injury to the eye or soft tissue.
- Protective eyewear must be worn when using the discs.
- Seek medical attention if a disc or fragment is aspirated or swallowed, or in the event of injury to the eye, skin, or oral mucosa.
- Do not use the product after the expiry date indicated on the packaging.
- After use, discard the disc. The mandrel may be reused only after mandatory cleaning, packaging, and steam sterilization; see "Cleaning and Sterilization of the Mandrel" below.

INSTRUCTIONS FOR USE

- Open the package immediately before use.
- Make sure the disc surface is free from cracks, chips, burrs, coating delamination, and contamination.
- Place the reprocessed mandrel in a compatible dental handpiece. Before starting work, make sure the mandrel is fixed firmly in the handpiece.
- Smoothly place the disc onto the mandrel until fully seated; the disc should not wobble. Check that the instrument rotates smoothly. Only then is the instrument ready for safe use.
- Avoid touching the restoration surface with the mandrel or disc bushing.
- Treat the restoration in one direction only, from the gingiva toward the restoration. Avoid moving the instrument in the opposite direction beyond the enamel margin.
- Apply light pressure and let the disc do the work.
- For best results, work through the grit sequence from coarse to extrafine without skipping steps; see "Recommended Sequence" below.
- After work, discard the disc. Clean, package, and steam sterilize the mandrel before reuse; see "Cleaning and Sterilization of the Mandrel" below.

RECOMMENDED SEQUENCE

- Coarse — Contouring: removal of excess restorative material and treatment of the restoration contour. Recommended speed: 10,000 rpm.
- Medium — Grinding: forming the final anatomical shape of the restoration, evening out roughness, and smoothing the transition between the restoration and the tooth. Recommended speed: 10,000 rpm.
- Fine — Polishing: producing a smooth restoration surface with an appearance similar to natural tooth tissue. Recommended speed: 20,000 rpm.
- Extrafine — Glossing: final finishing step for an entirely smooth, mirror-glossy restoration surface. Recommended speed: 20,000 rpm.

For best results, use the discs progressively from coarse to extrafine without skipping steps.

Do not exceed a speed of 20,000 rpm.

CLEANING AND STERILIZATION OF THE MANDREL

- The mandrel — supplied in short and standard sizes, both made of stainless steel — is reusable. The following reprocessing instructions apply to the mandrel only and follow the general principles of EN ISO 17664-1. RoundFlex discs are single-use only and must not be cleaned, disinfected, sterilized, or reused.
- Before first use and immediately after each patient use, remove the mandrel from the handpiece, remove the used disc from the mandrel, and discard the disc in accordance with local procedures. Begin reprocessing promptly because dried residue is more difficult to remove.
- For manual cleaning, remove visible residue from the mandrel by rinsing and brushing under warm running water above 40 °C with a soft brush until no residue remains visible. Do not use metal brushes or wire wool. If a detergent or enzymatic cleaning solution is used, follow the cleaning-agent manufacturer's instructions for concentration, water quality, temperature, and contact time; do not use agents containing strong acids, strong alkalis, hydrogen peroxide, or organic solvents.
- When automated cleaning and disinfection are used, process the mandrel in a properly maintained, inspected, calibrated, and approved washer-disinfector compliant with EN ISO 15883-1, using a validated programme suitable for reusable dental instruments and the cleaning-agent manufacturer's instructions.
- Dry the mandrel with a clean, lint-free cloth.
- Before every use, including before the first sterilization cycle, inspect the mandrel under normal lighting for cracks, chips, burrs, corrosion, discoloration, deformation, bent parts, embrittlement, or missing parts. Discard the mandrel if any such defect is found; a damaged mandrel must not be sterilized or reused.

- Place the cleaned, inspected, and dried mandrel into a paper/plastic steam sterilization pouch or container suitable for steam sterilization and compliant with EN ISO 11607-1 where applicable. Use packaging that is suitable for the mandrel and follow the packaging manufacturer's instructions.
- Do not use chemical autoclaves or cold sterilization solutions.
- During steam sterilization, avoid direct contact between the mandrel and metallic parts of the autoclave chamber, as those surfaces may exceed the set temperature.
- For EU use, steam sterilize the packaged mandrel in a validated pre-vacuum cycle at 134 °C with an exposure time of 3 minutes and a minimum drying time of 14 minutes. Use a steam sterilizer compliant with EN 285 or EN 13060, as applicable. Do not exceed a sterilization temperature of 135 °C.
- Have the steam sterilizer undergo a preventive maintenance programme according to the sterilizer manufacturer's instructions. The dental facility is responsible for staff training, routine monitoring, and validation of the reprocessing procedure used.
- After sterilization and before use, check the sterile packaging for damage. If the packaging is damaged, repack the mandrel and repeat the sterilization procedure. If the mandrel is not used immediately, keep it in its intact sterile packaging until use.

STORAGE, TRANSPORT AND SHELF LIFE

Store the product in closed premises at air temperature from +10 °C to +25 °C, with relative air humidity not more than 80%, in places protected from dirt, chemicals, heat, and possible mechanical damage. Keep away from direct sunlight.

The medical product may be shipped by any mode of covered transport in accordance with the shipment rules for the relevant transport mode.

Poor storage conditions can reduce shelf life and damage the product.

Warranty shelf life: 3 years.

The manufacture date, expiry date, LOT number, and article number are indicated on the product packaging (label).

DISPOSAL

The disc is a single-use dental consumable. After use, dispose of the disc in accordance with local regulations and the dental facility's procedures for used dental materials.

PACKAGE CONTENTS

RoundFlex discs — product line, diameter, grit, and quantity as indicated on the product packaging (label) and the article number; see "Products covered by this instruction" below.

Depending on the article number, the package may also include one or more mandrels (RoundFlex: one long and one short mandrel; RoundFlex T and RoundFlex M: one mandrel). RoundFlex H is supplied without a mandrel.

REPORTING SERIOUS INCIDENTS

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established. Enquiries about a suspected serious incident can also be sent to support@kagayaki.eu.

MANUFACTURER AND EU AUTHORISED REPRESENTATIVE

Manufacturer: Shenzhen Kagayaki Technology Co., Ltd., 301, Building 1, Zhenyu 2nd Road, Fifth Industrial Zone, Yulu Community, Yutang Subdistrict, Guangming District, Shenzhen, China. EUDAMED Single Registration Number (SRN): CN-MF-000050831.

EU Authorised Representative: Aleksandra Bashinskaia, Urbanização Crastos, Lote 43, 8400-450, Porches, Portugal. EUDAMED Single Registration Number (SRN): PT-AR-000050489. Phone: +351 926605123. Email: ra.pt@kagayakipolish.com.

For general enquiries or to submit a complaint, contact support@kagayaki.eu.

DOCUMENT INFORMATION

- Instructions for Use for Kagayaki RoundFlex Polishing Discs.

EXPLANATION OF SYMBOLS

 Consult instructions for use

 Caution

 CE marking

 Keep away from sunlight

 Non-sterile

 Authorised representative in the European Union

 Batch code

 Unique device identifier

 Do not reuse

 Medical device

 Temperature limit

 Keep dry

 Manufacturer

 Catalogue number

 Use-by date

 Country of manufacture

