



DISUKU-FELT

Disuku Polishing Wool Felt

Dental Polishing Wool Felt Discs

GENERAL INFORMATION

Disuku Polishing Wool Felt is a single-use, non-sterile, disc-shaped dental device made of sheep wool, intended for use in various fields of dentistry.

The wool felt is used for the mechanical finishing and polishing of the surface of restorations made of composites, compomers, and glass ionomers, as well as of various prosthetic restorations, in combination with Kagayaki brand polishing pastes.

The felt disc is supplied together with a disc holder (mandrel) for a contra-angle handpiece and a disc holder (mandrel) for a straight handpiece. The felt disc itself is intended for single use only.

The mandrels are made of stainless steel, are reusable, and are supplied non-sterile. They must be cleaned, packaged, and steam sterilized before first use and after each patient use; see "Cleaning and Sterilization of the Mandrel" below.

INTENDED PURPOSE AND INDICATIONS FOR USE

Disuku Polishing Wool Felt is intended to give a mirror-like shine and smoothness to the surface of dental restorations when used together with a Kagayaki brand polishing paste.

The product is intended for the mechanical finishing and polishing of restorations made of composites, compomers, glass ionomers, and other prosthetic restorative materials.

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

TECHNICAL SPECIFICATIONS

- Size F — diameter 17 mm; thickness 3 mm; recommended speed 4,000–6,000 rpm; maximum speed 8,000 rpm; impact force 0.3–1 N; treatment method: wet, dry, or combined; available with a CA (contra-angle) or HP (straight handpiece) shank.

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 sheep wool or to any other listed product material.

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

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

WARNINGS AND PRECAUTIONS

- For professional dental use only.
- The product is supplied non-sterile.
- The mandrel is reusable and must be reprocessed (cleaned, packaged, and steam sterilized) before first use and after each patient use; see "Cleaning and Sterilization of the Mandrel" below.
- Single use only. Do not reuse the wool felt disc.
- Do not use the product if the packaging is damaged or has been opened before use.
- Do not use the product if it is damaged or contaminated.
- Do not use the product after the expiry date indicated on the packaging.
- Not intended for use with air-turbine handpieces.
- Before starting work, inspect the mandrel for bends or wear and confirm it is fixed firmly in the handpiece, with the polisher rotating smoothly without run-out; only then is the tool ready for safe use.
- Never exceed the maximum permissible rotation speed stated in the technical specifications.
- Avoid excessive pressure, a long impact time, or high rotational speed: these can cause overheating of the treated surface, burns to soft tissue, or separation of wool fibres from the holder.
- Control the impact force by adjusting the pressure on the treated surface; use mild, moderate, intermittent pressing (recommended impact time: 5 seconds per application) with a polishing motion, and cool with air or water.

- Use care when working near soft tissues.
- Protective eyewear must be worn when using the polisher.
- If available, use local suction during treatment to help capture loose fibres and reduce the risk of inhalation.
- After work, remove the felt disc from the mandrel and dispose of it; do not reuse the felt disc. The mandrel may be reused only after mandatory cleaning, packaging, and steam sterilization; see "Cleaning and Sterilization of the Mandrel" below.
- Seek medical attention if the product is aspirated or swallowed, or in the event of injury to the eye, skin, or oral mucosa.

INSTRUCTIONS FOR USE

- Open the package immediately before use.
- Make sure the felt disc is not damaged or contaminated.
- Fix the wool felt disc to the mandrel (disc holder) securely.
- Place the reprocessed mandrel in a compatible dental handpiece. Before starting work, make sure the mandrel is fixed firmly in the handpiece and that the polisher rotates smoothly without run-out.
- Apply the Kagayaki polishing paste to the surface to be treated, spreading a thin layer with a spatula or with the felt disc itself running at the lowest speed.
- Treat the restoration surface using mild, moderate, intermittent pressing with a polishing motion; cool with air or water and avoid excessive pressure or prolonged contact.
- Rinse off the polishing paste with water after processing.
- After work, remove the felt disc from the mandrel and dispose of it; do not reuse the felt disc. Clean, package, and steam sterilize the mandrel before reuse; see "Cleaning and Sterilization of the Mandrel" below.

CLEANING AND STERILIZATION OF THE MANDREL

- The mandrels — supplied for contra-angle and straight dental handpieces, both made of stainless steel — are reusable. The following reprocessing instructions apply to the mandrels only and follow the general principles of EN ISO 17664-1. Disuku wool felt 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 felt disc from the mandrel, and discard the felt 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, repackage 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

After use, dispose of the felt disc in accordance with local legislation and the dental facility's procedures for used dental materials.

PACKAGE CONTENTS

Wool felt Disuku — design version and quantity as indicated on the product packaging (label).

Disc holder (mandrel) for contra-angle dental handpiece — 1 pc.

Disc holder (mandrel) for straight dental handpiece — 1 pc.

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 Disuku Polishing Wool Felt.

EXPLANATION OF SYMBOLS

	Consult instructions for use		Do not reuse
	Caution		Medical device
	CE marking		Temperature limit
	Keep away from sunlight		Keep dry
	Non-sterile		Manufacturer
	Authorised representative in the European Union		Catalogue number
	Batch code		Use-by date
	Unique device identifier		Country of manufacture

PRODUCTS COVERED BY THIS INSTRUCTION

Product	REF	EAN / GTIN
Felt wheels "Kagayaki Disuku F", 25 pcs + 2 felt wheel holders (1 for straight & 1 for angular handpiece)	DF01E	06978412680681