



SATORI-SHINE

Satori Shine Polishing Discs

Dental Finishing and Polishing Discs

GENERAL INFORMATION

Kagayaki Satori Shine is a colour-coded, four-step system of dental finishing and polishing discs, available in coarse, medium, fine, and extrafine grit.

The discs are mounted on a supplied disc mandrel that connects the disc to a compatible dental handpiece. Each package contains one reusable stainless-steel mandrel and two single-use plastic mandrels.

Each disc is intended for single use only. The stainless-steel 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 Metal Mandrel" below. The plastic mandrel is intended for single use only.

The discs and mandrels are supplied non-sterile.

INTENDED PURPOSE AND INDICATIONS FOR USE

Satori Shine discs are intended for the step-by-step mechanical finishing of dental restorations made from filling materials: 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 oral (lingual or palatal), vestibular (labial or buccal), and proximal (approximal or contact) surfaces of restorations on anterior and posterior teeth. They are not intended for treatment of occlusal surfaces.

The intended patient population is patients with anterior or posterior dental restorations made from filling materials that require contouring, finishing, polishing, or glossing. The clinical benefit is support for restoring the final anatomical form and achieving a smooth, polished restoration surface.

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

TECHNICAL SPECIFICATIONS

- Available grits and colour coding: Coarse (purple), Medium (rose), Fine (green), and Extrafine (white).
- Available disc diameters: 8 mm and 12 mm.
- Disc materials: polyethylene terephthalate base and aluminium oxide abrasive; central bushing material: polymer. The supplied reusable mandrel is made of stainless steel, and the supplied single-use mandrel is made of plastic.
- Each package contains one reusable stainless-steel mandrel and two single-use plastic mandrels.
- Maximum speed with the stainless-steel mandrel: 15,000 rpm.
- Maximum speed with the plastic mandrel: 5,000 rpm.
- 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 disc materials: polyethylene terephthalate, aluminium oxide, or polymer.

No adverse reactions have been identified when the product is used in accordance with these instructions for use.

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.
- The stainless-steel mandrel is supplied non-sterile, is reusable, and must be cleaned, packaged, and steam sterilized before first use and after each patient use.
- The plastic mandrel is supplied non-sterile and is intended for single use only.
- Not intended for treatment of occlusal surfaces.
- Not intended for use with air-turbine handpieces.
- Do not use the disc if its packaging is damaged or if cracks, chips, burrs, coating delamination, or contamination are visible on the disc. Do not use a damaged or defective plastic mandrel or a damaged, defective, corroded, or worn stainless-steel mandrel.
- 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 disc bushing, as this may cause discoloration.
- Avoid contact between the rotating disc and soft tissue.
- Move the disc in one direction only, away from the gingiva and across the restoration. Do not move the disc in the opposite direction, from the restoration toward the gingiva, or allow it to pass beyond the enamel margin.
- Apply light pressure and let the disc do the work.
- Using the disc at excessive speed, for a prolonged 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.
- Use suction to remove moisture and debris during the procedure. Wear a protective mask and protective eyewear when operating the handpiece.
- 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 and the plastic mandrel. The stainless-steel mandrel may be reused only after mandatory cleaning, packaging, and steam sterilization; see "Cleaning and Sterilization of the Metal Mandrel" below.

INSTRUCTIONS FOR USE

1. Remove the required disc from the package immediately before use.
2. Make sure the disc surface is free from cracks, chips, burrs, coating delamination, and contamination.
3. Select the supplied mandrel. Before using the reusable stainless-steel mandrel, make sure it has been cleaned, packaged, and steam sterilized. Use a new plastic mandrel for each patient. Place the selected mandrel in a compatible dental handpiece and make sure it is fixed firmly.
4. Smoothly place the disc onto the mandrel until fully seated; the disc should not wobble. Perform a test run and check that the disc rotates smoothly without run-out. Only then is the instrument ready for safe use.
5. Avoid touching the restoration surface with the mandrel or disc bushing and avoid contact with soft tissue.
6. Move the disc in one direction only, away from the gingiva and across the restoration. Do not move the disc in the opposite direction, from the restoration toward the gingiva, or allow it to pass beyond the enamel margin.
7. Apply light pressure and let the disc do the work. Use suction to remove moisture and debris during the procedure.
8. For best results, work through the grit sequence from coarse to extrafine without skipping steps; see "Recommended Sequence" below.
9. Remove debris from the restoration surface after each finishing or polishing step.
10. After work, remove and discard the disc. If the plastic mandrel was used, discard it after the patient. If the stainless-steel mandrel was used, clean, package, and steam sterilize it before reuse; see "Cleaning and Sterilization of the Metal Mandrel" below.

RECOMMENDED SEQUENCE

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

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 METAL MANDREL

1. The following reprocessing instructions apply only to the supplied reusable stainless-steel disc mandrel and follow the general principles of EN ISO 17664-1. Satori Shine discs and the supplied plastic mandrel are intended for single use only.
2. Before first use and immediately after each patient use, remove the stainless-steel 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.
3. 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.
4. 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.
5. Dry the mandrel with a clean, lint-free cloth.
6. 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.
7. 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.
8. Do not use chemical autoclaves or cold sterilization solutions.
9. During steam sterilization, avoid direct contact between the mandrel and metallic parts of the autoclave chamber, as those surfaces may exceed the set temperature.
10. 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.
11. 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.
12. 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 an 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 device 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.

Shelf life: 18 months.

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

DISPOSAL

After use, dispose of the single-use disc and the single-use plastic mandrels in accordance with local regulations and the dental facility's procedures for potentially contaminated dental materials.

Dispose of the reusable stainless-steel mandrel if it is damaged, defective, corroded, worn, deformed, or otherwise unsuitable for safe reuse, in accordance with local regulations and the dental facility's procedures.

PACKAGE CONTENTS

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

One reusable stainless-steel mandrel and two single-use plastic mandrels.

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 Bashinskiaia, 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 Satori Shine Dental Finishing and Polishing Discs.

EXPLANATION OF SYMBOLS

 Consult instructions for use	 Do not reuse - applies to the disc and plastic mandrel
 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 / 6TIN
Polishing discs "Kagayaki Satori Shine", 12 mm, Coarse (purple), 30 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD01011E	—
Polishing discs "Kagayaki Satori Shine", 12 mm, Medium (rose), 30 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD01021E	—
Polishing discs "Kagayaki Satori Shine", 12 mm, Fine (green), 30 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD01031E	—
Polishing discs "Kagayaki Satori Shine", 12 mm, Extrafine (white), 30 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD01041E	—
Polishing discs "Kagayaki Satori Shine", 12 mm, Coarse (purple), 10 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD01012E	—
Polishing discs "Kagayaki Satori Shine", 12 mm, Medium (rose), 10 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD01022E	—
Polishing discs "Kagayaki Satori Shine", 12 mm, Fine (green), 10 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD01032E	—
Polishing discs "Kagayaki Satori Shine", 12 mm, Extrafine (white), 10 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD01042E	—
Polishing discs "Kagayaki Satori Shine", 8 mm, Coarse (purple), 30 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD02011E	—
Polishing discs "Kagayaki Satori Shine", 8 mm, Medium (rose), 30 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD02021E	—
Polishing discs "Kagayaki Satori Shine", 8 mm, Fine (green), 30 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD02031E	—
Polishing discs "Kagayaki Satori Shine", 8 mm, Extrafine (white), 30 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD02041E	—
Polishing discs "Kagayaki Satori Shine", 8 mm, Coarse (purple), 10 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD02012E	—
Polishing discs "Kagayaki Satori Shine", 8 mm, Medium (rose), 10 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD02022E	—
Polishing discs "Kagayaki Satori Shine", 8 mm, Fine (green), 10 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD02032E	—
Polishing discs "Kagayaki Satori Shine", 8 mm, Extrafine (white), 10 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD02042E	—
Polishing discs "Kagayaki Satori Shine", assortment kit, 12 mm, Coarse, Medium, Fine, and Extrafine, 40 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD013E	—
Polishing discs "Kagayaki Satori Shine", assortment kit, 8 mm, Coarse, Medium, Fine, and Extrafine, 40 pcs, with 1 stainless-steel mandrel and 2 plastic mandrels	SD023E	—