

KENDA Polishers

Instructions for Use

EN

Please read the **Instructions for Use** carefully before using the product. Keep for later reference.

PRODUCT DESCRIPTION

Polishers are rotary devices that consist of a silicone/synthetic rubber polishing head impregnated with abrasive material. Polishers are used in conjunction with dental hand pieces for dental restoration procedures. Polishers are available in various head shapes and sizes, shank types and lengths as well as abrasive grits.

INTENDED USE

Polishers are intended to be used for the purpose of fine contouring and polishing hard structures in the mouth including teeth and dental restorations both intraorally or extraorally.

COMPOSITION

Shank: stainless steel (may contain nickel) or polyetherimide (PEI)
Matrix: silicone or synthetic rubber, pigments
Abrasives: diamonds, silicon carbide, aluminum oxide

INDICATIONS

- Dental treatments requiring contouring or polishing of the hard tooth structures and restorations
- Cosmetic dental treatments

CONTRAINDICATION

If a patient is known to be allergic to any of the above components, the polishers should not be used.

SAFETY INSTRUCTIONS

Safety



- Use personal protective equipment during use or handling of instruments.
- The instruments must be cleaned, sterilized, and checked in accordance with the reprocessing instructions below before the initial use and each subsequent re-use.
- Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. The use of KENDA polishers in the patient's mouth may only be undertaken by specialist personnel such as dentists.
- Don't use instruments showing signs of wear or damage (i.e. deterioration, non-concentric rotation, etc.). This increases the risk of injury, breakage, and can have a negative effect on the work result. Instruments showing signs of wear or damage should be discarded.
- The generation of heat during preparation can lead to damage of the tooth substance, pulp and adjacent fillings.
- Exceeding the maximum specified speed and/or contact pressure may result in excessive heat generation and/or damage to the instrument.

Residual risks

Users should be aware that any dental intervention in the oral cavity involves certain risks. Some of these risks are:

- Detachment of the polisher or parts of it during use, that could result in ingestion or inhalation. Mucosal laceration or burn.
- Postoperative sensitivity/irritation of the gingiva.
- Disproportionate abrasion, that could result in gloss or color changes

⚠️ WARNING

- KENDA polishers are supplied non-sterile and must be reprocessed before the initial use and each subsequent re-use. Single-use polishers  must be reprocessed before the initial use and must not be reused. Multi-use polishers do not bear the  symbol.
- Only use a cleaning agent/disinfectant suitable for polishers.
- Prolonged disinfection can damage the polisher or cause discoloration. Follow the manufacturer's specifications of the disinfectant with regard to the concentration and reaction time. Ensure that the process is effective.
- Strongly acidic and alkaline cleaning agents can damage the instrument. It is recommended to use pH neutral cleaning agents.
- Use a cleaning agent containing a corrosion inhibitor.
- Use sterilizing devices according to the manufacturer's recommended procedure.
- The drying of contaminants can impede proper cleaning of the instrument.
- Prolonged exposure of instruments to contaminants such as blood residues can lead to corrosion damage.

SIDE EFFECTS / INTERACTIONS

No side effects or interactions are known to the manufacturer.


USER- / PATIENT GROUP

Use by qualified dental professionals only. Suitable for all patient groups.

PREPARATION

- Only use technically and hygienically flawless handpieces and instruments.
- The instruments must be selected based on shape, size and type according to the type of application.
- Ensure that the instrument is securely connected to the handpiece.

PROPER USE

- The recommended speeds are indicated on the packaging label. Do not exceed the maximum speed indicated.
- Before applying the instrument to the preparation site, bring it up to working speed. Ensure that the instrument rotates without imbalance and that the water cooling – if applied – functions properly (min. 50 ml/min).
- During use, move the instrument continuously.
- To achieve best results, use the polishers in the indicated sequence when using multiphase polishing systems.
- Do not apply pressure exceeding 1.5 N.
- Use ShapeGuards only in correct rotation direction, which is indicated by the  symbol.
- Choose the polishing system according to the application as indicated in the table below.

Polishing System	Application
Nobilis	All Composites, Hybrid-Ceramics
Unicus	All Composites, Hybrid-Ceramics
Complete	All Composites, Compomers, Amalgam, Gold
Maximus	All Composites, Hybrid-Ceramics
Deluxe	All Composites, Compomers, Hybrid-Ceramics
Hybrid	Hybrid-Composites, Hybrid-Ceramics
Microfill	Microfilled Composites
C.G.I.	All Composites, Compomers, Glass-Ionomers
All Ceramic	All Ceramics
Prophy	Tooth Cleaning & Removal of Extrinsic Stains
Metals	All Metals (Amalgam, Titanium Alloys, Precious & Non-Precious Metals)
Polishette	All Composites, Hybrid-Ceramics

TESTMETHOD FOR CORRECT APPLICATION

- Check concentric rotation
- RPM of device is within the recommended speed range

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

General remarks

The instructions provided below have been validated by the manufacturer of the polishers as being capable of preparing a polisher for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

Special country-specific reprocessing and hygiene regulations may apply. The reprocessor is responsible to comply with the local regulations.

Reprocessing limitations

Repeated reprocessing has a minimal effect on the instruments. The end of use is determined by the wear and damage of the instrument due to use. Instruments showing signs of wear or damage must be sorted out immediately and disposed of properly.

Instructions

Place of use
Remove surface contamination immediately after use on the patient, then place instrument in container.

Storage and transport

Transport instruments in a closed container to the reprocessing site and start cleaning immediately.

Pre-Treatment

- For pre-cleaning, place instruments in a bath with suitable enzymatic cleaning agent (e.g. BioSonic UC32, manufactured by COLTENE, contact time: 5 minutes). Ensure that the instruments are completely covered by the cleaning agent and do not come into contact with each other.
- Remove remaining residues with a soft brush. Special attention must be taken to ensure that difficult to access areas of instruments are cleaned and that spreading of germs through spraying is prevented.
- Remove the instruments from the cleaning agent and rinse with cold water for 2 minutes and dry with compressed air.

Ultrasonic cleaning

- Fill the ultrasonic device with a suitable enzymatic cleaning agent (e.g. BioSonic UC32, manufactured by COLTENE).
- Place the instruments into a suitable instrument holder to avoid damage and ensure all surfaces are cleaned and disinfected. Place instrument holder with instruments in the ultrasonic device and ensure it is fully submerged into the cleaning agent.
- Start the ultrasonic device and treat the instruments for a duration of 10 minutes.
- Remove the instruments from the ultrasonic device at the end of the program.
- Rinse under cold water for 2 minutes and dry with compressed air.

Maintenance, inspection and testing

- Visual inspection for cleanliness and integrity, using magnification if necessary.
- In case of visible contamination, the process must be repeated.



Polishers cannot be properly sterilized unless they have been thoroughly cleaned and are free from visual contamination.

Packaging for sterilization

Place instruments in bags suitable for sterilization (e.g. self-adhesive bags from SPSmedical).

Sterilization

Device: Sterilizer according to DIN EN 285 or small steam sterilizer according to DIN EN 13060, type B process or ANSI/AAMI ST55.

Process: Steam sterilization with fractionated pre-vacuum, 132 °C (270 °F) (parameter of validation) or 134 °C with holding and drying time according to the manufacturer of the sterilizer (e.g. 4 and 20 minutes).

- Place the packaged products in the sterilization chamber.
- Start the program.
- Remove the products at the end of the program and allow to cool down.
- Then check the packaging for possible damage. Faulted packaging must be regarded as being non-sterile.



The instruments are not suitable for hot air or chemiclave sterilization.

Storage after sterilization

Store the sterilized instrument packed and protected from recontamination in the sterilization bag until use.

SHELF LIFE / STORAGE

Expiry date: see packaging
Storage temperature: 2-28 °C (36-82 °F)

Store in dry environment. Protect against exposure to heat and sun. Avoid extreme temperature fluctuations. Store in original packaging until first use to facilitate identification and traceability. Ensure identification and traceability after instrument has been removed from its original packaging.

DISPOSAL

KENDA multi-use polishers must be sterilized after use or in case of single-use instruments classified as biohazardous, stored in a suitable sharps container, and disposed of according to applicable legislation. Special country-specific regulations may apply. Dispose only of completely emptied packages together with household waste in compliance with official regulations.

REPORTING OBLIGATION

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority. In the unlikely event of inhalation, ingestion, eye contact, or similar incidents seek immediate medical attention from an appropriate medical specialist to mitigate potential harm.



Application Information



pxl.coltene.com/kenda-polishers

GLOSSARY	
	Consult instructions for use
	Marking of Conformity Europe
	Conformity mark Ukraine
	Restricted device for professional use only
	Medical Device
	Legal Manufacturer
	European Authorized Representative
	Importer
	Reference Number
	Manufacturing Date
	Expiry Date
	Batch Code
	Unique Device Identifier
	Single use only
	Keep dry
	Keep away from sun light
	Temperature limitation
	Non-sterile
	Packaging size
	ISO Code of instrument: 000 00 0 000 000 000 A B C D E F A. Material of working part B. Shank type or bore diameter C. Overall length D. Shape E. Specific characteristics: grit size F. Nominal size of working part (head diameter)
	Max. pressure
	Spray H ₂ O
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Maximum Speed RPM
	ShapeGuard rotation direction
	Caution. Please follow general application and safety instructions

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