

Instructions for use

These instructions are valid for all KENDA Dental Polishers that are used for restorative and preventive work.

Single-patient polishers are labelled with (2) and must not be used more than once, as multi-use of these polishers can cause unnecessary risk to the patient and staff.

Composition: The polishers consist of synthetic/silicone rubber, pigments and abrasive. The shanks are made of stainless steel or medical plastic.

Indication: KENDA Dental Polishers are used for polishing different materials which are specified on the packaging label.

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

Adverse effect: None known to date.

General security advices:



Do not exceed maximum speed



Wear breathing protection



Wear eye protection



Use waterspray minimum 50ml/min

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For polishers with steel shank = 2N plastic shank = 1N

Precautions:

- Products may only be used in the specified field of application.
- Check the safe connection of the polisher before using it and perform a test run.
- Use proper hand piece only and remove any damaged, bent, or no longer centrical running polishers immediately.
- Avoid excessive pressure which can cause tilting, bending or blocking of the polisher.
- Insufficient watercooling can result in irreversible damage to the tooth and the surrounding tissue.
- Using the wrong disinfectant and/or prolonged disinfection times can soak the polisher or cause discoloration. Therefore, make sure that the effectiveness of the disinfectant is approved and suitable for polishers, do not use disinfectants containing aldehydes and follow the manufacturer's specifications of the product with regard to the concentration and reaction time. Ensure that the process is effective.
- Always keep track of LOT numbers of polishers to ensure traceability.

Storage: A dry, dust-free storage at 2 - 28°C (36 - 82°F) is recommended. Improper storage conditions can shorten the shelf life and cause malfunction of the product.

Expiry date: See imprint on label.

Hygiene instructions: Please refer to back of this page for detailled hygiene instructions.

Translations on http://knd.li/ins

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http://knd.li/ins

These hygiene instructions are valid for all KENDA Dental Polishers for chairside use.

WARNINGS:

KENDA Polishers are supplied unsterile and therefore must be treated before use.

Single patient polishers (labelled with (2)) are not eligible for reuse, but need to be disinfected and sterilised before and only use.

During processing of all polishers, protective clothing, gloves and goggles must be worn at all times.

Only use cleaning and disinfection solutions which are specifically labeled "suitable for silicone or rubber polishers".

Limitation of reprocessing: The product's life is determined by the wear and tear of the polishing instrument. Repeated processing has minimal effect on these instruments.

Point of use: Remove surface contamination with a disposable cloth immediately after using on patient and put in a container.

Containment and transportation: Polishers should be transported immediately in a closed instrument tray to the treatment area. Proceed with cleaning and disinfection immediately.

Cleaning and disinfection: Proceed with either machine (recommended) or manual treatment.

a. Machine treatment:

- 1. Rinse thoroughly under running water.
- 2. Place polishers in the washer/disinfector (WD) and make sure they do not touch each other.
- Add the appropriate cleaning agent (aldehyde-free), according to the information on the product label and the instructions of the WD-manufacturer.
- 4. Start the desired program: cleaning and disinfection.
- 5. After termination of the program, take the polishers out of the WD and dry them preferably with clean compressed air.
- Visual inspection for cleanliness and integrity using a magnifying glass with 6 times magnification. In case of visual contamination, the process must be repeated.
- 7. If only mechanical cleaning (without proven disinfection) a final disinfection in a steam sterilizer (unpacked) in suitable racks or trays is required.
- 8. Documented approval of the proper treatment procedure in order to reuse or for storage.
- 9. A dry, dust-free storage at 2 28°C (36 82°F) is recommended.

b. Manual treatment:

- 1. Rinse thoroughly under running water. If necessary, use a nylon brush. NOTE: Use a suitable brush for cleaning blind holes.
- Cleaning and chemical disinfection with a suitable solution (aldehyde-free) according to manufacturer's instruction. Insert polisher into the solution. Make sure that polishers are free of air bubbles.
- The reaction time begins with the insertion of the last polisher and is according to the instruction of the disinfectant manufacturer.
- 4. After contact time is up, rinse polishers with plenty of deonized water.
- 5. Dry residual moisture preferably with clean compressed air.
- Visual inspection for cleanliness and integrity using a magnifying glass with 6 times magnification. In case of visual contamination, the process must be repeated.
- 7. Without a proven disinfection, a final disinfection in a steam steriliser (unpacked) in suitable racks or trays is required.
- 8. Documented approval of the proper treatment procedure in order to reuse or for storage.
- 9. A dry, dust-free storage at 2 28°C (36 82°F) is recommended.

Sterilisation: Moist heat sterilisation with fractional prevacuum. Full cycle, 134°C (273°F) / 3,1 bar for at least 5 minutes, drying time 10 minutes. Do not exceed 135°C (275°F).



IMPORTANT: Use suitable packaging for sterilisation.

Warning: KENDA Dental Polishers are not suitable for sterilisation with hot air or chemiclave.

This procedure was validated by an independent and accredited laboratory.

Additional information: When sterilising multiple instruments in one autoclave cycle ensure that the steriliser's maximum load is not exceeded in accordance with the steriliser's instructions.

Manufacturer contact:



Coltène/Whaledent AG Feldwiesenstrasse 20 9450 Altstätten, Switzerland http://www.coltene.com

Product website: http://www.kenda-dental.com

Date of preparation: 09/2020; Rev. 1

The instructions provided above have been validated by the medical device manufacturer as being capable of preparing KENDA Dental Polishers for reuse.

The material has been developed solely for use in dentistry. Processing should be carried out strictly according to the Hygiene Instructions. Liability cannot be accepted for damages resulting from failure to observe the instructions or the stipulated area of application. The user is responsible for testing the products for their suitability and use for any purpose not explicitly stated in the instructions. Descriptions and data constitute no warranty of attributes and are not binding.

Keep out of reach of children. For use in dentistry only.