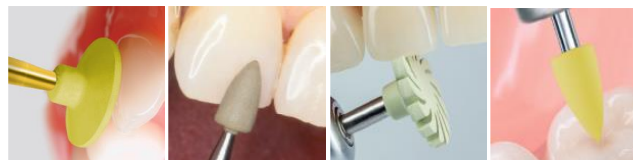




EDENTA Etablissement, Industriestrasse 13, LI-9486 Schaanwald – Liechtenstein
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SRN: LI-MF-000011937

Polishers / Arkansas stones

DiaGloss / TopGloss / Exa Special / Exa Composit / Flexi-Snap / CeraGloss / StarGloss / StarTec / Cerapol plus / Exa Cerapol / Cerapol Super / Alphaflex / Alphaflex supergrün / Goldstar / Amalgam Reducer / Nylon Brush / OrthoFlex / Exa Intrapol / Exa Dental / Prophylaxis Pasteless / Prophylaxis Cups / Prophylaxis Cups with nubs / Prophylaxis Brushlets / Screw-In Brushlets / Snap-On Brushlets / TopBrush / Abrasives / Arkansas / CompGloss

Basic-UDI-DI: ++E31216412DU

Use: Reusable instruments, supplied non-sterile – reprocess before first use.

Detailed reprocessing recommendations acc. DIN EN ISO 17664



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Storagerung: Protect packaged instruments from high temperatures and UV radiation. Store in a dry and clean place, do not store in a room with solvents or chemicals.

Storage temperature: 15°C – 25°C | Transport temperature: 10°C – 35°C.

Intended use:

Polishers are used for intraoral polishing (removal, smoothing, high-gloss polishing) of dental restoration materials such as zirconium, ceramic, composite, non-precious metal alloys, precious metal and amalgam. They are used to improve the surfaces of teeth and dentures and to achieve an aesthetically pleasing surface. The intended users are dentists (dental studies) and dental specialists (prophylaxis), who use the polishers as part of their dental treatments in professional healthcare facilities (dental practice, dental clinic).

Description:

Polishers are used for surface polishing of tooth enamel / plaque, fillings, inlays, crowns, bridges and prosthetic materials, as well as for removing adhesive residue from tooth enamel. They are used intraorally. Polishers help to improve the aesthetics and smoothness of tooth surfaces. They are available in different shapes, designs / grain levels, depending on the desired polishing effect. Polishers are offered in different types, as universal polishers, pre-polishers, gloss polishers and high-gloss polishers. Depending on the application, the polishers also have different shapes such as cylindrical, conical, disc-shaped and lamellar. A distinction is made between polishers for reusable use and single-use (single-use items). Polishers are sold non-sterile. The shafts of the polishers are designed to fit into standard handpieces. They are designed exclusively for use in drives (handpieces / contra-angles) in accordance with the EN ISO 14457:2017 standard

Anwendung:

Polishers are used for all intraoral preparations, from contouring and finishing to high-gloss polishing. They are used to improve the quality and performance of interdental concave / convex surfaces as well as occlusal zones. To create a natural shine or high gloss on all filling materials, such as amalgam, precious metal alloys, ceramics or plastics. Also for use for aesthetically demanding results on all modern zirconium oxide ceramic materials by polishers with special diamond grain.

Clinical benefit:

Restoration of aesthetics.

Symbols dental treatment:

Filling process



Orthodontic treatment



Propylaxis



Crown and Bridge technique

The dental treatment symbols only provide information on the possible applications of the polishers.

The user/specialist (dental studies) decides on the specific use on his/her own responsibility depending on the indication at hand.


Safety instructions:

- The instruments may only be used by qualified personnel (dental studies).
- Before first use on the patient and immediately after each use, the instruments must be disinfected, cleaned, dried and sterilized.
- see Validated procedure under:

Detailed reprocessing recommendations acc. DIN EN ISO 17664



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- Alkaline solutions must not be used to disinfect polishers and ceramic grinding wheels. The cleaning and disinfection solutions must be specifically labeled as “suitable for rubber polishers or plastic/silicone” (cleaning and disinfection agents for rotating instruments do not contain polishers). The manufacturer’s instructions on concentration and exposure time must be observed.
- Disposable items marked with  on the packaging can only be disinfected manually (not suitable for WD and steam sterilizers) with a suitable agent (e.g. HELVEMED Instrument Forte) before first use.
- Pay attention to the working speed (RPM) - the maximum speed is indicated on the product packaging. Using the instruments outside the speed range can lead to instrument breakage and injury to the patient and user.
- Ensure sufficient water spray cooling (min. 50ml/min) on the working part.
- Only polish with light pressure.
- Always place the polisher on the surface in a rotating motion and polish with circular movements.
- Blocking of the instruments due to excessive contact pressure, tilting and levering are to be avoided (increased risk of breakage).
- Excessive contact forces or insufficient water cooling can damage the restoration and the surrounding tissue, as well as accelerated wear of the polishing body.
- The drive systems (dental handpieces) must be in perfect technical condition.
- Insert instruments as deeply as possible into the dental handpieces and check that they are firmly seated.
- Damaged, bent or no longer running true instruments must be sorted out immediately and no longer to be used.
- The use of a rubber dam is recommended.
- The use of protective goggles is recommended.

Possible side effects:

At this time, no side effects are known.

Storage of reprocessed instruments:

Reprocessed instruments should be stored in hygienically maintained stands, trays or other suitable containers and in their original packaging at room temperature until they are used for the first time. The same applies to sterilized instruments and those with sterilization packaging. Storage must be protected from dust, moisture and recontamination.














Disposal:

For safe disposal, the instruments must be placed in break-proof, puncture-proof and leak-proof containers (contamination protection). The local official regulations for the disposal of medical instruments must be observed!

Serious incidents:

Informing the user and/or patient that all serious incidents related to the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Description of the symbols used:

| | | | | | |
|--|----------------------|---|--|---|---------------------------|
|  | Medical device |  | Manufacturer |  | Date of Manufacture |
|  | Packaging Unit |  | Observe instruction for use: www.edenta.com |  | Item Number |
|  | ISO – Nummer |  | LOT number for batch traceability |  | Maximum permissible speed |
|  | Speed recommendation |  | Ultrasonic |  | Washer disinfektor |
|  | Autoclave | | | | |

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