

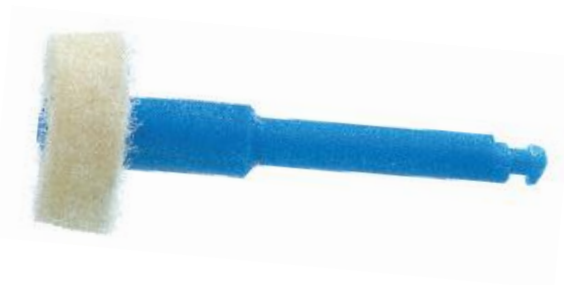
Diafix® - Oral Polisher

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**Example application*



**Example*

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1. User group

The instruments may only be used by appropriately qualified personnel in dental surgery or clinics.

- Maxillo-facial surgeons / dental/oral surgeons
- Dentist

2. Target patient group

Patients with dental medical indications in the area of the described indications and applications.

3. Materials / Components

- Instruments with plastic shank (PA) and working piece of natural felt (with diamond impregnation)

4. Product description

Diafix® Oral polishers are felt polishers with diamond impregnation (**for single use only**, not sterilizable) which deliver absolute high shine in seconds on ceramics, composites, metal fillings and dental materials

5. Indication

- High shine polishing of ceramics, composites, metal fillings and dental materials

6. Contraindication


- **Re-use of the instruments poses a high risk of contamination and/or infection and must be refrained from. (single use product)**
- The instruments may not be used for any other than the described indication or application area.
- The indicated speed may not be exceeded (possible damage of pulp due to excessive temperatures as well as deformation and risk of injury)
- Jamming or using the instrument as a lever must be avoided (risk of fracture/injury)
- Processing of soft materials must be avoided

7. Application mode

- Insert the instrument into the turbine/handpiece as deeply as possible. (There is a risk of injury if not inserted deeply enough!)
- For best results observe the recommended speeds as per the attached chart
- Insert the instrument into the mouth prior to rotation to avoid risk of injury
- Instrument must be rotating before touching the tooth or the dental material
- The use of suction is obligatory
- No water cooling is required when used in intermittent or dabbing mode with low pressure (max 15 sec. polishing time)
- We recommend wearing oral protection and safety goggles (*see also protective measures*)

8. Speed specification

Maximum speed for Diafix®-Oral Polisher

Connection type	Instrument	 Speed
CA / RA	Diafix®-Oral Polisher	1' – 3.000 rpm

9. Frequency of use

The instruments are **intended for single use only** and must not be reused or reprocessed. Multiple-use bears a high risk of contamination and is strictly forbidden.



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10. Instructions for disinfection before use

Diafix®-Oral is **not** sterilizable and is intended for single use only. The instrument **must** be treated with a clear alcohol-free disinfectant before use (e.g. OCTENISEPT® clear, Schülke & Mayr).

Procedure:

1. Apply the disinfectant completely, generously and evenly. Rotate the felt polisher while spraying.
2. The compulsory resting time of the disinfectant (**not less than 3 minutes**) must be observed.
3. A slight residual moisture before use has no influence on the performance of the felt polisher (*optionally dry the instrument with filtered compressed air*)
4. Use the instrument soonest possible after disinfection

Evidence of the general qualification of the instruments for an effective disinfection was provided by an independent, officially accredited and recognized (§ 15 (5) MPG) test laboratory using disinfectant OCTENISEPT® clear (Schülke & Mayr, Norderstedt). The procedure described above was considered.

11. Storage

- Do not store instruments in plastic pouches (damaged pouches can cause contamination of the instruments)
- Store in dry conditions



12. Protective measures / Warnings

Protect yourself by wearing appropriate protective gear (gloves, goggles, mask)

13. Residual risks

Possible residual risks are deformations due to gross faulty handling or contamination due to inappropriate disinfection or prohibited re-use which may lead to harm of the patient, user or third persons.

Faulty application of the instrument at excessive speed may lead to an excessive emission of the polishing agent. However, this does not pose any high risk for the patient, user or third person due to harmless ingredients of the impregnation.

In addition, there are the following further residual risks with regard to possible foreseeable application errors, which may result in harm to the patient:

- Incorrect use of speed (too low/too high)
- Contraindicated applications
- Applying excessive pressure

These residual risks are highly unlikely and are not expected in case of appropriate use and handling over the lifecycle of the instrument.

14. Traceability

We recommend keeping the original packaging over the entire lifetime of the instrument in order to ensure traceability via the lot number.

15. Disposal

Used and/or defective parts need to be disinfected before disposal to avoid transmission of germs. Please be careful with sharp edges or tips.

After disinfection instruments can be discarded with general clinical waste.

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16. Notification to competent authorities











Competent national authorities and the manufacturer need to be notified about all serious incidents occurring in the context of the product without delay.



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17. Explanation of symbols

Pictogram	Standard / Directive	Explanation
	EU RL 93/42/EWG (MDD)	Proof of product conformity with the mentioned European directive/regulation and the identification number of the notified body having confirmed this product conformity.
	DIN EN ISO 15223-1 (Reference number 5.1.1)	Manufacturer
	DIN EN ISO 15223-1 (Reference number 5.1.3)	Date of manufacture
	DIN EN ISO 15223-1 (Reference number 5.4.2)	Do not reuse
	DIN EN ISO 15223-1 (Reference number 5.4.3)	Observe instructions for use
	DIN EN ISO 15223-1 (Reference number 5.3.4)	Keep dry
	DIN EN ISO 15223-1 (Reference number 5.4.4)	Caution!
	DIN EN ISO 15223-1 (Reference number 5.1.6)	Article number
	DIN EN ISO 15223-1 (Reference number 5.1.5)	Batch code
	-	Medical device