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1 Indications


1.1 Intended use and indications

Dental polishers are used for polishing (removal, smoothing, high-gloss polishing) dental restoration materials such as zirconia, ceramics, composite resin, non-precious metal alloys and precious metal alloys/silver amalgam. These materials are used in restorations such as inlays, crowns, bridges etc. The polishers are also used to remove adhesive residue from dental enamel, to smooth dental enamel and to remove plaque. The dental polishers are used inside the oral cavity.

Possible applications (examples):

- Contouring, finishing and high-gloss polishing of restorations made of composite resin in the area of the restoration margins and proximal spaces, as well as the final polishing of tooth preparations.
- Contouring and polishing of zirconia restorations. Intraoral repolishing at the obligatory periodical revision sessions.
- Prophylactic treatments
- Removal of bracket adhesive residue

Dental polishers are to be used exclusively by dentists or dental assistants in professional health care facilities (dental practices, dental clinics).

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1.2 Contraindications and adverse reactions

There are no contraindications or adverse reactions.

2 Safety

2.1 General

Read these Instructions for Use completely. Keep these Instructions for Use for future reference. Failure to follow the Instructions for Use may result in injury or damage to the product.

According to the European Medical Device Regulation (2017/745) SUN Oberflächentechnik GmbH is obligated to inform you of the following:

All serious incidents that have occurred in relation to the medical device must be reported to SUN Oberflächentechnik GmbH and the competent authority of the member state in which the user and/or patient is established.

Note:

Serious incidents are understood to mean the death of a patient, user or other person, or the temporary or permanent serious deterioration in the state of health of a patient, user or other person. It does not matter whether these occurred or could occur. The exact definition can be found in Regulation (EU) 2017/745 Article 2 (65).

You can find the contact details of the competent authority in your member state on the Internet using the search terms "Competent Authorities for Medical Devices EU".

We reserve the right to make changes to the design to incorporate technical progress.

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2.2 Layout of safety instructions

CAUTION



The signal word CAUTION indicates dangers which, if ignored, can lead to minor to moderate injuries or impairment of therapy.

WARNING



The signal word WARNING indicates dangers which, if ignored, can lead to serious injuries or severe impairments of the therapy.

2.3 General safety instructions




CAUTION

Only use technically intact and faultlessly hygienic, well-maintained and cleaned turbines, handpieces and contra-angles.



WARNING

Before removing the dental polishers from their original packaging, make sure you have read and understood all information on their intended use, operating speeds in rpm, batch designation and any other information on the packaging.

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WARNING

Dental polishers are not delivered in sterile condition. They must be treated (reprocessed) before each use. You will find the exact reprocessing instructions in our separate “Instructions for reprocessing dental polishers”.



WARNING

Discard polishers immediately if one of the following applies:

- Breakouts are present on the polishing head
- Original geometry of the polishing head is no longer recognizable
- The polisher does not run concentrically (knocking sound)

Use of the dental polishers will not be safe under these circumstances, and effective polishing is no longer guaranteed.



WARNING

Always wear protective goggles. Parts of the instrument may break out as a result of improper use or material defects.



WARNING

Dental polishers may only be used by properly trained professional staff such as dentists and dental assistants.



WARNING





Dental polishers may only be reprocessed by properly trained professional staff such as dentists and dental assistants.




WARNING

Products labelled  are single-use (disposable) products and must not be reused.

2.4 Legend

Symbol	Meaning
	Manufacturer (combined with date of manufacture, address)
	Item number
	Follow instructions for use
 www.sun-dental.de/ifu	Follow instructions for use eIFU available via specified link

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Do not reuse



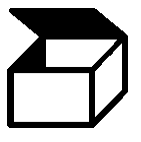
LOT or batch number



Medical Device



CE marking of conformity and number of notified body



Packaging unit



Steam sterilization



Speed of work (rpm)



ISO number



Orthodontics



Prophylaxis



Crown and bridge restorations



Direct restorations



Distributed by:

Address of distributor

(In case of making the device available on the market by a distributor)

Vertrieb durch:

Address of distributor

(In case of making the device available on the market by a distributor)

for Metal

polishing system for Metal

for Model Cast

polishing system for Model Cast

for Composite

polishing system for Composite

for Composite/Ceramic

polishing system for Composite/Ceramic

for Debonding

polishing system for Debonding

for Ceramic

polishing system for Ceramic

for Zirconia

polishing system for Zirconia

for Ceramic/Zirconia

polishing system for Ceramic/Zirconia

for Amalgam/Precious metals

polishing system for Amalgam/Precious metals

for Amalgam

polishing system for Amalgam

for Prophylactic

polishing system for Prophylactic with/without paste

for Composite/Precious metals

Polishing system for Composite/Precious metals

x-coarse

grit size extra-coarse

coarse

grit size coarse

medium

grit size medium

fine

grit size fine

x-fine

grit size x- fine

ultra-fine

grit size ultra- fine

3 Description

3.1 Functional description

Dental polishers consist of a polishing head and a shank (shaft). The shank transfers the energy of the dental handpiece to the polishing head.

The polishing head consists of an elastic bond interspersed with abrasive grain in appropriate particle sizes to produce the desired surface texture, usually after several polishing steps. Different standardized geometries have been defined for the different application zones of the polishing head in EN ISO 21671:2006 + A1:2011.

The shaft is made of metal or of plastic. Standardized connection dimensions according to EN ISO 1797:2017 ensure compatibility with the dental handpieces.

Dental polishers are available as disposable or reusable products; the latter are reprocessed by cleaning, disinfection and, if necessary, sterilization. Please consult our separate "Instructions for reprocessing dental polishers".

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3.2 Indications for use

The dental polisher portfolio comprises multiple product groups, which are designed for the treatment of several materials. The designations of the individual product, the corresponding fields of application and his grit size are indicated by special symbols on the label. A description of the symbols is given under 2.4.

3.3 Grits

The grit designations (UF to XC) are also integrated in the product codes:

- UF ultra-fine
- XF extra-fine
- F fine
- M medium
- C coarse
- XC extra-coarse

4 Instructions

4.1 Polishing of dental enamel/dental materials

- Insert a dental polisher into the chuck of the dentist's handpiece and secure it.
- Check the runout (endplay) of the turbine and handpiece to avoid damaging the enamel and restorations and to achieve the desired polishing result. The rotating axis must be exactly centered.
- Bring the polisher to speed before applying it to the object.
- Polish with slightly circular/oscillating movements to avoid denting.
- Avoid jamming or excessive leverage, as this will increase the risk of breakage.



WARNING

The instruments must be correctly seated in the handpiece chuck and must be engaged if necessary. Incorrectly seated instruments may become detached from the handpiece during polishing.



WARNING

Exposed tooth necks, fractured teeth and tooth roots must not be polished. Polishing these areas can lead to increased abrasion of the tooth.

4.2 Speed of work (rpm)

- Check the recommended and maximum permissible speeds by referring to the information on the packaging. Use the polishers at the recommended speed for best results and to prolong their service life.



WARNING

The maximum permissible speed must not be exceeded. Exceeding the maximum permissible speed may result in destruction of the shank or to instrument breakage, in addition to increased enamel abrasion.

4.3 Cooling/irrigation and applied pressure

- While polishing, cool the polisher using an air/water spray (min 50ml/min).

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WARNING

To avoid excessive heat build-up during polishing, ensure sufficient cooling with an air/water spray. Inadequate cooling may result in irreversible damage to the tooth and surrounding tissue.



WARNING

Excessive pressure may result in damage to the dental pulp due to overheating. In extreme cases, the possibility of instrument failure that could cause injury cannot be ruled out.

5 Additional information

5.1 Storage

It is recommended to store the products protected from dust, moisture and recontamination. Until first use, store the products in their original packaging. After first use, store the products in hygienically maintained instrument blocks, trays or other suitable containers.

5.2 Disposal

Contaminated instruments must be disposed of such that the risk of injury and health hazards to the treatment team or other persons is minimized. The instruments can be disposed of with the regular waste collection. The regionally valid waste regulations must be considered.

5.3 Contact

For product information of any kind, in case of problems or errors or for any questions regarding handling, please contact us:

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