

Instructions for use

RONDOflex™ Powder

1.000.5954

1.000.5955

1.000.5956

1.000.5957



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1 User instructions

1 User instructions

Dear user,
 Congratulations on purchasing this KaVo quality product. By following the notes below you will be able to work smoothly, economically and safely.

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Target group

The instructions for use are intended for medical professionals, in particular dentists and dental practice personnel.















General marks and symbols

| | |
|---|--|
|  | See Chapter on User Instructions/Hazard Levels |
|  | Important information for users and service technicians |
|  | Action request |
|  | CE- mark (European Community). A product bearing this mark meets the requirements of the applicable EC directives. |
|  | Medical device, labelling of medical devices |

Information on the packaging

| | |
|---|---|
|  | Material number |
|  | Lot de production |
|  | Quantity |
|  | Estimated projected amount (quantité estimée) |
|  | Adhere to the expiry date |
|  | Do not reuse – single use only |
|  | Shake before use |
|  | Manufacturer |
|  | Manufacturing date |

1 User instructions

| | |
|---|---|
|  | Follow the electronic instructions for use |
|  | Note: Please note accompanying documents |
|  | HIBC Code |
|  | CE mark for medical devices |
|  | EAC conformity mark (Eurasian Conformity) |
|  | Medical device, labelling of medical devices |
|  | Transportation and storage conditions (temperature range) |
|  | Transportation and storage conditions (air pressure) |
|  | Transportation and storage conditions (Humidity) |
|  | Protect from moisture (Keep dry) |
|  | Recyclable |
|  | Properly dispose of polyethylene terephthalate |
|  | Properly dispose of cardboard |
|  | Original language German |

Hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and material damage. The warning notes are designated as shown below:



 **HAZARD**

In cases which – if not prevented – directly lead to death or severe injury.



 **WARNING**

In cases which – if not prevented – can lead to death or severe injury.

1 User instructions



 **CAUTION**

In cases which – if not prevented – can lead to minor or moderate injury.

CAUTION

In cases which – if not prevented – can lead to material damage.



2 Safety

NOTE

All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority of the member state, in which the user and/or patient resides.

The instructions for use are an integral part of the product and must be read carefully prior to use and must be accessible at all times.

The device may only be used in accordance with the intended use, any other type of use is not permitted.

Also refer to: Safety data sheet RONDOflex Pulver

2.1 Infection hazard

Patients, users or third parties could be infected by contaminated medical devices.

- ▶ Take suitable personal protective measures.
- ▶ Follow the instructions for use of the components.
- ▶ In the case of injury to soft tissue, do not continue treatment in the oral cavity with instruments driven by compressed air.

2.2 Air embolism and skin emphysema

There is a hazard in that the insufflation of spray can cause air embolisms and skin emphysema.

- ▶ Do not insufflate spray in open wounds.

The improper use of the product might lead to emphysema. Emphysema may arise in extreme isolated cases, especially in the presence of pathological gingival pockets (> 3 mm), mucosal lesions, direct skin contact or contact with soft tissue and/or improper handling.

- ▶ The powder jet device must be used as briefly as possible.
- ▶ KaVo recommends always working with a rubber dam.

2.3 Allergic reactions

Also refer to: Safety data sheet RONDOflex Pulver

2.4 Accessories and combination with other equipment

The RONDOflex powder is intended solely for use with the KaVo RONDOflex 360 or the KaVo RONDOflex 2013.

Also refer to: Instructions for use KaVo RONDOflex 360

Also refer to: Instructions for use KaVo RONDOflex 2013

2.5 Qualification of personnel

Application of the product by users without the appropriate medical training could injure patients, users or third parties.

- ▶ Make sure that the user has read and fully comprehends the instructions for use.
- ▶ Make sure that the user has read and comprehends the national and regional regulations.
- ▶ The device may be used only if the user has completed the appropriate medical training.

2.6 Improper use

- ▶ Do not use RONDOflex plus 360 on patients with chronic respiratory diseases.

Removal of powder deposits

- ▶ Remove fine powder deposits with a dust extraction device.
- ▶ Do not wipe with a cloth. This may lead to scratches on sensitive surfaces.
- ▶ Rinse parts insensitive to moisture under running water to remove residual powder.

2.7 Protective equipment

RONDOflex Pulver can be aspirated or get in the eyes of the user or patient during treatment.

- ▶ Wear a surgical mask and gloves during use.
- ▶ Always use particle-impervious clothes and a hood for work.
- ▶ The patient and the dentist must wear eye protection.
- ▶ KaVo recommends always working with a rubber dam and a dust extraction system.
- ▶ Provide for adequate ventilation, avoid producing dust.
- ▶ Do not eat, drink or smoke during work. Wash your hands before breaks and at the end of work.
- ▶ For prophylactic skin protection use a skin care cream. Change contaminated clothing.

2.8 Property damage

The use of RONDOflex Powder and other powders may cause scratches on parts and/or products with sensitive surfaces. Wiping sensitive surfaces with a cloth can cause scratches.

- ▶ Remove fine powder deposits with a dust extraction device.

RONDOflex Powder gets deposited in the amalgam separator such that the amalgam separator needs to be replaced more frequently.

- ▶ Clean the suction hoses of the treatment centre after each use.
 - For this purpose, aspirate approximately 200 ml of water with the hose to be cleaned.
 - Make sure that the sliders at the cannula holders of the suction hoses are closed.

3 Description of the product



- RONDOflex™ Powder, 27 µm 1000 g (**Mat. no. 1.000.5957**)
- RONDOflex™ Powder, 50 µm 1000 g (**Mat. no. 1.000.5956**)
- RONDOflex™ Powder, 27 µm 75 g, RONDOflex plus 360 enclosed in delivery (**Mat. no. 1.000.5955**)
- RONDOflex™ Powder, 50 µm 75 g, RONDOflex plus 360 enclosed in delivery (**Mat. no. 1.000.5954**)

Primary components

Aluminium oxide, Corundum CAS-No. 1344-28-1 (EG-215-691-6)

3.1 Intended use

Indications for use:

This medical device is

- Intended only for dental treatment by a dental professional, the product must not be modified or used for any other purpose since this may be hazardous

The RONDOflex powders are designed to be used with the KaVo RONDOflex 2013 and KaVo RONDOflex 360 in the following applications:

- Preparation for fissure sealing
- Opening and expanding fissures

3 Description of the product | 3.2 Transportation and storage conditions

- Creating micromechanical retention for adhesive restorations to the enamel and dentin with a subsequent acid etching technique
- Preparation of small carious lesions
- Preparation of the adhesive surfaces of brackets
- Cleaning and removal of residual adhesive from bridges, crowns, etc. (extraoral)
- For single use only
- A medical device according to relevant national statutory regulations

Contraindications

RONDOflex and RONDOflex Powder are not designed for the following applications, materials and areas:

- Subgingival applications
- Gingiva treatments
- Treatments of root cement and exposed tooth necks
- The powder is not designed for supra-gingival or close-to-gingival areas as the powder is not soluble.
- Asthma patients
- People with severe dust allergy
- Chronic obstructive pulmonary disease
- Recent dental extraction
- Open wounds
- Sub-gingival caries removal
- Powder jets are not an efficient means for removal of major amalgam restorations since a concerning amount of mercury is released during the abrasion of amalgam.

Proper use:

According to these regulations, this product may only be used for the described application by a properly trained user. You need to comply with the following:

- the applicable health and safety regulations
- the applicable accident prevention regulations
- these Instructions for use

According to these regulations, the user is required:

- to only use equipment that is operating correctly
- to comply with the specified intended use
- to protect him or herself, the patient and third parties from hazards
- to prevent contamination from the product


3.2 Transportation and storage conditions


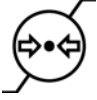

CAUTION

Startup after refrigerated storage.

Malfunction.

- ▶ Prior to startup, strongly refrigerated products must be allowed to warm up to a temperature of 20 °C to 25 °C (68 °F to 77 °F).

| | |
|---|---|
|  | Temperature: -29 °C to +50 °C (-20 °F to +122 °F) |
|---|---|

| | |
|---|--|
|  | Relative humidity: 5% RH to 85% RH absence of condensation |
|  | Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi) |
|  | Protect from moisture (Keep dry) |



NOTE

Store the powder in a cool and dry location. Filling date is printed on the product.

RONDOflex powder is durable for a virtually unlimited time. The minimum storage life in terms of pourability is 3 years.

- ▶ Lumps that may have formed can be disintegrated with little mechanical force.

Currently applicable packaging law

Dispose of and recycle the packaging appropriately in accordance with current packaging law, employing waste management / recycling companies. Comply with the comprehensive return system. KaVo has had its packaging licensed for this purpose. Please comply with the regional public waste-disposal system.

4 Operation

4.1 Filling the powder container



CAUTION

Open powder container.

Infection hazard from contaminated powder.

- ▶ Only use original KaVo powder
- ▶ Reprocess and refill the powder container before each patient
- ▶ Comply with the safety data sheets for KaVo powders
- ▶ Safety data sheets are available for inspection at www.kavo.com, "Safety data sheets".

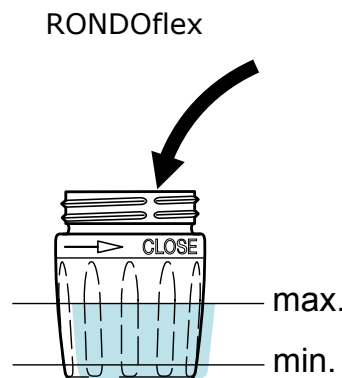
Also refer to: Instructions for use of the RONDOflex handpiece



NOTE

The powder should be in absolutely dry, fine-grained and pourable condition.

- ▶ Unscrew the powder container in anticlockwise direction.
- ▶ Before filling the powder container, shake the powder in the refilling bag well.
- ▶ Fill the powder container to the recommended level.



- ▶ To screw-on the powder container and to tighten it, keep the container upright and turn it clockwise.
- ⇒ Minimum filling level 20%
- ⇒ Optimal abrasion performance at a filling level of 70%

4.2 Application instructions RONDOflex Powder

The front part of the instrument can be rotated to reach the optimum working position at all times.

- ▶ For practicing with the RONDOflex plus, produce a cavity on a disposable mirror to familiarise yourself with the handpiece.



NOTE

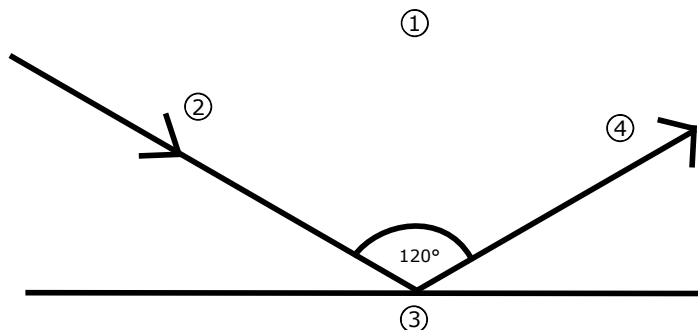
KaVo recommends to use a disposable mirror during treatment.

Selection of grain size:

- 27 µm for smooth polishing force
- 50 µm for more intense abrasion force

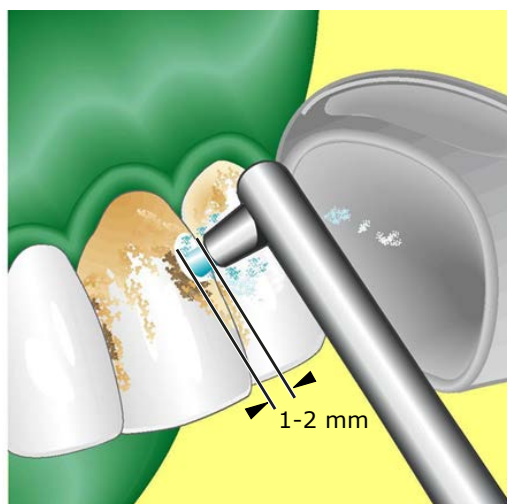
Working motion:

- ▶ Perform slow, brushing motion over the tooth substance.
- ▶ Make sure to check for intermittent or continuous application of the powder.
- ▶ Aspirate at an angle of 120° to the cannula, as closely as possible without impeding.



Optimal entry and exit angle of the powder jet

- | | |
|--------------------|-------------------|
| ① Continuous jet | ③ Tooth surface |
| ② Entry powder jet | ④ Exit powder jet |



Optimal working angles and distances

4.3 Applications

To create cavities

- ▶ Focus on a spot.
- ▶ Improve the abrasion performance with an intermittent powder jet.
- ▶ Keep a working distance of 1 mm.
- ▶ Hold the powder jet perpendicular to the surface of the tooth.
- ▶ Select a cannula with a diameter of 0.46 mm.

To roughen surfaces, e.g. for adhesive surfaces of brackets

- ▶ Work with brush-like strokes.
- ▶ Keep a distance of 1 - 2 mm.
- ▶ Hold the powder jet perpendicular to the surface of the tooth.
- ▶ Select a cannula with a diameter of 0.6 mm.



NOTE

Keeping a short distance to the site of preparation results in focused abrasion performance.

With the larger distance to the preparation side, the abrasion is wider-spread and lesser.

- ▶ Rinse the patient's mouth with water after the treatment.

Use outside of the oral cavity (Extraoral use)

The RONDOflex plus can also be used outside of the oral cavity, e.g. in order to remove residual adhesive from crowns. If you work outside of the oral cavity, please remember that powder dust is being generated around the working field. The powder dust may impair the function of devices/handpieces situated in the vicinity.

- ▶ Provide for adequate dust extraction.
- ▶ Objects that may contact the powder jet should be covered with a cloth to protect the surface from damage. If necessary, remove dust-sensitive objects from the respective environment.

5 Troubleshooting

Possible application errors:

| Cause | Remedy |
|---|---|
| The distance from the tooth surface is too large leading to lesser abrasion performance | Keep a work in distance of 1 mm |
| Brushing motion with the tip during cavity preparation leads to a smaller cavity depth | Focus on one spot during cavity preparation |
| Working on overly large carious lesions | It is not possible to work, or only to a limited degree, since the soft carious material dissipates the kinetic energy of the powder particles. Abrade the carious lesion ahead of time using conventional technique. |
| Insufficient amount of powder in the container | Fill the powder container at least 20%. Ideally, the powder container is half-filled (approximately 20 grams). |
| Low drive pressure | Attach the RONDOflex accurately to the MULTIflex coupling and push it backward until you hear it snap in. |



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