Instructions for use
RONDOflex plus 360 - REF 1.002.2179

KaVo. Dental Excellence.

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Contents

1 User instructions

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

Symbols

	Refer to the Chapter on Safety/Warning symbol
	Important information for users and service technicians

▶	Action request
CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfectable

Target group

This document is intended for dentists and their assistants. The section on starting up is also intended for service technicians.

2 Safety

2.1 Description of safety instructions

	Warning symbol

Structure

⚠ DANGER

The introduction describes the type and source of the hazard.
This section describes the potential consequences of non-observance.

- ▶ The optional step includes necessary measures for hazard prevention.

Description of hazard levels

The safety instructions listed here, together with the three levels of danger will help avert property damage and injury.

	⚠ CAUTION **CAUTION** indicates a hazardous situation that can cause damage to property or mild to moderate injuries.

	⚠ WARNING **WARNING** indicates a hazardous situation that can cause death or serious injury.

⚠ DANGER

DANGER
indicates a hazardous situation that can directly cause death or serious injury.

2.2 Safety instructions

⚠ WARNING

Damage from soiled and moist compressed air.
Contaminated and moist compressed air can cause malfunctions and lead to premature bearing wear.

- ▶ In general, ensure dry, clean uncontaminated compressed air according to EN ISO 7494-2.

⚠ CAUTION

Premature wear and malfunctioning from improper storage during long periods of nonuse.
Reduced product life.

- The medical device should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of non-use.

⚠ CAUTION

Injury or damage due to wear.
Irregularities in the product.

- Stop work and seek service support.

⚠ CAUTION

Hazard from aerosols.
Infection from aerosols.

- Never work without safety goggles, a dust mask (P 2), protective gloves, particle-impervious clothes and a hood.
- We recommend using a dental dam and a dust extraction system.

⚠ CAUTION

Hazard from the jet directly contacting the gingiva and the insufflation of blown air into open wounds.
This can cause injury, air embolisms as well as skin emphysema.

- Keep the jet from directly contacting the gingiva and avoid the insufflation of blown air into open wounds.

⚠ CAUTION

Cleansers and disinfectants can attack the plastic housing.
This can form hairline cracks and cause other damage which can create a hazardous situation.

- ▸ The RONDOflex plus therefore has to undergo a safety check every two years.

Note

Never use the RONDOflex plus on patients with chronic diseases of the respiratory passages.

Note

It is easiest to remove fine powder deposits with a vacuum cleaner. Wiping them off with a cloth can easily cause scratches in sensitive surfaces. Rinse parts insensitive to moisture under flowing water to remove residual powder.

The following individuals are authorized to repair and service KaVo products:

- Technicians at KaVo branches throughout the world
- Technicians specially trained by KaVo

3 Product description

RONDOflex plus 360, **Mat. no. 1.002.2179**

3.1 Purpose – Intended use

Purpose:

This medical device is

- only for dental treatment by a dental professional. The product may not be changed or used for any other purpose since this may be hazardous.
  The RONODflex plus is an air abrasion system that accelerates aluminium oxide particles in an air jet to a high speed to abrade material from the surface of teeth.
- A medical device according to relevant national statutory regulations.

The RONDOflex plus is suitable for the following indications:

- Preparation for sealing fissures
- Opening and expanding fissures
- Creating micromechanical retention for adhesive restorations to the enamel and dentin with a subsequent acid etching technique
- Preparing small carious defects
- Preparing the adhesive surfaces of brackets
- Cleaning and removing residual adhesive from bridges, crowns, etc. (extraoral)

Proper use:

According to these regulations, this medical device may only be used for the described application by a knowledgeable user. The following must be observed:

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

According to these regulations, it is the responsibility of the user to:

- only use equipment that is operating correctly,
- use the equipment for the proper purpose,
- protect him or herself, the patient and third parties from danger, and
- avoid contamination from the product.

3.2 Technical data

Drive pressure	3.2 - 6.0 bar (46 - 87 psi)
Water pressure	1.5 ± 0.1 bar (22 ± 1 psi)
Air consumption	5 - 11 Nl/min depending on the type of cannula
Water quantity	35-45 ml/min.
Port:	Can be attached to all MULTIflex (LUX) / MULTIflex LED coupling.

Note

The pressure set for the turbine drive is automatically increased 20%, from 2.8 to 3.2 bar (41 to 46 psi)..

Have a service technician regularly check the manufacturer's recommended pressure for your unit to ensure that the instruments function properly.

3.3 Transportation and storage conditions

⚠ CAUTION

It is hazardous to start up the medical device after it has been stored strongly refrigerated.
This can cause the medical device to malfunction.

- Prior to start-up, very cold products must be heated to a temperature of 20°C to 25°C (68°F to 77°F).

	Temperature: -20°C to +70°C (-4°F to +158°F)
	Relative humidity: 5% RH to 95% RH absence of condensation
	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
	Protect from moisture

4 First use

⚠ WARNING

Hazard from nonsterile products.
Infection danger to the care provider and patient.

- ▶ Before first use and after each use, prepare and sterilise the medical device if needed.

5 Operation

5.1 Operating instructions

Practice creating a cavity in a disposable mirror with the RONDOflex plus to familiarize yourself with the device.
Use surgical loupes or a microscope to check the minimally invasive work.

Note

It is recommendable to use a disposable mirror during treatment.

To create cavities

- Focus on a point
- An intermittent powder jet can improve abrasion.

- Working distance: 1 mm
- Hold the powder jet perpendicular to the surface of the tooth

To roughen surfaces, for example adhesive surfaces of brackets

- Use a brushing motion
- Distance: 1 mm
- Hold the powder jet perpendicular to the surface of the tooth

Extraoral use

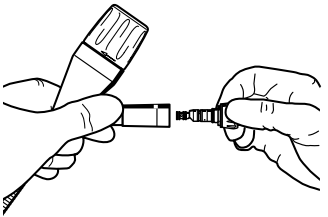
You can of course also use the RONDOflex plus outside of the oral cavity.
When for example adhesive residue needs to be removed from crowns. Remember that dust accumulates around the working field. This can impair the function of nearby devices and instruments. You should therefore provide suitable dust extraction. Objects that may contact the powder jet

should be protected with a cloth. Otherwise, the surface may become damaged. if necessary, removed dust-sensitive objects from the affected environment.

5.2 Attaching the medical device

Note

Pull on the RONDOflex plus to check its seat on the MULTIflex coupling.

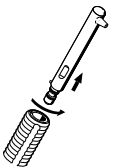


- Position the RONDOflex plus precisely on the MULTIflex coupling and push it to the back until it audibly locks into place.

5.3 Removing the medical device

- Grasp the MULTIflex (LUX) / MULTIflex LED coupling, and pull the RONDOflex plus forward twisting slightly.

5.4 Inserting the cannula



- Before inserting the cannula, blow out the receiving hole with compressed air.

- Insert the cannula into the handpiece, and turn it all the way to the right with the key opposite the direction of the arrow.

⚠ CAUTION

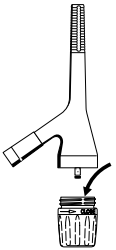
The marks must be adjacent; otherwise the cannula can come loose.
If the cannula comes off during treatment, it could substantially endanger the patient and user.

- Pull on the cannula each time before treatment and check its seat.
- Before each treatment, make sure that the cannula operates properly.

5.5 Removing the cannula

- Turn the cannula with the key all the way to the left in the direction of the arrow, and remove it.

5.6 Filling the powder container



- Unscrew the powder container to the left against the direction of the arrow.
- Fill the powder container half way with RONDOflex powder (20 g).
- Screw on the powder container straight on to the right in the direction of the arrow.

⚠ CAUTION

Close the powder container if it is not needed.
If you do not need the powder container, close it with the rubber cover.

- Only use original KaVo RONDOflex powder.

Note

Observe the safety data sheet for the RONDOflex 2013 powder 50 µm or 27 µm! This can be read under www.kavo.com, „Safety data sheets".

6 Troubleshooting

- The distance to the tooth surface is too far
- When preparing cavities, "paint" with the tip
- The caries lesions are too large since the kinetic energy of the powder particles is lost due to the soft caries material
- Too little powder in the container (min. 20% full)
- Too little drive pressure

6.1 O-rings on the coupling

⚠ CAUTION

Missing or damaged O-rings.
Malfunctions and premature failure.

- Make sure that all O-rings are on the coupling and undamaged.

All O-rings must be present and undamaged.

7 Reprocessing methods according to ISO 17664

7.1 Preparation at the site of use

⚠ WARNING

Hazard from nonsterile products.
There is a risk of infection from contaminated medical devices.

- ▸ Take suitable personal protective measures.

- ▸ Remove all residual cement, composite or blood without delay.
- ▸ The medical device must be dry when transported for reconditioning.
- ▸ Do not place it in a solution or similar.
- ▸ Recondition the medical device as soon as possible after treatment.
- ▸ Remove the insert from the medical device.

7.2 Cleaning

⚠ CAUTION

Malfunctions from cleaning in the ultrasonic unit.
Defects in the product.

- ▶ Only clean manually or in a thermodisinfector.

⚠ CAUTION

Malfunction from cleaning with oils or maintenance spray.
Defective product.

- ▶ Do not clean the medical device with oils or maintenance of spray.

7.2.1 Cleaning: Manual external cleaning

Accessories required:
- Tap water 30 °C ± 5 °C (86 °F ± 10 °F)
- Brush, e.g. medium-hard toothbrush

▸ Brush off under flowing tap water.

7.2.2 Cleaning: Automated external cleaning

KaVo recommends thermodesinfectors in accordance with EN ISO 15883-1 that are operated with alkaline cleaning agents at a pH value of max. 10 (e. g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" program, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).
- In order to prevent impairment of the KaVo medical device, make sure that the inside and outside of the device is dry after the end of the cycle.

7.2.3 Cleaning: Manual internal cleaning

Note

Remove the cannula prior to the manual internal cleaning!

Can only be done with KaVo CLEANspray or KaVo DRYspray.

- Cover the medical device with the KaVo CLEANpac bag, and place it on the corresponding care adapter. Press the spray button three times for 2 seconds each time. Remove the medical device from the spray attachment and let the cleaner work for one minute.
- Afterwards, rinse for 3-5 seconds with KaVo DRYspray.

See also: KaVo CLEANspray / KaVo DRYspray Instructions for Use

Note

KaVo CLEANspray and KaVo DRYspray for manual interior cleaning are only available in the following countries:
Germany, Austria, Switzerland, Italy, Spain, Portugal, France, Luxembourg, Belgium, Netherlands, United Kingdom, Denmark, Sweden, Finland and Norway.
In other countries, only automated interior cleaning with thermodisinfectors in accordance with ISO 15883-1.

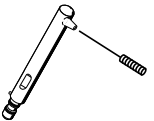
7.2.4 Cleaning: Automated internal cleaning

KaVo recommends thermodesinfectors in accordance with EN ISO 15883-1 that are operated with alkaline cleaning agents at a pH value of max. 10 (e. g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" program, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).

- In order to prevent impairment of the KaVo medical device, make sure that the inside and outside of the device is dry after the end of the cycle.

7.2.5 Cleaning: Cleaning the cannulas



- Remove the cannulas.
- Twist the nozzle needle from the front and then from the back into the cannula.
- Remove the nozzle needle, and blow out the cannula with compressed air.

or

- Remove the cannula and rinse it with tap water.

7.3 Disinfection

⚠ CAUTION

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine.
Defects in the product.

- ▶ Only disinfect in a thermodisinfector or manually.

7.3.1 Disinfection: Manual external disinfection

KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer.

- Mikrozid AF Liquid made by Schülke & Mayr
- FD 322 made by Dürr
- CaviCide made by Metrex

Consumables required:
- Cloths for wiping off the medical device.

▶ Spray the disinfectant on a cloth, then wipe down the medical device and allow the disinfectant to act according to the instructions of the disinfectant manufacturer.

▶ Follow the instructions for use of the disinfectant.

7.3.2 Disinfection: Manual internal disinfection

The efficacy of manual internal disinfection must be demonstrated by the manufacturer of the disinfection agent. With KaVo products, use only disinfection agents that have been released by KaVo with respect to the compatibility of materials (e.g. WL-cid / made by ALPRO).

- ▸ Follow the instructions for use of the disinfectant.

7.3.3 Disinfection: Automated external and internal disinfection

KaVo recommends thermodesinfectors in accordance with EN ISO 15883-1 that are operated with alkaline cleaning agents at a pH value of max. 10 (e. g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" program, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent and "neodisher® mielclear" rinsing

agent and extends only to the compatibility of materials with respect to KaVo products).

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).
- In order to prevent impairment of the KaVo medical device, make sure that the inside and outside of the device is dry after the end of the cycle.

7.4 Drying

Manual Drying

- Blow off the outside and inside with compressed air until water drops are no longer visible.

Automatic Drying

The drying procedure is normally part of the disinfection program of the thermodisinfector.

Note

Please follow the instructions for use of the thermodisinfector (compressed air quality - see the Warning under "Start-up").

7.5 Care products and systems - Servicing

⚠ CAUTION

Insufficient product care.
This can cause damage and malfunction.

- ▶ Before each thermodisinfection or sterilisation, unscrew the powder container, empty it and thermodisinfect or sterilise it with the handpiece.
- ▶ Likewise, clean off any powder residue on the the RONDOflex, especially the cannulas, tubes and powder nozzle.

7.6 Packaging

Note

The sterilisation bag must be large enough for the handpiece so that the bag is not stretched.
The quality and use of the sterilisation packaging must satisfy applicable standards and be suitable for the sterilisation procedure!

- Individually weld the medical device in the sterilised item packaging (such as KaVo STERIclave bags **Mat. no. 0.411.9912**)!

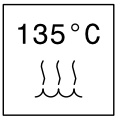
7.7 Sterilisation

Sterilisation in a steam steriliser (autoclave) in accordance with EN 13060/ISO 17665-1

⚠ CAUTION

Contact corrosion due to moisture.
Damage to product.

- Immediately remove the product from the steam steriliser after the sterilisation cycle!



The KaVo medical device has a maximum temperature resistance up to 138 °C (280.4 °F).

(Depending on the available autoclave,) select a suitable procedure from the following sterilisation processes:

- Autoclave with three times initial vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Autoclave using the gravitation method:
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F) or alternatively
  - at least 60 minutes at 121 °C -1 °C / +4 °C (250 °F -1.6 °F / +7.4 °F)

- Use according to the manufacturer's Instructions for Use.

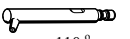
7.8 Storage

- Reprocessed products should be stored protected from dust with minimum exposure to germs in a dry, dark and cool space.
- Comply with the expiry date of the sterilised items.

8 Tools and consumables

1 set consists of

Available from dental suppliers.



Name	Mat. no.
cannula 110° - 0.64 mm	1.002.6251
cannula 110° - 0.46 mm	1.002.9176
Wrench	1.002.6250
Powder container 27 µm	1.003.1235
Rubber cover	1.000.2678
Powder 27 µm 1000 g	1.000.5957
Powder 50 µm 1000 g	1.000.5956
Cleaning drill	1.001.3602
Nozzle tube	1.002.9920

Further tools and consumables

Name	Mat. no.
cannula 90° - 0.46 mm	1.002.9182
cannula 90° - 0.64 mm	1.002.9179

Name	Mat. no.
O-ring for cannulas	0.200.6019
Powder container 50 µm	1.003.1236
Container seal	0.573.6072

9 Terms and conditions of warranty

The following warranty conditions apply to this KaVo medical device:

KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 12 months from the date of the invoice, subject to the following conditions:
In case of justified complaints, KaVo will honor its warranty with a free replacement or repair. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
KaVo shall not be liable for defects and their consequences that have or may have arisen from natural wear, improper handling, improper cleaning, maintenance or care, non-compliance with operating or connection instructions, calcination or corrosion, contaminated air or water supplies

as well as chemical or electrical influences that are deemed abnormal or non-permissible in accordance with KaVo's instructions for use or other manufacturer's instructions. The warranty does not usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts.
All liability is excluded if defects or their consequences originate from manipulations or changes to the product made by the customer or a third party that is not authorised by KaVo.
Service warranty claims will only be accepted if the product is submitted along with proof of purchase in the form of a copy of the invoice/delivery note. The dealer, purchase date, type and serial number must be clearly evident from this document.

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