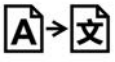
Instructions for use

RONDOflex plus 360 - 1.002.2179

KAVO
Dental Excellence

Distribution:
KaVo Dental GmbH
Bismarckring 39
88400 Biberach
Germany
Phone +49 7351 56-0
Fax +49 7351 56-1488

Manufacturer:
KaVo Dental GmbH
Bismarckring 39
88400 Biberach
Germany
www.kavo.com



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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.

RONDOflex® is a registered trademark of KaVo Dental GmbH.

All other trademarks are property of their respective owners.

KaVo Original Factory Repair

In the event of a repair, please ship your product to the KaVo Original Factory Repair using https://www.kavobox.com.

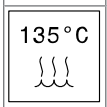
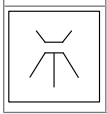
KaVo Technical Service
If you have any questions or complaints, please contact the KaVo Technical Service:
+49 (0) 7351 56-1000
service.instrumente@kavo.com

Target group

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

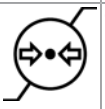
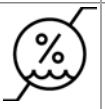
The section on startup is also intended for the service staff.

General marks and symbols

	See Chapter on User Instructions/Hazard Levels
	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 directives.
	Can be steam sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfectable

Information on the packaging

REF	Material number
SN	Serial number

	Manufacturer
	Manufacturing date
	Note: Please note accompanying documents
	Follow the electronic instructions for use
	HIBC Code
	CE mark for medical devices
	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)
	Protect from impact
	Do not dispose of with household waste
	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.

⚠ 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.

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.
- Before initial startup and after each use, reprocess the product and accessories appropriately.
- Carry out the reprocessing as described in the instructions for use. The procedure has been validated by the manufacturer.
- If you deviate from this validated procedure, make sure that the reprocessing procedure is effective.
- Reprocess the product and accessories appropriately before disposal.
- Use gloves or a finger guard when you test, insert and remove the dental bur.
- 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 Technical condition

If damaged, the device or components could injure patients, users and third parties.

- Only operate devices or components if they show no signs of damage on the outside.
- Check to make sure that the device is working properly and is in satisfactory condition before each use.
- Have parts with sites of breakage or surface changes checked by the service personnel.
- If the following defects occur, stop working and have the service personnel carry out repair work:
  - Malfunctions
  - Damage

- Irregular running noise
- Excessive vibration
- Overheating

To ensure optimum function and to prevent property damage, please comply with the following instructions:

- Service the medical device regularly with care products and systems as described in the instructions for use.
- The device should be reprocessed and stored in a dry location, according to instructions, if it is not to be used for an extended period of time.

2.4 Accessories and combination with other equipment

Use of non-authorised accessories or non-authorised modifications of the device could lead to injury.

- Only use accessories that have been approved for combination with the product by the manufacturer.
- Only use accessories that are equipped with standardised interfaces.
- Do not make any modifications to the device unless these have been approved by the manufacturer of the product.
- Use original KaVo spare parts only.
- The RONDOflex plus 360 is designed solely for use with KaVo RONDOflex Powder.
  Also refer to: Instructions for use KaVo RONDOflex Powder

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.
- Observe national and regional regulations.

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 Service and repair

Repairs, servicing and safety checks may only be performed by trained service personnel. The following persons are authorised to do this:

- Service technicians of KaVo branches after the appropriate product training
- Service technicians of KaVo authorised dealers after the appropriate product training

Observe all the following items during servicing work:

- Have the service and testing tasks carried out according to the Medical Device Operator Ordinance.
- KaVo recommends specifying in-house service intervals where the medical device is brought to a professional shop for cleaning, servicing and a function check. Define the service interval depending on the frequency of use.

Cleansers and disinfectants that have not been approved can damage the plastic housing possibly leading to hairline cracks and other damage which can ultimately cause hazards.

- Only use spare parts that comply with the specification for repair; original KaVo spare parts comply with the specification.
- Subject the product to a safety check every 2 years. Please contact your local dealer or the KaVo Repair Service directly: www.kavobox.com

NOTE

If a repair is done with NON-KaVo original spare parts, this may constitute a product modification that leads to the loss of CE conformity. In the event of damage, the responsibility is with the service company or the operator.

The introduction of a modified product in the market, in which the reasonable suspicion exists to endanger the safety and health of patients or users, is prohibited by Medical Device Law §4, Abs.1 No. 1 and therefore requires its own conformity check.

2.8 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.

2.9 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

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 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

RONDOflex plus is designed for the following indications:

- Preparation for fissure sealing
- Opening and expanding fissures
- 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)

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 Technical specifications

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.

Can be attached to all MULTIflex (LUX) / MULTIflex LED couplings.

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

NOTE
Have a service technician regularly check the manufacturer's recommended pressures for your treatment centre to ensure that the handpiece works properly.

3.3 Scope of delivery

Description	Mat. no.
Set consisting of:	
RONDOflex plus 360	**Mat. no. 1.002.2179**

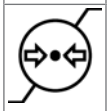
Description	**Mat. no.**
Cannula 110/0.6 mm	**Mat. no. 1.002.6251**
Powder container blue 50µm	**Mat. no. 1.003.1236**
Accessories:	
Cannula 110°/0.46 mm	**Mat. no. 1.002.9176**
Key for fixing the cannula	**Mat. no. 1.002.6250**
Powder container blue 27µm	**Mat. no. 1.003.1235**
2 x cover for powder container (rubber cover)	**Mat. no. 1.000.2678**
Cleaning bur	**Mat. no. 0.573.0321**
Nozzle needle	**Mat. no. 0.573.6052**
RONDOflex Powder 27µm 75g	**Mat. no. 1.000.5955**
RONDOflex Powder 50µm 75g	**Mat. no. 1.000.5954**

4 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)

5 Startup and shut down

⚠ WARNING

Hazard from contaminated products.

Infection hazard to the dentist and patient.

- Prior to initial startup and after each use, reprocess the product and accessories.

⚠ WARNING

Dispose of the product in appropriate manner.

Infection hazard.

- Reprocess the product and accessories before disposal.

Also refer to:
8 Reprocessing steps in accordance with ISO 17664, Page 22

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.

CAUTION

Damage from soiled and moist cooling air/compressed air.
Contaminated and moist cooling air can cause malfunctions.

- Make sure that the supply of cooling air is dry, clean and uncontaminated according to DIN EN ISO 7494-2.

5.1 MULTIflex (LUX) / MULTIflex LED coupling

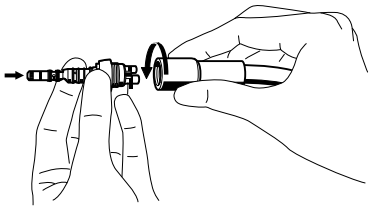
⚠ WARNING

Detaching the medical device during treatment.

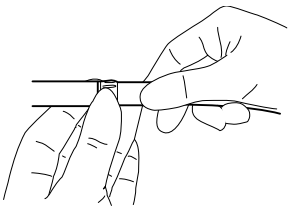
A medical device that is not properly locked can detach from the coupling during treatment.

- Before each use, check if the medical device is securely locked onto the coupling.

- Screw the MULTIflex coupling onto the turbine hose and tighten it with the wrench (**Mat. no. 0.411.1563**).



- Open the water supply all the way using the spray ring on the MULTIflex coupling.



5.2 Checking the pressures

CAUTION

Damage from soiled and moist cooling air/compressed air.
Contaminated and moist cooling air can cause malfunctions.
- Make sure that the supply of cooling air is dry, clean and uncontaminated according to DIN EN ISO 7494-2.

A drive pressure of 3.2 bar (46 psi) is required for operation of the RONDOflex.

- Insert the pressure gauge (**Mat. no. 0.411.8731**) between the coupling and the medical device and check the following pressures:
- Drive air: 3.2 - 6.0 bar (46 - 87 psi)
- Water: 1.5 ± 0.1 bar (22 ± 1 psi)

5.3 Checking the O-rings

CAUTION

Missing or damaged O-rings.
Malfunction and premature failure.
- Make sure that all O-rings are on the coupling and are undamaged.

Number of available O-rings: 5

6 Operation

⚠ WARNING

Respiratory difficulties.

Respiratory difficulties due to the powder jet device.

Do not treat patients who suffer from chronic bronchitis or asthma with the powder jet device. The jet of air and powder could lead to respiratory difficulties.

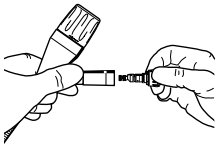
⚠ WARNING

Bacteraemia.

The treatment of deep periodontal pockets can lead to bacteraemia.

- For the treatment of patients at risk (generally weakened immune system, endocarditis) make necessary restrictions for treatment.

6.1 Attaching the medical device



- Place the RONDOflex plus accurately on the MULTIflex coupling and push it to the back until it audibly locks into place
- Pull on the RONDOflex plus to check its secure seating on the MULTIflex coupling.

6.2 Removing the medical device

- Grasp the MULTIflex coupling, and pull the RONDOflex plus forward while twisting it slightly.

6.3 Filling the powder container

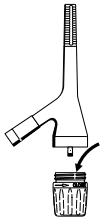
⚠ CAUTION

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".

- Unscrew the powder container to the left against the direction of the arrow.



- Before filling the powder container, shake the powder in the refilling bag well.
- Fill the powder container half way with RONDOflex powder (20 g).
- Keep the rubber cover on the powder container to close it until the powder is used on the patient.
- Remove the rubber cover before use.

- RONDOflex Pulver powder is durable for a virtually unlimited time.
- Screw on the powder container straight on to the right in the direction of the arrow.

6.4 Inserting the cannula

- Select a cannula to match the application:

Technical Specifications	Cannula mounted 110°/0.6 (1.002.6251)	Cannula mounted 110°/0.46 (1.002.9176)	Cannula mounted 90°/0.6 (1.002.9179)	Cannula mounted 90°/0.46 (1.002.9182)
Diameter	**0.6 mm** ▪ For widespread abrasion power, e.g. powder jets for preparation for adhesive technique.	**0.46 mm** ▪ For more precise, rather spot-like abrasion and working in depth.	**0.6 mm** ▪ For widespread abrasion power, e.g. powder jets for preparation for adhesive technique.	**0.46 mm** ▪ For more precise, rather spot-like abrasion and working in depth.
Flow rate	4.0 g/min	2.0 g/min	4.0 g/min	2.0 g/min
Angle	**110°** ▪ Higher power: powder does not need to be deflected as strongly.	**110°** ▪ Higher power: powder does not need to be deflected as strongly.	**90°** ▪ Improved access to molar, distal region.	**90°** ▪ Improved access to molar, distal region.

- Before inserting the cannula, blow out the receiving hole with compressed air.
- Insert the cannula into the handpiece, and turn clockwise to the end stop with the key (**Mat. no. 1.002.6250**) opposite to the direction of the arrow.

⚠ WARNING

Cannula falls off during the treatment.

Unless the cannula is inserted properly, it can detach from the handpiece during the treatment.

- Pull on it before each treatment to check if the cannula is safely inserted in the handpiece.
- Before each treatment, make sure that the cannula operates properly.

6.5 Removing the cannula

- Turn the cannula anticlockwise to the end stop with the key in the direction of the arrow, and remove it.

6.6 Use

- 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.

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.

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.

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.

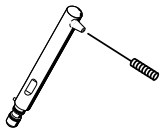
7 Checking for malfunctions and troubleshooting

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	Place the RONDOflex plus accurately on the MULTIflex coupling and push it to the back until it audibly locks into place.

7.1 Cleaning a blocked cannula

NOTE
After using a nozzle needle or cleaning bur, the instrument must be reprocessed before further use. Nozzle needle and cleaning bur cannot be reprocessed.



- Unscrew the cannula with the wrench (**Mat. no. 1.002.6250**).
- Slide the nozzle needle into the cannula from the front while rotating it.
- Then remove the nozzle needle, and blow out the cannula with compressed air.

7.2 Cleaning a clogged main body

NOTE
After using a nozzle needle or cleaning bur, the instrument must be reprocessed before further use. Nozzle needle and cleaning bur cannot be reprocessed.

- Pull off the cannula.
- Unscrew the powder container in anticlockwise direction.
- Push the nozzle needle through the aperture of the nozzle.

Unscrew the nozzle and use the cleaning bur to clean or remove obstructions from the media tube:

- Carefully insert the cleaning bur until there is noticeable resistance.
- Screw the cleaning bur in by 0.5 to 1 turns in clockwise direction exerting a mild pressure and pull it out again.
- Keep the media tube as perpendicular as possible to allow the detached powder to drop out.
- Repeat this process until there is no obstruction present in the media tube.

- Then blow through with compressed air.
- Re-attach the nozzle carefully and with gentle force with the wrench.

8 Reprocessing steps in accordance with ISO 17664

8.1 Preparations at the site of use

⚠ WARNING

Hazard from contaminated products.

Contaminated products are associated with an infection hazard.

- Take suitable personal protective measures.

- Reprocess the medical device right after treatment.
- The medical device must be dry when transported to reprocessing.
- To minimise the risk of infection during reprocessing, always wear protective gloves.
- Remove the dental bur from the medical device.
- Remove all residual cement, composite or blood immediately.
- Do not place in solutions or similar substances.

8.2 Disassembly

⚠ WARNING

Incomplete reprocessing.

Infection hazard.

- To ensure complete reprocessing of all parts, the medical device needs to be disassembled before reprocessing.

- Unscrew the powder container.
- Unscrew the cannula with the wrench (**Mat. no. 1.002.6250**).

8.3 Pre-cleaning

CAUTION

Never reprocess this medical device in an ultrasonic cleaner.
Malfunction and material damage.

- Reprocess in a washer disinfector or by hand only.

Accessories required:

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

- Disassemble the instrument completely.
- Brush off all individual parts under running tap water.

8.4 Manual reprocessing

CAUTION

Never reprocess this medical device in an ultrasonic cleaner.
Malfunction and material damage.

- Reprocess in a washer disinfector or by hand only.

8.4.1 Manual external cleaning

This product is not designed for manual external cleaning.

For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with EN ISO 15883-1.

8.4.2 Manual internal cleaning

This product is not designed for manual internal cleaning.

For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with EN ISO 15883-1.

8.4.3 Manual external disinfection

This product is not designed for manual external disinfection.

For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with EN ISO 15883-1.

- Manual external disinfection is permissible only as an occupational safety measure (personal protection measure).

CAUTION

Never reprocess the medical device with chloride-containing products.
Malfunction and material damage.

- Reprocess in a washer disinfector or by hand only.

KaVo recommends the following products based on the compatibility of the materials. The microbiological efficacy must be ensured by the disinfectant manufacturer and proven by an expert opinion.

Approved disinfectants:

- CaviWipes and CaviCide made by Metrex
- Mikrozid AF made by Schülke & Mayr (Liquid or wipes)
- FD 322 made by Dürr

Consumables required:

- Cloths for wiping 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.

8.4.4 Manual internal disinfection

This product is not designed for manual internal disinfection. For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with EN ISO 15883-1.

8.4.5 Manual drying

This product is not designed for manual drying.

For effective reprocessing, automated internal and external cleaning as well as automated internal and external disinfection with a cleaning and disinfection unit in accordance with EN ISO 15883-1 is required.

8.5 Automated reprocessing

⚠ WARNING

Incomplete disinfection.

Infection hazard.

- Only use disinfection procedures that are verified to be bactericidal, fungicidal and virucidal.
- If the disinfectants/disinfection procedures fail to meet the mandatory national requirements, perform a final sterilisation with the sterilisation parameters as described.

CAUTION

Never reprocess the medical device with chloride-containing products.
Malfunction and material damage.

- Reprocess it in a washer disinfector only.

CAUTION

Never reprocess this medical device in an ultrasonic cleaner.
Malfunction and material damage.

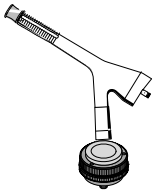
- Reprocess it in a washer disinfector only.

8.5.1 Preparation for automated internal and external cleaning as well as internal and external disinfection

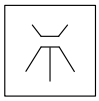
NOTE

Adapters are needed for automated cleaning.

Order adapter separately.

Main body	Requisite material: Cleaning cover (**Mat. no. 3.005.4213**) Reprocessing with Miele AUF adapter ▸ Remove the cannula ▸ Attach the cleaning cover (3.005.4213) and snap it into place	
Cannula	Requisite material: Cleaning adapter (**Mat. no. 3.006.4667**) Reprocessing with Miele AUF adapter	
Powder container	Requisite material: Reprocessing in Miele sieve basket	
Rubber cover	Requisite material: Reprocessing in Miele sieve basket	
Wrench for cannulas	Requisite material: Reprocessing in Miele sieve basket	

8.5.2 Automated internal and external cleaning and internal and external disinfection



KaVo recommends washer disinfectors in accordance with EN ISO 15883-1, which are operated using alkaline cleaning agents.

The validation was performed in a Miele washer disinfector using the "VARIO-TD" programme and the "neodisher MediClean forte" cleaner from Dr. Weigert.

In addition, KaVo recommends the use of a neutraliser and a rinsing agent.

- For programme settings and the adaptation options to be used, please refer to the Instructions for Use of the washer disinfector.

8.5.3 Automated drying

The drying procedure is usually part of the cleaning programme of the washer disinfector.

NOTE
Please comply with the instructions for use of the washer disinfector.

- In order not to affect the KaVo medical device, make sure that the product is dry on the inside and outside after completion of the cycle.

8.6 Care products and systems - Servicing

CAUTION

Improper care.
Malfunction or property damage.

- Do not service the medical device with oil or maintenance spray.
- Before each thermodisinfection or sterilisation, unscrew the powder container, empty it and thermodisinfect or sterilise it together with the handpiece.
- Clean off any powder residue on the RONDOflex plus 360, especially the cannula, tubes and powder nozzle.

8.7 Packaging

NOTE
The sterile goods package must be large enough to accommodate the product without stretching the packaging. The quality and use of the packaging of the items to be sterilised must meet the applicable standards and be appropriate for the sterilisation process!

- Seal the medical device separately in a sterile pack.

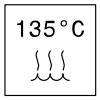
8.8 Sterilisation

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

CAUTION

Contact corrosion due to moisture.
Damage to product.
- Immediately remove the product from the steam steriliser after the sterilisation cycle.

NOTE
Prior to attaching the powder container, all powder-conducting parts and air channels must be absolutely dry. Screw together the powder container and handpiece only while the parts are cold.



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

Select a suitable process from the following sterilisation processes (depending on the available steriliser):

Steriliser with triple pre-vacuum:
- at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)

Steriliser using the gravity method:
- at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- 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.

8.9 Storage

Reprocessed products must be stored appropriately protected from dust in a dry, dark and cool space with a low germ level.

NOTE
Comply with the expiry date of the sterilised items.

9 Consumables

Available from specialised dental dealers.

Cleaning cover		**Mat. no. 3.005.4213**
Cleaning adapter		**Mat. no. 3.006.4667**
Protective goggles for patient and user		**Mat. no. 1.000.9006**
RONDOflex Powder 27µm 1000g		**Mat. no. 1.000.5957**
RONDOflex Powder 50µm 1000g		**Mat. no. 1.000.5956**
Cannula mounted 90°/0.6 for improved access to molar region		**Mat. no. 1.002.9179**
Cannula mounted 90°/0.46 for improved access to molar region		**Mat. no. 1.002.9182**
Powder container blue 27µm		**Mat. no. 1.003.1235**
Powder container blue 50µm		**Mat. no. 1.003.1236**
Rubber cover		**Mat. no. 1.000.2678**
Cannula mounted 110°/0.6		**Mat. no. 1.002.6251**
Cannula mounted 110°/0.46		**Mat. no. 1.002.9176**
Nozzle needle		**Mat. no. 0.573.6052**
Nozzle tube 0.9		**Mat. no. 1.002.9920**
Key for changing the cannula		**Mat. no. 1.002.6250**
Cleaning bur		**Mat. no. 0.573.0321**
Flat container seal		**Mat. no. 0.573.6072**

O-ring for cannulas		**Mat. no. 0.200.6019**

10 Terms and conditions of warranty

This KaVo medical device is subject to the following warranty conditions:
KaVo grants the end customer a warranty of proper function and guarantees zero defects in respect of material and workmanship for a period of 12 months from the date of the invoice, subject to the following conditions:
With regard to justified complaints KaVo grants warranty in the form of a free of charge repair or delivery of a replacement. Other claims of any kind whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply insofar as this does not conflict with mandatory statutory provisions.
KaVo shall not be liable for defects and consequences thereof that have arisen or may arise from natural wear, improper handling, cleaning, servicing or maintenance, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with the KaVo instructions for use or other manufacturer's instructions. The warranty granted does, in general, not extend to lamps, optical fibres made of glass and glass fibres, glassware, rubber parts, and the colourfastness of plastic parts.
Any liability is excluded if defects or the consequences thereof are due to the customer or third parties not authorized by KaVo interfering with or modifying the product.
Warranty claims can only be asserted if proof of sale in the form of a copy of the invoice or delivery note is presented with the product. The dealer, purchase date, type, and serial number must be clearly evident from this document.

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