

Instructions for use

RONDOflex plus 360



KaVo. Dental Excellence.

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User instructions

Dear user,
KaVo hopes that you enjoy your new high-quality product. Following the instructions below will allow you to work smoothly, economically and safely.

Symbols

	See the section Safety/Warning Symbol
	Important information for users and technicians
	Disinfectable with heat

	Sterilisable up to 138°C
	CE mark (Communauté Européenne). A product with this mark meets the requirements of the relevant EC directives, i.e. the applicable standards in Europe.
	Action request

Target group

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

Purpose – Proper use

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.

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)

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.
- A medical device according to relevant national statutory regulations.

According to these provisions, 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, the user is required to:

- Only use equipment that is operating correctly
- use the equipment for the proper purpose.
- to protect himself, the patient and third parties from danger.
- to avoid contamination from the product.

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.

Warranty terms and conditions

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 date of invoice, subject to the following conditions:

In case of justified complaints, KaVo will honour its warranty with a repair or free replacement. 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 cannot be held liable for defects and their consequences that are or may be due to natural wear, improper handling, cleaning or maintenance, non-compliance with operating or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with KaVo's instructions for use or other manufacturer specifications. The warranty does not

usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts.

Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party not authorised by KaVo are excluded from the warranty.

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, unit number or type and serial number must be clearly visible on this document.

Description of safety instructions: Warning symbol

Warning symbol



Description of safety instructions: Structure

The introduction describes the type and source of the hazard.

This section describes the potential consequences of non-observance.

- ▶ The optional step contains necessary measures for avoiding hazards.

Description of safety instructions: Description of hazardous steps

The herein cited safety instructions with the three levels of danger will help avert property damage and injury.

**CAUTION****CAUTION**

indicates a hazardous situation that can lead to property damage or minor to moderate injury.

**WARNING****WARNING**

indicates a hazardous situation that can lead to serious injury or death.

**DANGER**

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



Safety instructions

Premature wear and malfunction due to improper storage or longer periods of nonuse.

Reduced product life.

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

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.

**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

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 authorised to repair and service KaVo products:

- The technicians of KaVo branches throughout the world
- Technicians of authorised dealers specially trained by KaVo
- Independent technicians especially trained by KaVo

Product description



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

Technical data

Drive pressure	3.2 - 6.0 bar
Water pressure	1,5 ± 0,1 bar
Air consumption	5 - 11 NI/min depending on the type of cannula
Water quantity	35-45 ml/min.
Connection:	Attachable to all MULTIflex couplings.

**Note**

The pressure set for the turbine drive is automatically increased 20%, from 2.8 to 3.2 bar.

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







Transportation and storage conditions

Hazard from starting the medical device after very cold storage.

The medical device can malfunction.

- ▶ Products that are very cold must be warmed to 20°C to 25°C before use.

	Temperature: -50 °C to 80°C
	Relative humidity: Non-condensing
	Air pressure: 700 hPa to 1060 hPa
	Protect from moisture.



WARNING

First use

Hazard from nonsterile products.

Infection danger to the care provider and patient.

- ▶ Before first use and after each treatment, sterilize the medical device.

Checking the MULTiflex Coupling

All O-rings must be present and undamaged.

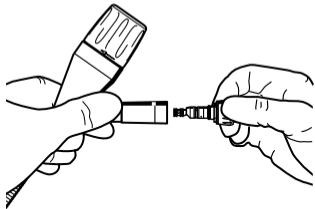


Missing or damaged O-rings

If the O-rings are missing or damaged, malfunctions and premature failure can occur.

- ▶ Check that all O-rings are present and undamaged on the coupling.

Changing the RONDOflex plus: Mounting



- ▶ Place the RONDOflex plus precisely on the MULTiflex coupling and push it to the back until it audibly locks into place.



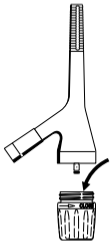
Note

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

Changing the RONDOflex plus: Disconnection

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

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 datasheet for the RONDOflex 2013 powder 50 μm and 27 μm ! This can be found at www.kavo.com by searching for "Safety data sheets".

Changing the cannula: Insertion

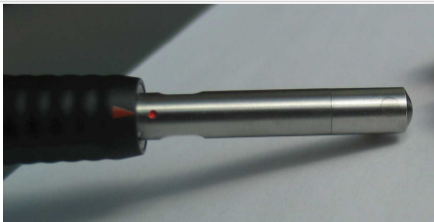
- ▶ Before inserting the cannula, blow out the receiving hole with compressed air.
- ▶ Insert the cannula into the handpiece, and turn it all the way to the right with the key opposite the direction of the arrow.





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.



Changing the cannula: Removal

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

Check for malfunctions

- ▶ 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



Preparation at the site of use

Hazard from nonsterile products.

An infection hazard exists from contaminated medical devices.

- ▶ Observe suitable personal protective measures.

- ▶ Remove residual cement, composite or blood at the Site of use .
- ▶ The medical device must be dry when transporting it to be prepared.
Do not place it in a solution or the like.
- ▶ The medical device should be prepared as close to the treatment time as possible.
- ▶ Remove the cannulas.



Cleaning

Malfunctions from cleaning in the ultrasonic unit.

Defects in the product.

- ▶ Only clean manually!

Malfunction from cleaning with oils or maintenance spray.

Defective product.

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

Manually cleaning the outside

Necessary accessories:

- Tap water $30^{\circ}\text{C} \pm 5^{\circ}\text{C}$ or a 60 to 70% alcohol solution
- Brush such as a medium-hard toothbrush

- ▶ Brush off under flowing tap water, or clean with a 60 - 70 % alcohol solution. alcohol solution. .

Manually cleaning the interior



Note

Remove the cannula before manually cleaning the inside.

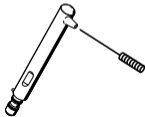
To effectively set up, the inside of the machine must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1. (The interior of this product is not to be cleaned manually).

Mechanically cleaning the exterior and interior

KaVo recommends thermodesinfectors in accordance with DIN EN ISO 15883 such as the Miele G 7781/ G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear").

- ▶ The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermodisinfectant.
- ▶ Directly before machine cleaning, blow dry the inside and outside of the medical device or dry in a thermodesinfektor.



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 or a 60% alcohol solution.



Disinfection

Malfunctions from using a disinfectant bath or chlorine-containing disinfectant.

Defects to the product.

- ▶ Only clean manually or in the thermodesinfector!

Manually disinfecting the exterior

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

- ▶ Microcide AF by Schülke&Mayr (liquid or cloths)
- ▶ FD 322 by Dürr
- ▶ CaviCide by Metrex

Required tools:

Cloths for wiping off the medical device.

Spray the disinfectant on a cloth then wipe the medical device and let it work according to the disinfectant manufacturer.

**Note**

Observe the instruction for use for the disinfectant.

Manual disinfection of the interior

To effectively set up, the inside of the machine must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1. (The interior of this product is not to be disinfected manually).

Mechanically disinfecting the exterior and interior

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- ▶ The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermodesinfektor.
- ▶ Directly before machine cleaning, blow dry the inside and outside of the medical device or dry in a thermodesinfektor.

Drying

Manual drying

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

Machine 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 "Startup").



Care products and systems

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 hand-piece.
- ▶ Likewise, clean off any powder residue on the the RONDOflex, especially the cannulas, tubes and powder nozzle.

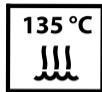
Packaging



Note

The sterilisation bag must be large enough for the instrument so that the bag is not stretched.

The quality and use of the packaging of the items to be sterilised must satisfy the applicable standards and be appropriate for sterilising.



Sterilisation

Sterilisation in a steriliser in compliance with DIN EN 13060

Contact corrosion from moisture.

Damage to the product.

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

The medical device has a max. temperature resistance of 138°C.

KaVo recommends for example

- STERlclave B 2200/ 2200P by KaVo
- Citomat/ K-series by Getinge

Autoclave three times with an initial vacuum for at least 4 minutes at 134°C ± 1

Autoclave using the gravitation method for at least 10 minutes at $134^{\circ}\text{C} \pm 1$

Autoclave using the gravitation method for at least 60 minutes at $121^{\circ}\text{C} \pm 1$

Follow the manufacturer's instructions for use.

Storage

Prepared products should be stored protected germ-free from dust in a dry, dark and cool room.



Note

Observe the expiration date of the sterilised item.

Accessories**1 set consists of**

Accessories obtainable from dental and medical suppliers.



Designation	Mat. no.
cannula 110° - 0.64 mm	1.002.6251
cannula 90° - 0.64 mm	1.002.9179
cannula 110° - 0.46 mm	1.002.9176

Designation	Mat. no.
cannula 90° - 0.46 mm	1.002.9182
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

Additional accessories

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



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