

Instructions for use
INTRA Micro head L22 - REF 1.008.1835



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User instructions 6

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.

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Symbols

	Refer to the chapter on Safety/Warning symbol
	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 directive.

2 Safety**2.1 Description of safety instructions**

	Warning symbol
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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.

2.2 Safety instructions

	 WARNING
	Hazard to the care provider and patient Damage, irregular noise during operation, excessive vibration, unusual build-up of heat or if the bud bur or cone bur cannot be firmly held.
	► Stop work and seek service support.

	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfected

Target group

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

Structure

	 DANGER
	The introduction describes the type and source of the hazard. This section describes potential consequences of non-compliance.
	► The optional step includes necessary measures for hazard prevention.

	 WARNING
	WARNING indicates a hazardous situation that can lead to death or fatal injury.
	 DANGER
	DANGER indicates a maximal hazard due to a situation that can directly cause death or fatal injury.

	 CAUTION
	Safety hazard due to incorrectly stored dental instrument. Injury and infection due to by chucked round bur or inverted cone bur.
	► After treatment, place the instrument properly in the holder.

	 CAUTION
	<p>Burning hazard from hot handpiece head and handpiece cover. Burn injuries in the mouth may be caused if the handpiece overheats.</p> <ul style="list-style-type: none"> ▶ Never touch soft tissue with the handpiece head!

	 CAUTION
	<p>Premature wear and malfunctioning from improper storage during long periods of nonuse. Reduced product life.</p> <ul style="list-style-type: none"> ▶ The medical device should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of nonuse.

	 CAUTION
	<p>Hazard to patients. Set the direction of rotation of the round drill to clockwise only.</p> <ul style="list-style-type: none"> ▶ The blades work in clockwise rotation only.

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

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

To ensure proper function, the medical device must be set up according to the reprocessing methods described in the KaVo Instructions for Use, and the care products and care systems described therein must be used. KaVo recommends specifying a service interval at the dental office for a licensed shop to clean, service and check the functioning of the medical device. This service interval depends on the frequency of use and should be adjusted accordingly.

Service may only be carried out by KaVo-trained repair shops using original KaVo replacement parts.

3 Product description



INTRA Micro Kopf L22 (Mat. no. 1.008.1835)

3.1 Purpose – Intended use

Purpose:

This medical device is

- intended for dental treatment only. Any other type of use or alteration to the product is impermissible and can be hazardous. The medical device is intended to be used for the following applications: scope of application microsurgery.
- a medical device according to relevant national statutory regulations

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.



Note

Read and take note of Instructions for Use of the KaVo shanks in which the head can be inserted.

3.2 Technical Specifications

Drive speed	max. 20,000 rpm
Transmission	1 : 1

The round bur and the inverted cone bur can be used.

Use the special key to change the drill bit.

The head can be inserted in all KaVo reducing shanks.

	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

	⚠ WARNING
	Disposal of the product in the appropriate manner. Prior to disposal, the product must be appropriately prepared or sterilised if this is necessary.

<ul style="list-style-type: none"> ▶ Do not mount or remove the head while rotating. Before each treatment, check that the head is firmly seated and that the clamping ring is tight.
--



- ▶ Rotate the clamping ring in the direction of the arrow to the stop and hold it there.

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).

4 Start up and shut down

	⚠ 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 Attach the medical device

	⚠ CAUTION
	Loosening of the medical device during treatment. If the head is not properly locked in place, it can fall out during treatment.

- ▶ Insert the medical device to the stop. Observe the correct intervention of the guidestud.
- ▶ Rotate the clamping ring in the opposite direction and tighten it.

5.2 Remove the medical device

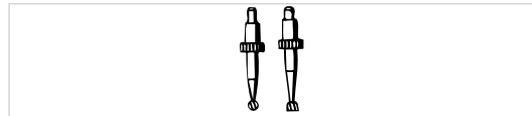
- ▶ Rotate the clamping ring in the direction of the arrow to the stop and hold it there.
- ▶ Remove the medical device.
- ▶ Release the clamping ring.

5.3 Insert the bud bur or inverted cone bur.



Note
Only use the following round burs or inverted cone burs:
 - Round bur size 2 blade diameter: 1.1 mm
 (Mat. no. 0.549.0032)
 - Round bur size 0 blade diameter: 0.9 mm
 (Mat. no. 0.549.0042)
 - U inverted cone bur size 2 blade diameter: 1.1 mm
 (Mat. no. 0.549.0062)

- U inverted cone bur size 0 blade diameter: 0.9 mm
 (Mat. no. 0.549.0072)



	⚠ WARNING
	<p>Use of impermissible bud burs or cone burs. Injury to the patient or damage to the medical device.</p> <p>▶ Only use bud burs or cone burs that do not deviate from the indicated data.</p>

	⚠ CAUTION
	<p>Injury hazard from bud burs or cone burs. Infections or cuts.</p> <p>▶ Wear gloves or fingerstalls.</p>

▶ Insert the round bur or the inverted cone bur ② into the head housing.

- ▶ Position the bearing cover ③ and tighten with screwdriver ④ and torque wrench with 22 N/cm in the direction of the arrow.
- ▶ Check functioning by turning the knob ①.

5.4 Remove bud bur or cone bur

	⚠ WARNING
	<p>Safety hazard due to rotating round bur or inverted cone bur. Lacerations and damage to the chuck system.</p> <p>▶ Do not touch the rotating round bur or inverted cone bur!</p>

▶ Loosen the bearing cover ③ with screwdriver ④.

- ▶ Remove the round bur or inverted cone bur ② from the head housing in the direction of the arrow, while turning the knob ① gently.

**Note**

The bud bur or cone bur remains in the head during preparation. All of the following preparation steps refer to both the head as well as the bud bur and cone bur.

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

6.2.1 Cleaning: Manual cleaning - external

Accessories required:

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

6.2.2 Cleaning: Automated external cleaning**Note**

Prior to cleaning or disinfection in a thermidisinfector, attach the head to an appropriate shank.



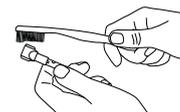
KaVo recommends thermidisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781 / G 7881 – Validation was carried out

6 Preparation methods according to ISO 17664**6.1 Preparations at the site of use**

	⚠ WARNING
	<p>Hazard from nonsterile products. There is a risk of infection from contaminated medical devices.</p> <ul style="list-style-type: none"> ▶ Take suitable personal protective measures.

6.2 Cleaning

	⚠ CAUTION
	<p>Malfunctions from cleaning in the ultrasonic unit. Defects in the product.</p> <ul style="list-style-type: none"> ▶ Only clean manually or in a thermidisinfector.



- ▶ Brush off under flowing tap water.

with the "VARIO-TD" programme, cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermidisinfector (complying with max. pH value of 10).
- ▶ In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry,

and then lubricate immediately with care agents from the KaVo care system.

6.2.3 Cleaning: Manual cleaning of the inside



Note

Before cleaning with KaVo CLEANspray and KaVo DRYspray, attach the head to a suitable shank.

Can only be done with KaVo CLEANspray or KaVo DRYspray.



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 interior cleaning can only be carried out with thermoisinfectors in accordance with EN ISO 15883-1.

with the "VARIO-TD" programme, cleaning agent "neodisher® med-clean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermoisinfector (complying with max. pH value of 10).
- ▶ In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry,

6.3 Disinfection

	<p>⚠ CAUTION</p> <p>Malfunctioning from using a disinfectant bath or disinfectant containing chlorine. Defects in the product.</p> <ul style="list-style-type: none"> ▶ Only disinfect in a thermoisinfector or manually.
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- ▶ 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

6.2.4 Cleaning: Automated internal cleaning



Note

Prior to cleaning or disinfection in a thermoisinfector, attach the head to an appropriate shank.



KaVo recommends thermoisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781 / G 7881 – Validation was carried out

and then lubricate immediately with care agents from the KaVo care system.

6.3.1 Disinfection: Manual disinfection - external



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

- Mikrozyd 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.

- ▶ Immediately after internal disinfection, lubricate the KaVo medical device immediately with care agents from the KaVo care system.

6.3.3 Disinfection: Automatic External and Internal Disinfection**Note**

Prior to cleaning or disinfection in a thermoisinfectant, attach the head to an appropriate shank.



- ▶ In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry, and then lubricate immediately with care agents from the KaVo care system.

6.4 Drying**Manual Drying**

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

 WARNING	
	<p>Sharp round bur or inverted cone bur in the medical device. Risk of injury from sharp and/or pointed round burs or inverted cone burs.</p> <ul style="list-style-type: none"> ▶ Special precautions are required in the care and conditioning of the medical device.

- ▶ Follow the instructions for use of the disinfectant.

6.3.2 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.

KaVo recommends thermoisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781 / G 7881 – Validation was carried out with the "VARIO-TD" programme, cleaning agent "neodisher® med-clean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

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

Automatic Drying

The drying procedure is normally part of the cleaning program of the thermoisinfectant.

- ▶ Follow the instructions for use of the thermoisinfectant.

6.5 Care products and systems - Servicing**Note**

Remove the bud bur or cone bur to care for the product.

 CAUTION	
	<p>Premature wear and malfunctions from improper servicing and care. Reduced product life.</p> <ul style="list-style-type: none"> ▶ Perform proper care regularly!

**Note**

KaVo only guarantees that its products will function properly when the care products used are those listed as accessories, as they were tested for proper use on our products.

6.5.1 Care products and systems - Servicing: Care with KaVo spray

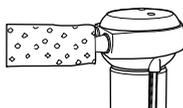
**Note**

Head can be serviced alone or attached to a shank.

6.5.2 Care products and systems - Servicing: Care with the KaVo SPRAYrotor

**Note**

Head can be serviced alone or attached to a shank.



6.5.3 Care products and systems - Servicing: Servicing with KaVo QUATTROcare PLUS

**Note**

Head can be serviced alone (with head adapter) or attached to a shank.

6.6 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!

- ▶ Weld each medical device individually in a sterilised item package!



KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- ▶ Cover the product with the Cleanpac bag.
- ▶ Place the product on the cannula, and press the spray button for one second.

KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- ▶ Place the product on the appropriate coupling of the **KaVo SPRAYrotor** and cover it with a Cleanpac bag.
- ▶ Servicing the product.

See also: Instructions for use **KaVo SPRAYrotor**



KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- ▶ Care for the product in QUATTROcare PLUS.

See also: Instructions for use **KaVo QUATTROcare PLUS**

6.7 Sterilisation

Sterilisation in a steam steriliser (autoclave) in accordance with EN 13060 / ISO 17665-1 (e.g. KaVo STERiclave B 2200 / 2200 P)

**CAUTION**

Premature wear and malfunctions from improper servicing and care.
Reduced product life.

	▶ Before each sterilisation cycle, service the medical device with KaVo care products.
	CAUTION
	Contact corrosion due to moisture. Damage to product. ▶ Immediately remove the product from the steam steriliser after the sterilisation cycle!

(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 Tools

Available from dental suppliers.

Material summary	Mat. no.
Screwdriver	1.008.5493
Torque handle 22 Ncm	1.003.1523
Spray head INTRA (KaVo Spray)	0.411.9911
Service coupling for heads (QUATTROcare)	0.411.7941
Instrument stand 2151	0.411.9501
Cleanpac 10 units	0.411.9691



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

6.8 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.

Material summary	Mat. no.
Cellulose pad 100 units	0.411.9862
Universal bit holder	1.002.4577

Material summary	Mat. no.
Adaptor INTRAmatic (CLEANspray and DRYspray)	1.007.1776
KaVo CLEANspray 2110 P	1.007.0579
KaVo DRYspray 2117 P	1.007.0580
KaVo Spray 2112 A	0.411.9640
ROTA spray 2 2142 A	0.411.7520
QUATTROcare plus Spray 2140 P	1.005.4525

8 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 24 months from the date of the invoice, subject to the following conditions:

In case of justified complaints, KaVo will honour 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 arisen or may arise from natural wear, improper handling, cleaning 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 KaVo's instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to 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.
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 or note of delivery. The dealer, purchase date, type, and serial number must be clearly evident from this document.

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