Instructions for use

MASTERmatic LUX M07 L - 1.009.3610
MASTERmatic LUX M20 L - 1.009.3620
MASTERmatic LUX M29 L - 1.009.3580

KaVo. Dental Excellence.

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CE 0124

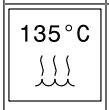
Table of contents

Table of 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
	Sterilization parameters 1. Sterilizer with pre-vacuum: at least 3 minutes at 135 °C (275 °F) Drying time: 16 min. 2. Sterilizer using the gravity method: at least 10 minutes at 135 °C (275 °F) Drying time: 30 min.
	Suitable for disinfection in a washer disinfector

Target group

This document is intended for dentists and dental assistants. The chapter on commissioning is also intended for service technicians.

2 Safety

2.1 Description of the safety instructions

	Warning symbol

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.

Description of hazard levels

The safety instructions listed here, together with the three hazard levels, help to avoid 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 lead to serious or fatal injury.

⚠ DANGER

DANGER

indicates a maximal hazard due to a situation that can directly cause serious or fatal injury.

2.2 Safety instructions

⚠ WARNING

Hazard from incorrectly processed products.

Contaminated products are associated with an infection risk.

- Take suitable personal protective measures.

⚠ WARNING

Hazard for dentists and patients.

In the case of damage, irregular running noise, excessive vibration, un-typical warming or when the bur is not held firmly.

- Stop working and contact service support.

⚠ CAUTION

Hazard from use as a light probe.

Do not use the medical device as a light probe since the rotating bur can cause injury.

- Use an appropriate light probe for additional illumination of the oral cavity or site of preparation.

⚠ CAUTION

Premature wear and malfunctioning from improper storage during long periods of non-use.

Reduced product life.

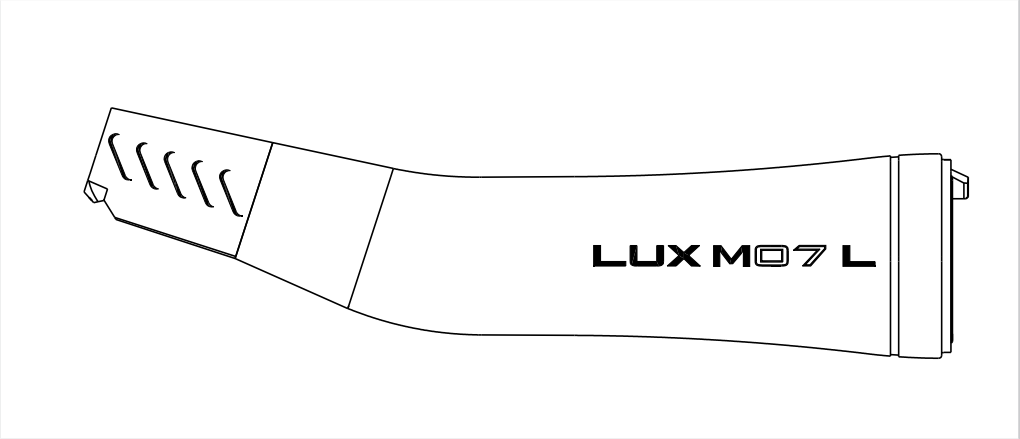
- ▸ The medical device should be cleaned, serviced and stored in a dry location, in accordance with the instructions, before long periods of non-use.

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

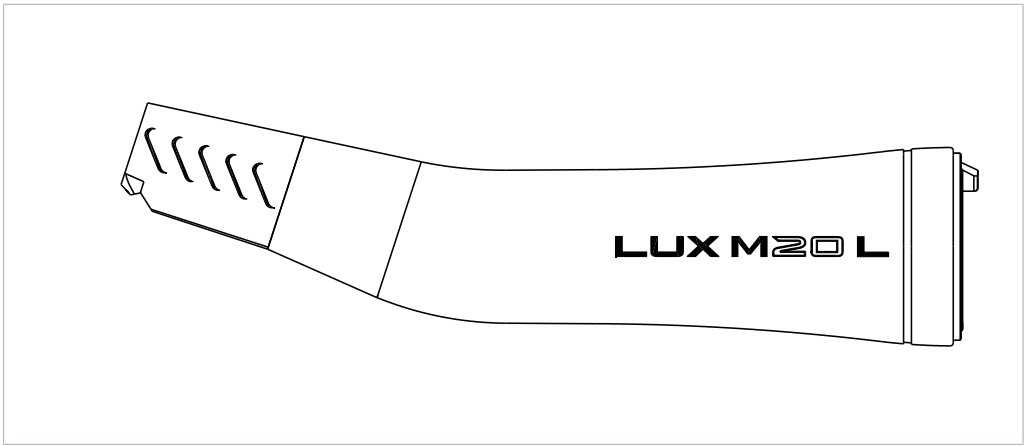
- technicians at KaVo branches throughout the world
- technicians specifically trained by KaVo on the respective product

To ensure proper function, the medical device must be set up in accordance with the processing 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 proper function of the medical device. This service interval depends on the frequency of use and should be adjusted accordingly.
Service may only be performed by KaVo-trained repair shops using original KaVo replacement parts.

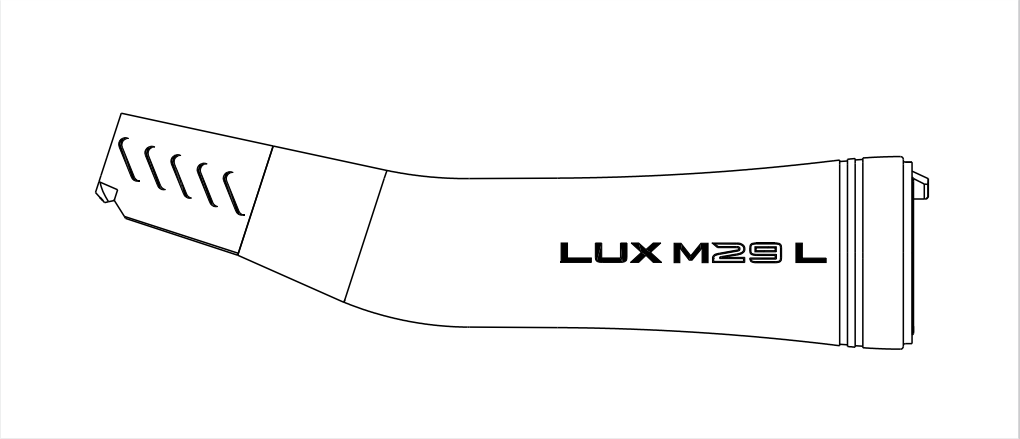
3 Description of the product



MASTERmatic LUX M07 L (**Mat. no. 1.009.3610**)



MASTERmatic LUX M20 L (**Mat. no. 1.009.3620**)



MASTERmatic LUX M29 L (**Mat. no. 1.009.3580**)

The MASTERmatic LUX electrical-driven handpieces are dental handpieces in accordance with 21 CFR § 872.4200 (dental handpieces and accessories) for the use by a trained professional in the field of general dentistry.

The devices are electric-driven handpieces that are reusable and ergonomically shaped, and provided with a fiber optic light system. The devices can be sterilized in a steam sterilizer (autoclave). MASTERmatic LUX handpieces equipped with a handpiece connector in accordance with ISO 3964 are connected to a dental unit by means of a tube and the electrical motor and receive the energy for the gear, cooling water

and air for conservative dental treatment as well as the light for illumination of the operation area through corresponding output openings. Dental burs in accordance with ISO 1797-1 must be used with the MASTERmatic LUX handpieces. Due to their ISO 3964-compliant INTRAmatic connection, MASTERmatic LUX handpieces fit on every electrical dental motor that complies with said standard. MASTERmatic LUX handpieces used in accordance with the intended use interact with the teeth of the patient by means of the rotating bur.

3.1 Intended use

Indications for use:

The MASTERmatic LUX handpieces are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

⚠ CAUTION

US Federal law restricts this device to sale by or on the order of a healthcare professional / dentist.
For dental use only.

Proper Use:

In accordance with these regulations, this medical device may only be used by a properly trained user and for the application described herein. You need to comply with the following:

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

In accordance with these regulations, the user is required to:

- only use equipment that is operating properly
- adhere to the specified intended use
- protect himself or herself, the patient and third parties from danger, and
- avoid contamination from the product

3.2 Technical Specifications M07 L

Drive speed	max. 40,000 rpm
Step-down ratio	2.7 : 1
Maximum speed	max. 15,000 rpm
Labeling	1 green ring
Spray water pressure	0.8 to 2.0 bar (12 to 29 psi)
Spray air pressure	1.0 to 2.0 bar (15 to 29 psi)
Amount of spray air	min. 1,5 Nl/min (at 2 bar / 29 psi)
Cooling air flow	5.5 to 9.5 Nl/min

All INTRA heads and INTRA LUX heads can be used.

The shank can be mounted on all INTRAmatic motors and motors fitted with a connection in accordance with ISO 3964.

3.3 Technical Specifications M20 L

Drive speed	max. 40,000 rpm
Step-down ratio	1 : 1
Maximum speed	max. 40,000 rpm
Labeling	1 blue ring
Spray water pressure	0.8 to 2.0 bar (12 to 29 psi)
Spray air pressure	1.0 to 2.0 bar (15 to 29 psi)
Amount of spray air	min. 1,5 Nl/min (at 2 bar / 29 psi)
Cooling air flow	5.5 to 9.5 Nl/min

All INTRA heads and INTRA LUX heads can be used.

The shank can be mounted on all INTRAmatic motors and motors fitted with a connection in accordance with ISO 3964.

3.4 Technical Specifications M29 L

Drive speed	max. 40,000 rpm
Step-down ratio	7.4 : 1
Maximum speed	max. 5,000 rpm
Labeling	2 green rings
Spray water pressure	0.8 to 2.0 bar (12 to 29 psi)
Spray air pressure	1.0 to 2.0 bar (15 to 29 psi)
Amount of spray air	min. 1,5 Nl/min (at 2 bar / 29 psi)
Cooling air flow	5.5 to 9.5 Nl/min

All INTRA heads and INTRA LUX heads can be used.

The shank can be mounted on all INTRAmatic motors and motors fitted with a connection in accordance with ISO 3964.

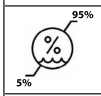
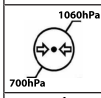
3.5 Transportation and storage conditions

⚠ CAUTION

It is hazardous to start-up the medical device after it has been stored refrigerated.

This can cause the medical device to malfunction.

- Prior to start-up, very cold products must be allowed to warm up 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 (Keep dry)

4 Startup and shut-down

⚠ WARNING

Hazard from non-sterile products.

Infection hazard for dentist and patient.

- Before first use and after each use, process and sterilize the medical device and accessories accordingly.

⚠ WARNING

Dispose of the product in the appropriate manner.

Infection hazard.

- Before disposal, process and sterilize the product and accessories appropriately.

4.1 Checking the water quantity

⚠ WARNING

Overheating of the tooth due to insufficient amount of cooling water.

Thermal damage to the dental pulp.

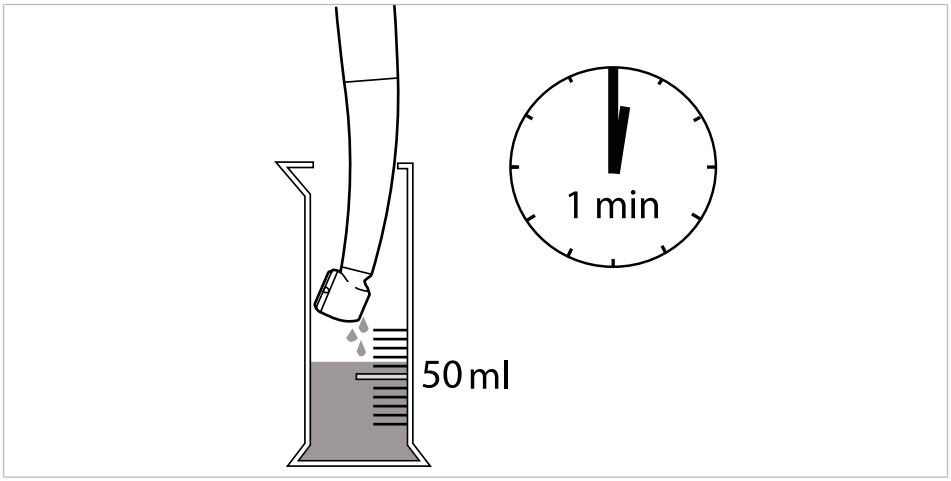
- Adjust the water amount for the spray cooling to a minimum of 50 ml/min!

⚠ WARNING

Hazard from insufficient amount of spray water.

Insufficient spray water can cause the medical device to overheat and damage the tooth.

- Check the spray water channels and clean the spray nozzles with the nozzle needle **Mat. no. 0.410.0921**, if needed.



5 Operation

5.1 Attaching the medical device

⚠ WARNING

Detachment of the medical device during treatment.

A medical device that is not properly locked in place can become disconnected from the motor coupling and fall off.

- Carefully pull on the medical device before each treatment to make sure that it is securely locked onto the motor coupling.

⚠ CAUTION

Removing and attaching the handpiece while the drive motor is rotating.

Damage to the driver.

- Never attach or remove the shank while the drive motor is rotating!

- Attach medical device to the (LUX) motor coupling and turn it until the latch audibly snaps into place.
- Pull on the medical device to make sure that it is securely affixed to the coupling.

5.2 Removing the medical device

- Unlock the medical device from the motor coupling and then pull it off along its axis.

5.3 Inserting an INTRA LUX head

⚠ CAUTION

Loosening of the medical device during treatment.

If the head is not properly locked in place, it can fall out during treatment.

- 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.
- Insert the head to the stop. Make sure that the catches engage properly.
- Rotate the clamping ring opposite to the direction of the arrow (-> close) and tighten it.

5.4 Removing an INTRA LUX head

- Rotate the clamping ring in the direction of the arrow to the stop and hold it there. Pull the head out of the shank toward the front.

6 Checking for malfunctions and troubleshooting

6.1 Check for malfunctions

⚠ CAUTION

Missing or damaged O-rings.

Malfunctions and premature failure.

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

⚠ WARNING

Product heats up.

Burn injury or product damage due to over-heating.

- Do not continue working if the product heats up irregularly.

- The medical device overheats while idling:
  Check the amount of cooling air.
- The medical device overheats while working:
  Service the medical device.
- When the speed drops or is uneven:
  Service the medical device.
- Missing O-ring on the motor coupling:
  Replace O-ring.

6.2 Troubleshooting

6.2.1 Replacing the O-rings

⚠ CAUTION

Hazard due to improper servicing of the O-rings.

Malfunctions or complete failure of the medical device.

- Do not use Vaseline or other grease or oil.

Note

The O-rings on the coupling may only be lubricated with a cotton ball wetted with KaVo Spray.

- Press the O-ring between your fingers to form a loop.
- Push the O-ring to the front, and remove it.
- Insert new O-rings into the grooves.

6.2.2 Cleaning the spray nozzle

⚠ WARNING

Hazard from non-sterile products.

Infection hazard for dentist and patient.

- Reprocess and sterilize the medical device properly before the next use.

⚠ WARNING

Hazard from insufficient amount of spray water.

Overheating of the medical device and damage to the tooth.

- Check the spray water channels and clean the spray nozzles with the nozzle needle **Mat. no. 0.410.0921**, if needed.
- Check the water filter and exchange, if needed.

- Use the nozzle needle (**Mat. no. 0.410.0921**) to free the water passage in the spray nozzles.

6.2.3 Changing the water filter

⚠ WARNING

Hazard from non-sterile products.

Infection hazard for dentist and patient.

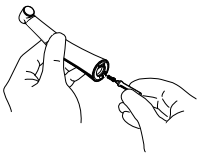
- Reprocess and sterilize the medical device properly before the next use.

⚠ WARNING

Hazard from insufficient amount of spray water.

Insufficient spray water can cause the medical device to overheat and damage the tooth.

- Check the filter and exchange it, if needed.
- Check the spray water channels and clean the spray nozzles with the nozzle needle **Mat. no. 0.410.0921**, if needed.



- Push out and remove the filter with the wrench (**Mat. no. 1.002.0321**).

- Insert a new filter (**Mat. no. 1.002.0271**) and screw it in with the wrench.

7 Processing steps in accordance with ISO 17664

7.1 Preparations at the site of use

⚠ WARNING

Hazard from non-sterile products.

There is a risk of infection from contaminated medical devices.

- Take suitable personal protective measures.

Note

For processing purposes, remove the head from the shank.

- Remove all residual cement, composite or blood immediately.
- Process the medical device as soon as possible after treatment.
- The medical device must be dry when transported to processing.
- Do not immerse in solutions or the like.

7.2 Cleaning

⚠ CAUTION

Malfunctions from cleaning in the ultrasonic unit.

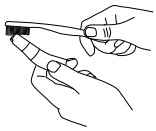
Defects on the product.

- Only clean manually or in a washer disinfector!

7.2.1 Manual external cleaning

Accessories required:

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



- Brush under flowing tap water.

7.2.2 Automated external cleaning

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

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.
- In order to prevent negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then lubricate it immediately with care products from the KaVo care system.

7.2.3 Manual internal cleaning

Not applicable.

This product is suitable for automated cleaning only.

7.2.4 Automated internal cleaning

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

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.
- In order to prevent negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then lubricate it immediately with care products from the KaVo care system.

7.3 Disinfection

⚠ WARNING

Incomplete disinfection.

Infection hazard

- Principally, KaVo recommends carrying out a final disinfection of the unpackaged item in the sterilizer unit if complete disinfection cannot be guaranteed without this measure.

⚠ CAUTION

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

Defects on the product.

- Only disinfect in a washer disinfector or manually!

⚠ CAUTION

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

Defects on the product.

- Do not use an ultrasonic bath.

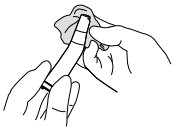
⚠ CAUTION

Never use alkaline or chlorine-containing disinfectants.

Saline solution corrodes metal parts.

- Immediately remove all residue.

7.3.1 Manual external disinfection



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

- CaviCide made by Metrex

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 in accordance with the instructions of the disinfectant manufacturer.
- Comply with the instructions for use of the disinfectant.

7.3.2 Manual internal disinfection

Not applicable.

This product is suitable for automated disinfection only.

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

7.3.3 Automated external and internal disinfection

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

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.
- In order to prevent negative effects on the KaVo medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then lubricate it immediately with care products from the KaVo care system.

7.4 Drying

Manual drying

- Clean the outside and inside with compressed air until no drops of water are visible.

Automated drying

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

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

7.5 Care products and systems - Servicing

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

- Service regularly with suitable agents!

Note

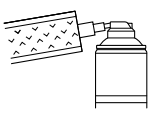
KaVo only guarantees that its products will function properly if the care products listed as accessories are used, since these products have been tested for proper use on our products.

7.5.1 Servicing with KaVo Spray

Note

The shank can be serviced either alone or with a head attached to it.

KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.



- Cover the product with the Cleanpac bag.

- Plug the product onto the cannula, and press the spray button for one second.

7.5.2 Servicing with KaVo QUATTROcare 2104 / 2104A

Note

QUATTROcare 2104 / 2104 A is no longer included in the current delivery program.

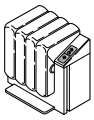
Follow-up product:

- QUATTROcare PLUS 2124 A

Note

The shank can be serviced either alone or with a head attached to it.

Servicing and cleaning device with expansion pressure for internal cleaning of inorganic residues and optimum servicing.



KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.

- Remove the bur.
- Service the product.

See also:

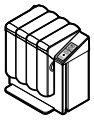
Instructions for use KaVo QUATTROcare 2104 / 2104A / 2124A

7.5.3 Servicing with KaVo QUATTROcare PLUS 2124 A

Note

The shank can be serviced either alone or with a head attached to it.

Servicing and cleaning device with expansion pressure for internal cleaning of inorganic residues and optimum servicing.
KaVo recommends servicing the product as part of the processing after each use, i.e. after each cleaning, disinfection, and before each sterilization.



- Remove the bur.

- Service the product in the QUATTROcare PLUS.

See also:

Instructions for use KaVo QUATTROcare PLUS

7.6 Packaging

Note

The sterilization bag must be large enough for the handpiece to fit without stretching the bag.
The quality and use of the sterilization packaging must comply with applicable standards and be suitable for the sterilization procedure!

- Seal each medical device individually in a sterilization item package.

7.7 Sterilization

Sterilization in a steam sterilizer (autoclave) in accordance with ISO 17665-1

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

- ▸ Before each sterilization cycle, service the medical device with KaVo care products.

⚠ CAUTION

Contact corrosion due to moisture.

Damage to the product.

- ▸ Remove the product from the steam sterilizer immediately after the sterilization cycle!

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

Select a suitable procedure (depending on the available autoclave) from the following sterilization processes:

- ▪ Sterilizer with pre-vacuum:
  - at least 3 minutes at 135°C (275 °F)
  - – Drying time: 16 min.
- ▪ Sterilizer using the gravity method:
  - at least 10 minutes at 135°C (275 °F)
  - – Drying time: 30 min.
- ▸ Use in accordance with the manufacturer's Instructions for Use.

7.8 Storage

- ▸ Processed products should be stored protected from dust in a dry, dark and cool place with minimum exposure to bacteria.

Note

Comply with the expiration date of the sterilized items.

8 Tools and consumables

Available from dental suppliers.

Material summary	Mat. No.
Instrument stand 2151	0.411.9501
Cleanpac 10 units	0.411.9691
Cellulose pad 100 units	0.411.9862
Nozzle needle	0.410.0921
Replacement filter	1.002.0271
Wrench	1.002.0321
O-ring	0.200.6120

USA only

Material summary	Mat. No.
KaVo Spray USA and Canada 2113 A	0.411.9660
QUATTROcare plus Spray USA and Canada 2141 P	1.005.4524

9 Terms and conditions of warranty

The following Terms and conditions of warranty 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 honor its warranty with a free repair or replacement, as needed. 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, optical fibers made of glass and glass fibers, glassware, rubber parts, and the colorfastness of plastic parts.
All liability shall be 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 authorized by KaVo.
Warranty claims shall be accepted only 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, unit number or type and serial number must be clearly evident from this document.

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