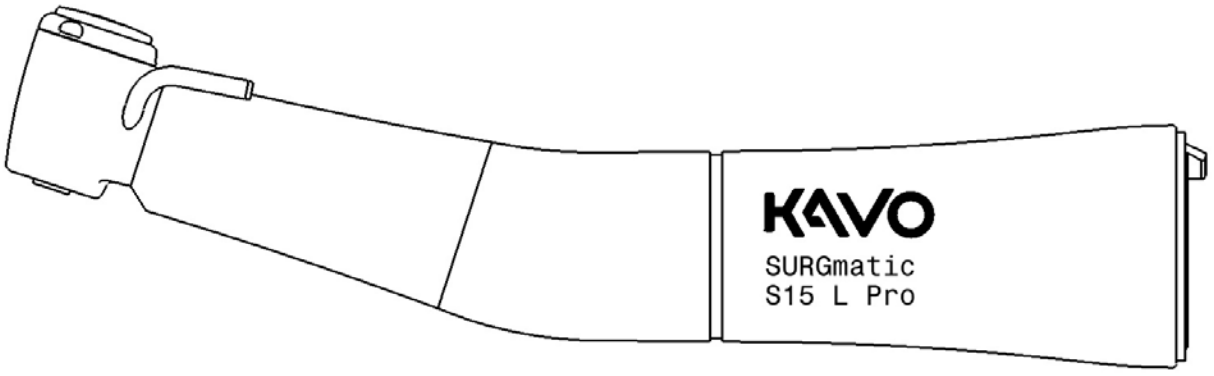
Instructions for use

SURGmatic S15 L Pro – 1.014.4000



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Dental Excellence

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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.

KaVo and SURGmatic are either registered trademarks or trademarks 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

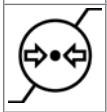
The instructions for use are intended for medical professionals, in particular dentists and dental practice personnel.

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.
MD	Medical device, labelling of medical devices
135 °C	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
	Note: Please note accompanying documents
	Follow the electronic instructions for use
	HIBC Code
	CE mark for medical devices
	EAC conformity mark (Eurasian Conformity)
MD	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

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 a component 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.

2.2 Improper use

Because the operation with an electric motor involves a higher torque, patients, users and other people can suffer injuries and serious burns if an instrument is damaged or used improperly.

- Check the technical condition before each use.

Also refer to:
2.3 Technical condition, Page 7

- Never press the push-button during operation of the device.
- Never use the instrument to keep the cheek, tongue or lip at a distance.
- Never touch soft tissue with the handpiece head or instrument cover.
- Do not allow the medical device to rotate at eye level.
- Do not use the medical device as a light probe.
- Use an appropriate light probe for illumination of the oral cavity or site of preparation.
- After treatment, place the medical device properly in the cradle without the tool.

2.3 Technical condition

A damaged 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
- Dental bur is not seated firmly in the handpiece

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 lack of control equipment for changing the speed range and the direction of rotation can lead to injury.

- Control facility for changing the speed and the direction of rotation must be present.
- The medical device may only be combined with a treatment centre / control unit released by KaVo.
- Comply with the Instructions for Use of the treatment centre / control unit.

2.5 Qualification of personnel

Application of the product by users without the appropriate medical training could injure the patients, the users or third parties.

- Make sure that the user has read and 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.

2.6 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.
- Following expiry of the warranty, have the tool holding system checked once a year.

- 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.

As a result of the use of NON-KaVo original spare parts during the repair, parts such as covers may become undone and injure the patient, user or other people. This may result in aspiration, swallowing of parts and possibly even a risk of suffocation.

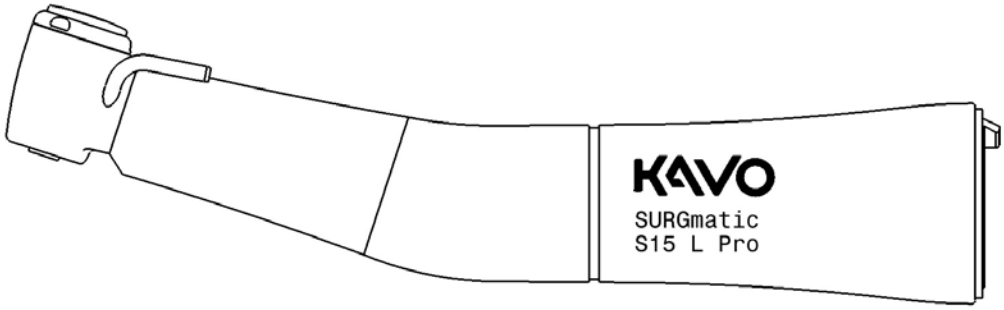
- Only use spare parts that comply with the specification for repair; original KaVo spare parts comply with the specification.

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 into the market of a modified product, where there is reasonable suspicion that the safety and health of patients or users may be jeopardised, is prohibited by the German medical device law §4, section 1 no. 1 and requires a separate conformity check.

3 Description of the product



SURGmatic S15 L Pro (**Mat. no. 1.014.4000**)

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 medical device is designed for general dentistry and oral surgery. Application fields include, e.g.:
  - Hemisection
  - Dental extraction
  - Root removal
  - Osteotomy
  - Removal of wisdom teeth
  - Apicectomy
  - Removal of carious material
  - Tooth, cavity and crown preparations
  - Processing of fillings
- A medical device according to relevant national statutory regulations

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
- adhere to 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 speed	max. 40,000 rpm
Speed transmission	1 : 5
Identification	1 red ring

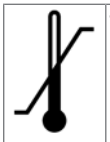
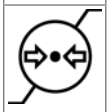
Pushbutton chuck	Ø 1.6 mm
Can be attached to	All INTRA (LUX) surgical motors with a connector in accordance with DIN EN ISO 3964
Insert	Dental burs and diamond grinders in accordance with DIN EN ISO 1797 type 3

Also refer to:
5.3 Inserting the dental bur, Page 15

3.3 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)

4 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:
7 Reprocessing steps in accordance with ISO 17664, Page 19

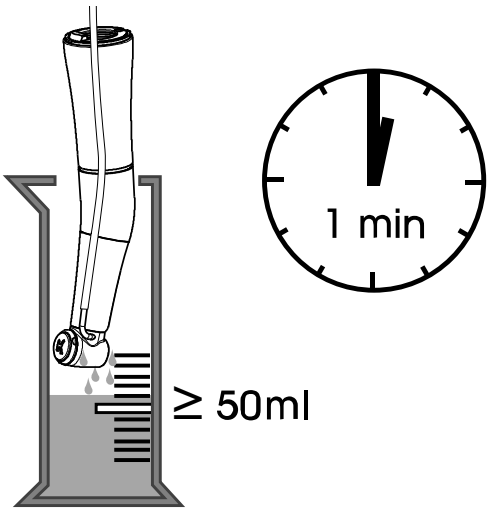
4.1 Checking the amount of water

⚠ CAUTION

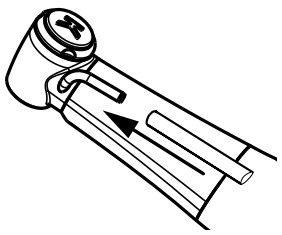
Overheating of the tooth due to insufficient amount of cooling water.

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

- Adjust the water amount for the spray cooling to a minimum of 50 ml/min (3.1 inch^3).
- Check the spray water channels and if necessary clean the spray nozzles with the nozzle needle (**Mat. no. 1.014.6211**).



- Switch off spray-air and spray-water supply on the treatment device.
- Cool the cutter or diamond grinder via an external supply.
- During surgical interventions, comply with the necessary precautions regarding cooling.
- Use physiological, sterile cooling fluid.
- Ensure that the coolant supply is free of air.
- Do not use any other coolants.



- Carefully plug the coolant hose in central position onto the media tube proceeding in axial direction.

5 Operation

5.1 Attaching the medical device

⚠ WARNING

Detachment of 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.

CAUTION

Connection to the drive motor.
Straight or contra-angle handpiece jams.

- Operate the straight or contra-angle handpiece only with the chuck being closed.

CAUTION

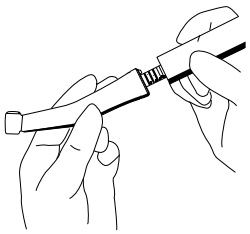
Removing and attaching the straight or contra-angle handpiece while the drive motor is rotating.
Damage to the catch pin.

- Never attach or remove the straight or contra-angle handpiece while the drive motor is rotating.

CAUTION

Pressing the foot switch while attaching or detaching the medical device.
Property damage to the medical device.

- Do not connect or remove the medical device while pressing the foot switch.



- Place the medical device on the motor coupling and lock it into place.
- Pull on the medical device to make sure that it is securely affixed to the coupling.

5.2 Removing the medical device

⚠ CAUTION

Pull off the medical device.

Injury hazard from slipping while pulling off the medical device.

- Mind the spray tube when you pull off the medical device.

NOTE
Do not pull the medical device off the motor coupling while holding it by the instrument head.

- Unlock the medical device from the motor coupling by twisting it slightly and then pulling it along its axis.

5.3 Inserting the dental bur

NOTE

Only use carbide burs or diamond grinders that comply with DIN EN ISO 1797 type 3, are made of steel or hard metal and meet the following criteria:

- Shaft diameter: 1.59 to 1.60 mm
- Overall length: max. 25 mm
- Shaft clamping length: at least 12 mm
- Blade diameter: max. 2 mm

⚠ WARNING

Use of unauthorised dental burs.

Injury to the patient or damage to the medical device.

- Comply with the instructions for use and the intended use of the dental bur.
- Only use dental burs that do not deviate from the specified data.

⚠ CAUTION

Contaminated, sharp-edged dental bur.

Infections or cuts.

- Use gloves or a finger guard when you test, insert and remove the dental bur.

⚠ CAUTION

Dental bur with damaged, worn or deformed shafts.

Risk of injury, dental bur may fall out during treatment.

- Never use dental burs with damaged, worn or deformed shafts.

⚠ CAUTION

Defective chuck system.

Injury hazard, dental bur may fall out during treatment.

- Pull on the dental bur to check if the chuck system works properly and if the dental bur is firmly clamped.

CAUTION

Dental bur with damaged, worn or deformed shafts.

Material damage to the chuck system, dental bur is difficult or impossible to remove from the chuck system.

- Never use dental burs with damaged, worn or deformed shafts.

CAUTION

Incorrectly clamped dental bur.

Material damage to the chuck system, dental bur is difficult or impossible to remove from the chuck system.

- Never use dental burs with shortened shafts.
- Never use dental burs that show recesses, tapering, diamond coding or cutting geometries in the section corresponding to the clamped length.

CAUTION

Dental bur shaft slips inside the chuck due to excessive speed of the dental bur or abrupt engagement of the dental bur.
Material damage to dental bur shaft and chuck system, reduction of the service life of dental bur and chuck system.

- Do not operate the dental bur at a higher speed than recommended by the manufacturer.

- Firmly press the push-button with your thumb and, simultaneously, always insert the dental bur until it hits the stop.
- Check if the dental bur is seated securely by pulling on it.

5.4 Removing the dental bur

⚠ WARNING

Rotating dental bur.

Cuts, infection and burn injury.

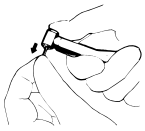
- Never push the press-button while the dental bur is rotating.
- Do not touch the dental bur while it is rotating.
- Never touch soft tissue with the handpiece head or instrument cover.
- Remove the dental bur from the handpiece after treatment to avoid injury and infection during storage.

CAUTION

Damage to the chucking system.
Material damage.

- Never push the press-button while the dental bur is rotating.

KaVo recommends changing the dental bur with tweezers or a similar tool.



- After the dental bur has stopped rotating, firmly press the push-button down with your thumb and simultaneously remove the dental bur.

6 Checking for malfunctions and troubleshooting

6.1 Check for malfunctions

⚠ CAUTION

Overheating of the device.

Burns or product damage from overheating.

- If the device overheats, stop working and have the service personnel repair the device.

- If the medical device overheats when exposed to load, the medical device needs to be serviced.
- When the speed drops or is uneven, the medical device needs to be serviced.

Also refer to:

Instructions for use of motor

6.2 Troubleshooting

⚠ WARNING

Repair WITHOUT using KaVo original spare parts.

Parts such as the cover can come loose and cause injury. Aspiration, swallowing of parts and danger of suffocation.

- Only use spare parts that comply with the specification for repair; original KaVo spare parts comply with the specification.

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 into the market of a modified product, where there is reasonable suspicion that the safety and health of patients or users may be jeopardised, is prohibited by the German medical device law §4, section 1 no. 1 and requires a separate conformity check.

6.2.1 Cleaning the spray nozzle and spray tube

⚠ WARNING

Hazard from contaminated products.

Infection hazard to the dentist and patient.

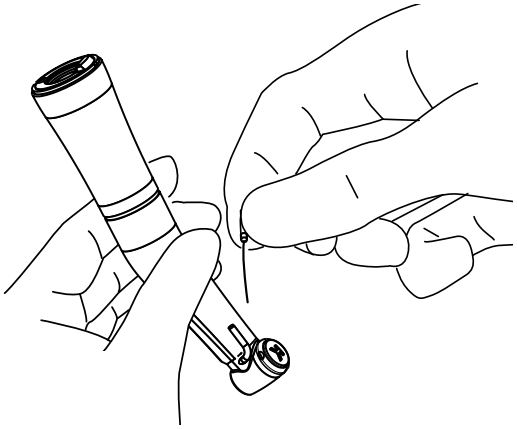
- Prior to initial startup and after each use, reprocess the product and accessories.

⚠ CAUTION

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

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

- Check the spray water channels and if necessary clean the spray nozzles with the nozzle needle (**Mat. no. 1.014.6211**).



7 Reprocessing steps in accordance with ISO 17664

7.1 Preparations at the site of use

⚠ WARNING

Hazard from contaminated products.

Contaminated products are associated with an infection hazard.

- Take suitable personal protective measures.

⚠ WARNING

Sharp dental bur in the medical device.

Injury hazard from sharp and/or pointed dental bur.

- Remove the dental bur.

- 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.

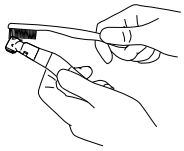
7.2 Non-fixing pre-cleaning

The non-fixing preliminary cleaning is a central constituent and must be carried out prior to the automatic reprocessing.

Accessories required:

- Demineralised water 30 °C ± 2 °C (86 °F ± 3.6 °F)
- Nozzle needle
- Brush, e.g. medium-hard toothbrush
- Disposable syringe

- Check the patency of the media ducts on the spray insert/spray boreholes and on the spray tube and clean them using the nozzle needle (**Mat. no. 1.014.6211**).
- Rinse the spray tube with at least 20 ml demineralised water using a disposable syringe.
- Brush the spray tube under running tap water water for at least 20 seconds using a medium-hard toothbrush.
- If there is soiling, brush the optical fibre exit window under running tap water using a medium-hard toothbrush.



For validated internal cleaning of the media ducts in the cleaning and disinfecting device, preliminary non-fixing cleaning is required.

7.3 Manual reprocessing

This product is not designed for manual internal and external disinfection and manual internal and external disinfection.

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.

7.4 Automated reprocessing

⚠ WARNING

Incomplete disinfection.

Infection hazard.

- Only use disinfection procedures that are verified to be bactericidal, fungicidal and virucidal.
- If the disinfectants used do not meet these requirements, the process must be concluded by disinfection of the unit(s) without packaging using a steam steriliser.

⚠ WARNING

Sharp dental bur in the medical device.

Injury hazard from sharp and/or pointed dental bur.

- Remove the dental bur.

CAUTION

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

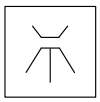
- Reprocess it in a washer disinfector only.

CAUTION

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

- Reprocess it in a washer disinfector only.

7.4.1 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.
- For the spray tube, also use the adapter for external spray channels.

7.4.2 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 to prevent impairment of the KaVo medical device, make sure that the product is dry on the inside and outside after completion of the cycle.
- Remove any residual liquids with KaVoDRYspray.
- Immediately after drying, lubricate the KaVo medical device with care agents from the KaVo care system.

7.5 Care products and systems - Servicing

⚠ WARNING

Sharp dental bur in the medical device.

Injury hazard from sharp and/or pointed dental bur.

- Remove the dental bur.

⚠ CAUTION

Improper service and care.

Risk of injury.

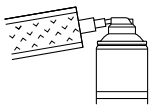
- Service regularly with suitable agents.

NOTE

KaVo guarantees the proper function of KaVo products only if the care products listed by KaVo as accessories are used, since these were tested for proper use on our products.

7.5.1 Servicing with KaVo Spray

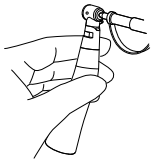
KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilisation.



- Remove the dental bur from the medical device.
- Cover the medical device with the KaVo Cleanpac bag, and place it on the corresponding care adapter.
- Press the spray key for 1 to 2 seconds.

Servicing the chuck

KaVo recommends servicing the chucking system once weekly.



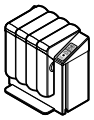
- Remove the dental bur from the medical device.
- Position the tip of the spray nipple in the opening, and apply the spray.
- Press the spray key for 1 to 2 seconds.

7.5.2 Servicing with KaVo QUATTROcare PLUS

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

(no validated cleaning of the interior in accordance with German RKI requirements)

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



- Remove the dental bur from the medical device.
- Service the device in the QUATTROcare PLUS.

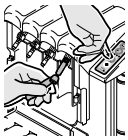
Also refer to:
Instructions for use KaVo QUATTROcare PLUS

Servicing the chuck

KaVo recommends servicing the chuck system once weekly using the chuck servicing programme integrated in the device.

NOTE
Handpieces must be taken off the service couplings before the chuck service can be started and performed.

- Close the front flap and press the chuck service button for at least three seconds until the spray canister control LED flashes three times consecutively.
  ⇨ The device is in chuck service mode.
- Remove the service coupling of the chuck from the side hatch of the QUATTROcare PLUS and attach it to coupling service point four, on the far right. A MULTIflex adaptor must be mounted there.
- Press the handpiece together with the guide bush of the chuck to be serviced against the tip of the service coupling.
- Press the button marked with the chuck service symbol.



NOTE
Close the chuck service mode.
Option 1: Place the dental handpieces in the QUATTROcare PLUS 2124 A, close the front flap and start the service procedure.
Option 2: After three minutes with no service procedure running, the device automatically switches back to normal service mode.

Also refer to:
7.5.2 Servicing with KaVo QUATTROcare PLUS, Page 21

7.6 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.

7.7 Sterilisation

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

⚠ CAUTION

Improper service and care.

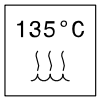
Risk of injury.

- Service regularly with suitable agents.

CAUTION

Contact corrosion due to moisture.
Damage to product.

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



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

Sterilisation parameters:

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)

▸ Remove the medical device from the steriliser immediately after the sterilisation cycle is completed.
▸ Use according to the manufacturer's Instructions for Use.

7.8 Storage

Reprocessed products must be stored appropriately protected from light in a dry, dark, cool low-germ room.

NOTE
Comply with the expiry date of the sterilized items.

8 Optional aids and consumables

Available from specialised dental dealers.

Material summary	Mat. no.
INTRA Instrument stand	**3.005.5204**
Cleanpac 10 units	**0.411.9691**
Cellulose pad 100 units	**0.411.9862**
Nozzle needle	**1.014.6211**
Adapter INTRAmatic	**1.007.1776**
KaVo DRYspray 2117 P	**1.007.0580**
KaVo Spray 2112 A	**0.411.9640**
QUATTROcare plus Spray 2140 P	**1.005.4525**
Chuck servicing set	**1.003.1253**

9 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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