Instructions for use
SURGmatic S11 L - 1.009.1010
SURGmatic S11 C - 1.009.1005

KaVo. Dental Excellence.

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CE 0124

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

	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfectable
CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
▶	Action request

Target group

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

2 Safety

2.1 Description of 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 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.

	⚠ 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 death or fatal injury.

2.2 Safety instructions

⚠ WARNING

Hazards for the care provider and the patient.
In the case of damage, irregular running noise, excessive vibration, untypical warming or when the cutter or grinder cannot be held.

- ▶ Do not use further and notify Service.

⚠ CAUTION

Risks due to lack of control equipment.
Hazards can arise if control equipment is not available for changing the speed and the direction of rotation.

- The dental treatment unit connected must have control equipment for changing the speed and direction of rotation.
- A note is to be included in the documents accompanying the dental treatment unit, referring to responsibilities arising from safety, reliability and performance.
- The medical device may only be combined with a treatment centre released by KaVo.

⚠ CAUTION

Risk due to incorrectly stored instrument.
Injury and infection caused by chucked cutters or grinders.
Damage to clamping system from dropping the instrument.

- After treatment, place the instrument properly in the cradle, without the cutter or grinder.

⚠ CAUTION

Premature wear and malfunctioning from improper storage during long periods of nonuse.
Reduced product life.

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

Note

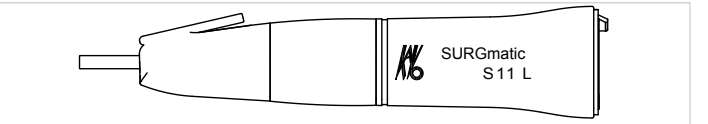
For safety reasons, we recommend that the tool holder system be checked annually after the warranty period expires.

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

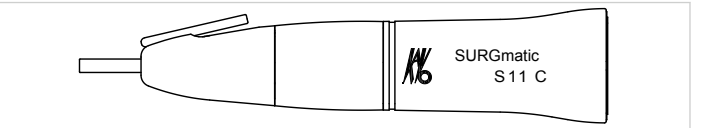
- Technicians at KaVo branches throughout the world
- Technicians specially trained by KaVo

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



SURGmatic S11 L (**Mat. no. 1.009.1010**)



SURGmatic S11 C (**Mat. no. 1.009.1005**)

3.1 Purpose – Proper use

Purpose:

This medical device is

- Only intended for dental treatment. Any other type of use or alteration to the product is impermissible and can be hazardous. The medical device is intended for the following uses: Surgery such as setting an implant, bone augmentation, sinus lift, tooth extraction, implantology and oral, jaw and facial surgery.
- 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.

3.2 Technical Specification

Drive speed	max. 40,000 rpm
identification	1 blue ring
Transmission	1 : 1
Maximum speed	max. 40,000 rpm

Handpiece cutters or grinders can be used.
Short handpiece cutters or grinders can be used after conversion.

The handpiece can be mounted on all INTRAmatic (LUX) motors, and motors with a connection in accordance with ISO 3964 / DIN 13940.

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).

	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

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.

⚠ WARNING

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

4.1 Checking the amount of water

⚠ CAUTION

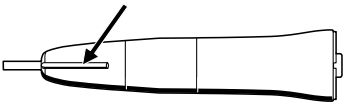
Overheating of the tooth due to lack of cooling water.
Thermal damage to the dental pulp.

- Adjust the water amount for the spray cooling to a minimum of 50 cm^3/min

⚠ CAUTION

Hazard from insufficient amount of spray water.
Insufficient spray water can cause the medical device to overheat and damage the tooth.

- Check spray water channels and if necessary clean spray nozzles with the nozzle needle (**Mat. no. 0.410.0931**).



- Switch off spray-air and spray-water supply on the treatment device.

- Cooling the drill bit or bur via external supply.
- During surgical interventions, comply with the necessary precautions regarding cooling.

- Use physiological, sterile cooling fluid.

5 Operation

5.1 Attach 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 ensure that it is securely locked onto the motor coupling.

⚠ CAUTION

Connect to the drive motor.
Handpiece blocked.

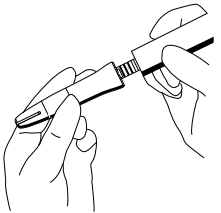
- Only start the handpiece when the chuck is closed.

⚠ CAUTION

Removing and attaching the handpiece while the drive motor is rotating.
Damage to the catch.

- Never attach or remove the handpiece while the device is rotating!

- Lightly spray O-rings on motor coupling with KaVo Spray.



- Place the medical device on the motor clutch and lock it into place. With the **SURGmatic S11 L**, the latch must lock into place audibly.

- Pull on the medical device to make sure that it is securely affixed to the coupling.

5.2 Remove the medical device

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

5.3 Insert the handpiece or contra-angle handpiece drill bit.

Note

Only use handpiece or contra-angle handpieces that correspond to ISO 1797-1 type 1 and type 2, are made of steel or hard metal and meet the following criteria:
- Shaft diameter: 2.334 to 2.35 mm

In contra-angle drills with drill bur stop:
- Shaft clamping length: at least 12 mm
- Overall length: max. 22 mm

In handpiece drills without drill bur stop:
- Shaft clamping length: at least 30 mm
- Overall length: max. 44.5 mm

⚠ WARNING

Use of unauthorised cutters or grinders.
Injury to the patient or damage to the medical device.

- Observe the instructions for use and use the cutter or grinder properly.
- Only use cutters or grinders that do not deviate from the specified data.

⚠ CAUTION

Injury from using worn drill bits or burs.
Drill bits or burs could fall out during treatment and injure the patient.

- Never use drill bits or burs with worn shafts.

⚠ CAUTION

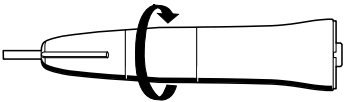
Injury hazard from cutters or grinders.
Infections or cuts.

- Wear gloves or fingerstalls.

⚠ CAUTION

Hazard from defective chucking system.
The cutter or grinder could fall out and cause injury.

- Pull on the cutter or grinder to check that the chucking system is okay and the cutter or grinder is securely held. When checking, inserting and removing, use gloves or a fingerstall to prevent an injury or infection.



- Rotate the clamping ring in the direction of the arrow to the backstop and insert the handpiece cutter or polisher into the chuck.
- Turn the clamping ring back into its initial position.
- Check that the cutter or grinder is securely attached by pulling on it.

5.4 Remove the handpiece or contra-angle drill bit

⚠ WARNING

Hazard from rotating cutter or grinder.
Lacerations and damage to the chucking system.

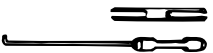
- Do not touch the cutter or grinder when it is rotating!
- Remove the cutter/grinder from the contra-angle handpiece after treatment to avoid injury and infection when putting it away.

- After the milling or grinding tool has come to a standstill, turn the clamping ring as far as it will go and remove the milling or grinding tool.
- Turn the clamping ring back into its initial position.

5.5 Conversion for contra-angle handpiece drill bit

Note

The handpiece must be converted to use contra-angle handpiece drill bits.



- Open the handpiece chuck.
- Insert the enclosed drill stop in the chuck.
- Press the contra-angle drill bit onto the stop, close the clamping ring, and check for firm seating.

- To remove the drill bit stop, use the accompanying hook.

6 Troubleshooting

6.1 Check for malfunctions

⚠ CAUTION

Heating of the product.
Burns or product damage from overheating.

- ▶ Do not use the product if it is irregularly heated.

- ▶ The medical device is too hot while working:
  Service the medical device.
- ▶ When the speed drops or is uneven:
  Service the medical device.

- An O-ring is missing on the motor coupling:
  Replace O-ring.

See also: Instructions for use of motor

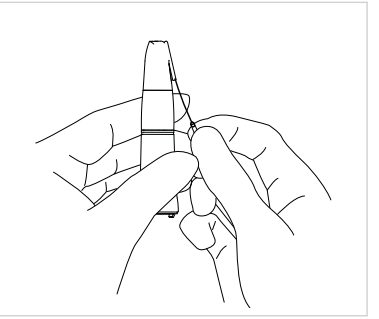
6.2.1 Troubleshooting: Cleaning the spray tube

⚠ CAUTION

Hazard from insufficient amount of spray water.
Insufficient spray water can cause the medical device to overheat and damage the tooth.

- Check spray water channels and if necessary clean spray tubes with the nozzle needle (**Mat. no. 0.410.0931**).

- Use the nozzle needle (**Mat. no. 0.410.0931**) to free the water passage at the spray tubes.



7 Reprocessing steps in accordance with ISO 17664

7.1 Preparation at the site of use

⚠ WARNING

Hazard from inappropriately reprocessed products.
There is a risk of infection from contaminated medical devices.

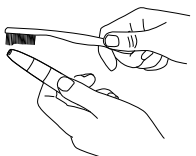
- ▸ Take suitable personal protective measures.

- ▸ Remove the cutter or grinder from the medical device.
- ▸ Remove all residual cement, composite or blood immediately.
- ▸ Recondition 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.

7.2 Non-fixing preliminary cleaning of the spray tube

Accessories required:

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



- ► Check the patency of spray tube and clean it using the nozzle pin (**Mat. no. 0.410.0931**).

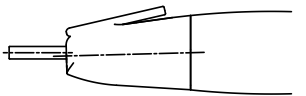
- ► Rinse through the spray tube with at least 20 ml demineralised water with the aid of a disposable syringe.

- If the passability of the spray tube cannot be determined after the manual rinsing procedure, the dental product must be replaced.

Brush the spray tube under running tap water water for at least 20 seconds using a medium-hard toothbrush.
The non-fixing preliminary cleaning is a central constituent and must be carried out prior to the automatic reconditioning.

In the KaVo QUATTROcare CLEAN, a validated interior cleaning of the spray tube can be achieved by using the surgical adapter coupling.

In the cleaning and disinfecting device, validated internal cleaning of the spray tube necessitates preliminary non-fixing cleaning.



7.3 Cleaning

⚠ CAUTION

Malfunctions from cleaning in the ultrasonic unit.
Defects in the product.

- ▶ The instrument must not be cleaned in ultrasonic devices!

7.3.1 Cleaning: Manual external and internal cleaning

Not applicable.

7.3.2 Cleaning: Automated external cleaning

KaVo recommends thermodisinfectors 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 Programme "VARIO-TD", 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 thermodisinfector (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 after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

- Manual external and internal cleaning cannot be performed. Following the non-fixing preliminary cleaning (item 7.2), the reprocessing must be continued in the thermodisinfector.

In the KaVo QUATTROcare CLEAN, validated interior cleaning of the spray tube using the surgical adapter coupling is permissible.

7.4 Disinfection

⚠ CAUTION

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine.
Defects in the device.

- ▶ Only disinfect in the thermodisinfector.

7.4.1 Disinfection: Manual external and internal disinfection

Not applicable.

7.4.2 Disinfection: Machine disinfection - external and internal

KaVo recommends thermodisinfectors 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 Programme "VARIO-TD", 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 thermodisinfector (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 after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

7.5 Drying

Manual Drying

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

Automatic Drying

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

- Follow the instructions for use of the thermodisinfector.

7.6 Care products and systems - Servicing

⚠ WARNING

Sharp cutters or grinders in the medical device.
Risk of injury from sharp or pointed cutters or grinders.

- Remove cutter or grinder.

⚠ CAUTION

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

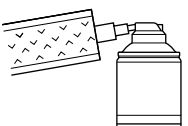
- Perform proper care regularly!

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.

7.6.1 Care products and systems - Servicing: Care with KaVo Spray

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

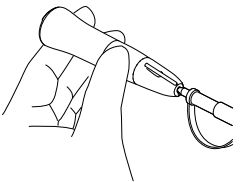


- Remove the cutter or grinder.
- Cover the product with the Cleanpac bag.

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

Servicing of the clamping chuck

KaVo recommends cleaning and servicing the chuck system once a week.

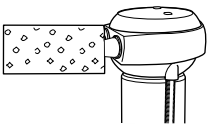


- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

Note

Carry out servicing according to instructions in the section "Care with KaVo Spray".

7.6.2 Care products and systems - Servicing: Care with KaVo SPRAYrotor



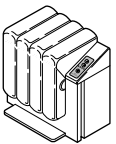
KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- ▸ Place the product on the appropriate coupling of the **KaVo SPRAYrotor** and cover it with a CLEANpac bag.
- ▸ Service the product.

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

7.6.3 Care products and systems - Servicing: Servicing with KaVo QUATTROcare 2104 / 2104A

Servicing device with expansion pressure for the cleaning of inorganic residues and optimum care.

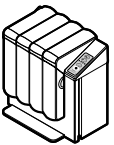


KaVo recommends servicing the product after each disinfection, and before each sterilisation, in the scope of the reprocessing.

- ▸ Remove the cutter or grinder.
- ▸ Servicing the product.

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

KaVo recommends servicing the product after each disinfection, and before each sterilisation, in the scope of the reprocessing.



- ▸ Remove the cutter or grinder.

- ▸ Servicing the product in QUATTROcare PLUS.

See also: Instructions for Use **KaVo QUATTROcare PLUS 2124 A**

Servicing the clamping chuck

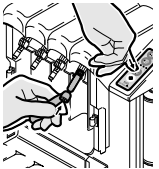
KaVo recommends cleaning and servicing the chuck system once a week.

See also: Instructions for Use **KaVo QUATTROcare PLUS 2124 A**

Note

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

- Remove the service coupling chuck from the side hatch of the QUATTROcare PLUS and attach it to coupling service point four, on the far right. A MULTIflex adapter 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 chuck.

- Press the button showing the chuck service symbol.

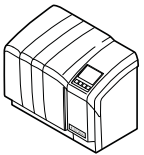
Note

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

See also: Care with KaVo QUATTROcare PLUS

7.6.5 Care products and systems - Servicing: Servicing with KaVo QUATTROcare CLEAN 2140 A

Programme-controlled cleaning and servicing device for perfect instrument and turbine care.



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 cutter or grinder.
- Service the product in QUATTROcare PLUS.

See also: Instructions for use **KaVo QUATTROcare CLEAN** 2140 A

Servicing the clamping chuck

KaVo recommends cleaning and servicing the chuck system once a week using the collet servicing program integrated in the device.

See also: Instructions for use **KaVo QUATTROcare CLEAN** 2140 A

7.7 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!

- ▸ Individually seal the medical device in the sterilised item packaging.

7.8 Sterilisation

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

⚠ 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!

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

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

- Autoclave with three times pre-vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Autoclave using the gravity method:
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)

▸ Use according to the manufacturer's Instructions for Use.

7.9 Storage

Prepared products must be stored, protected from germs (as far as possible) and dust, in a dry, dark, cool room.

- Comply with the expiry date of the sterilised items.

8 Tools

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
Drill stop	0.524.0892
Hook	0.410.1963
Nozzle needle	0.410.0931
Coupling piece	0.593.0361
Spray head INTRA (KaVo Spray)	0.411.9911
Service coupling for heads (QUAT-TROcare)	0.411.7941
Surgery service coupling	1.009.9489

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
ROTAspray 2 2142 A	0.411.7520
QUATTROcare plus Spray 2140 P	1.005.4525

9 Terms and conditions of warranty

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 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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