Instructions for use
SURGmatic S201 L - 1.009.0470
SURGmatic S201 C - 1.009.1100

KaVo. Dental Excellence.

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CE 0124

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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

	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

Burning hazard from hot instrument head and instruments cover.
If the instrument overheats, burns may arise in the oral area.

- Never contact soft tissue with the instrument head.

⚠ 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

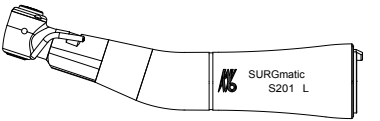
For safety reasons, we recommend that the tool holder system be checked annually after the warranty period expires.

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

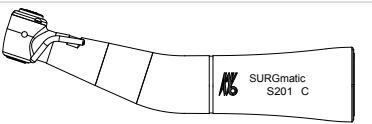
- Technicians at KaVo branches throughout the world
- Technicians specially trained by KaVo

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 S201 L (**Mat. no. 1.009.0470**)



SURGmatic S201 C (**Mat. no. 1.009.1100**)

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 Specifications S201 L / S201 C

Drive speed	max. 40,000 rpm
Identification	1 green ring
Speed transmission	20 : 1

With press-button chuck.

Usable with surgical drill bits or burs with inner cooling.
Internal cooling system (acc. Kirschner and Meyer) and external cooling-medium connection.

The contra-angle handpiece can be mounted on all INTRAmatic (LUX) motors and motors with a connector in accordance with ISO 3964 / DIN 13940.

⚠ CAUTION

The SURGmatic S201 L/ C contra-angle handpiece consists of a base and a head.
It is not permissible to combine the unit with other heads/bases.

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.

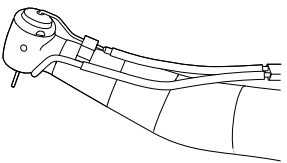
4.1 Checking the amount of water

⚠ 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.

- Cool the dental bur or grinder via the external and/or internal feed, if available. The supply can be fed individually or via a coupling piece.
- During surgical interventions, comply with the necessary precautions regarding cooling.
- Use physiological, sterile cooling fluid.
- Ensure that the supply of coolant is free of air.

5 Operation

5.1 Inserting the head

⚠ CAUTION

The SURGmatic S201 L/ C contra-angle handpiece consists of a base and a head.
It is not permissible to combine the unit with other heads/bases.

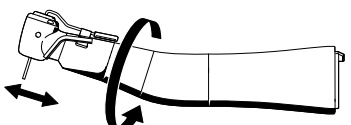
Note

The head of the **SURGmatic S201 L / C** should be taken off the base for purposes of reconditioning only.

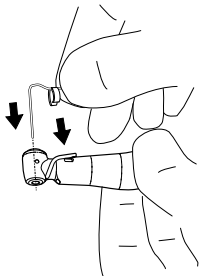
⚠ WARNING

Detachment 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 it is rotating. Before each treatment, check that the head is firmly seated and that the clamping ring is tight.

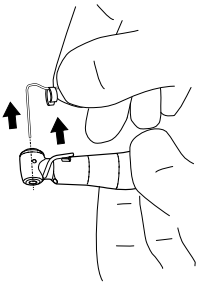


- Rotate the clamping ring in the direction of the arrow to the stop and hold it there.
- Insert the head to the stop. Make sure that the catches engage properly.



- Rotate the clamping ring in the direction of the arrow (-> close) and tighten it.
- Attach the spray clip.
- Ensure secure seating of spray-clip.

5.2 Pulling off the head



- Pull the spray clip off.

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

- Pull off the medical device.
- Release the clamping ring.

5.3 Attaching the contra-angle handpiece to motor coupling

⚠ 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.

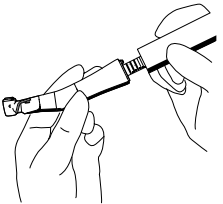
- Carefully pull on the medical device before each treatment to ensure that it is securely locked onto the motor coupling.

⚠ CAUTION

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

- ▸ Never attach or remove the contra-angle handpiece while the drive motor is rotating!

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



- Attach the medical device to the motor coupling and turn it until the guide stud audibly snaps into place.

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

5.4 Pulling the contra-angle handpiece off the motor coupling

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

5.5 Inserting the milling tool or diamond grinder

Note

Only use carbide cutters or diamond drill bits that conform to EN ISO 1797-1 type 1, are made of steel or hard metal, and meet the following criteria:
- Shaft diameter: 2.334 to 2.350 mm
- Overall length: max. 45 mm
- Blade diameter: max. 10 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 cutters or grinders.
Cutters or grinders could fall out during treatment and injure the patient.

- Never use cutters or grinders with worn shafts.

⚠ CAUTION

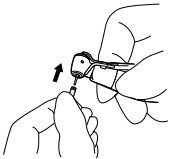
Danger of injury from cutters or grinders.
Infections or cuts.

- 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.



- Insert the cutter or grinder into the segment of the head drive by twisting the tool slightly, and push to the stop. Press the push-button, if applicable.

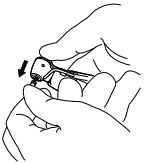
- Check that the tool is seated securely by pulling on it.

5.6 Removing the milling tool or diamond grinder

⚠ WARNING

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

- Do not touch rotating cutter or grinder.!
- Never press the press-button while the cutter or grinder is rotating!
- Remove the cutter or grinder from the contra-angle handpiece after treatment to avoid injury or infection while storing it.



- After the cutter or grinder has stopped rotating, firmly press the press-button with your thumb and simultaneously pull out the drill bit or bur.

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.

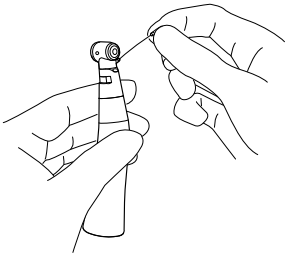
See also: Instructions for use of motor

6.2.1 Troubleshooting: Cleaning the spray clip and the spray tube

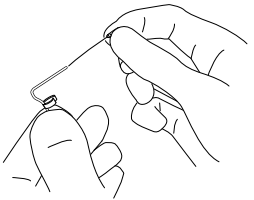
⚠ CAUTION

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.



- Use the nozzle pin (**Mat. no. 0.410.0931**) to free the water passage on the spray clip on both sides.

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.

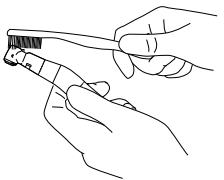
- ▸ Take suitable personal protective measures.

- ▸ Remove the cutter or grinder from the medical device.
- ▸ Remove the spray clip for internal cooling.
- ▸ Remove all residual cement, composite or blood immediately.
- ▸ Reprocess the medical device as soon as possible after treatment.
- ▸ The medical device must be dry when transported for reprocessing.

- Do not place it in a solution or similar.

7.2 Non-fixing preliminary cleaning of the spray clip and 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



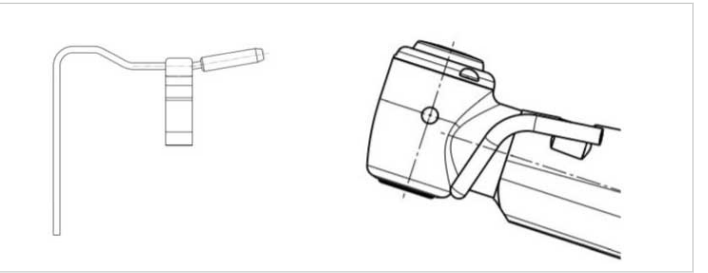
- Check the patency of spray clip and spray tube and clean them with the nozzle pin (**Mat. no. 0.410.0931**).

- Rinse the spray clip and spray tube with at least 20 ml demineralised water using a disposable syringe.
- If the spray clip and spray tube are not patent after the manual rinsing procedure, the medical device and/or the spray clip must be replaced.

Brush the spray clip and spray tube under flowing tap water for at least 20 seconds using a medium-hard toothbrush.
The non-fixing preliminary cleaning is an integral component and must be carried out before automated reprocessing.

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

Validated internal cleaning of spray clip and spray tube in the cleaning and disinfecting device necessitates prior non-fixing preliminary 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!

Note

The spray clip for internal cooling may be additionally cleaned in the ultrasonic cleaner.

7.3.1 Cleaning: Manual external and internal cleaning

Not applicable.

7.3.2 Cleaning: Automated external cleaning

Note

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

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

Note

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

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

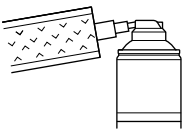
KaVo only guarantees that its products will function properly when the care products used are those listed as accessories, as they were tested for proper use on our products.

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

Note

Head can be serviced alone or attached to a shank.

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

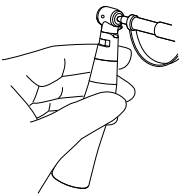


- Remove the cutter or grinder.
- Cover the product with the Cleanpac bag.

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

Care of chucking system

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



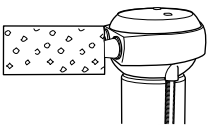
- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

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

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

Note

Head can be serviced alone or attached to a shank.



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.

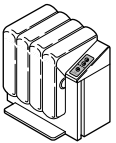
See also: Instructions for use **KaVo SPRAYrotor**

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

Note

Head can be serviced alone or attached to a shank.

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.

Care of chucking system

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

See also: Instructions for use **KaVo QUATTROcare 2104 / 2104A**

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

- Subsequently treat with the care products and care systems specified.

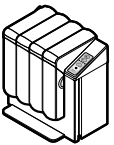
See also: Servicing with KaVo **QUATTROcare 2104 / 2104A**

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

Note

Head can be serviced alone or attached to a shank.

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**

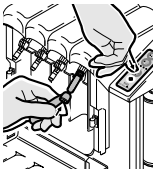
Servicing the clamping chuck

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.

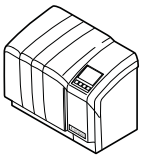
See also: Care with KaVo QUATTROcare PLUS

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

Note

Head can be serviced alone or attached to a shank.

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.

Note

Comply with the expiry date of the sterilised items.

8 Tools and consumables

Available from dental suppliers.

Material summary	Mat. No.
Spray head INTRA (KaVo Spray)	0.411.9911
Service coupling for heads (QUATTROcare)	0.411.7941
Spray clip	1.002.3377
Coupling piece	0.593.0361
Nozzle pin	0.410.0931
Instrument stand 2151	0.411.9501
Cleanpac 10 units	0.411.9691
Cellulose pad 100 units	0.411.9862
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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