Instructions for use
INTRA surgical handpiece 3610 N3 - REF 0.524.5620

KaVo. Dental Excellence.

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Contents

1 User instructions

Dear user,
KaVo hopes that you enjoy your new high-quality product. Following the instructions below will allow you to work smoothly, economically and safely.

Symbols

	See the section Safety/Warning Symbols
	Important information for users and technicians

	Disinfectable with heat
	Sterilizable in steam up to 135°C (275°F)
	CE mark (Communauté Européenne). A product with 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.

1.1 Warranty terms and conditions

The following warranty conditions apply to this KaVo medical device:

KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 12 months from data of invoice, subject to the following conditions:
In case of justified complaints, KaVo will honour its warranty with a repair or free replacement. 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 cannot be held liable for defects and their consequences that are or may be due to natural wear, improper handling, cleaning or maintenance, non-compliance with operating 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 instruc-

tions for use or other manufacturer specifications. The warranty does not usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts.
No liability is assumed when defects or their consequences arise from manipulations or changes to the product by the customer or a third party.
Service 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/delivery note. The dealer, purchase date, unit number or type and serial number must be clearly visible on this document.

2 Safety

2.1 Description of safety instructions

	Warning symbol

Structure

⚠ DANGER

The introduction describes the type and source of the danger.
This section describes the possible consequences of misuse.

- ▶ The optional step contains necessary measures for avoiding hazards.

Description of hazardous steps

The safety instructions cited herein with the three levels of danger will help avert property damage and injury.

	⚠ CAUTION **CAUTION** indicates a hazardous situation that can lead to property damage or minor to moderate injury.

	⚠ WARNING **WARNING** indicates a hazardous situation that can lead to serious injury or death.

⚠ DANGER

DANGER
indicates a maximum hazardous situation that can directly cause serious injury or death.

2.2 Purpose – Proper use

This medical device is

- only for dental treatment by a dental professional. The product may not be changed or used for any other purpose since this may be hazardous. The medical device is intended for the following use: Surgery.
- A medical device according to relevant national statutory regulations.

According to these provisions, 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, the user is required to:

- only use properly operating equipment
- use the equipment for the proper purpose
- to protect himself, the patient and third parties from danger.
- to avoid contamination from the product

2.3 Safety instructions

⚠ CAUTION

Premature wear and malfunction due to improper storage or longer periods of nonuse.
Reduced product life.

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

⚠ WARNING

Hazard to the care provider and patient
Damage, irregular noise during operation, excessive vibration, unusual build-up of heat or if the cutter or grinder cannot be firmly held.

- Stop work and seek service support.

⚠ CAUTION

Hazard from improperly putting away instruments.
Injury and infection caused by chucked cutters or grinders.
Damage to the chucking system when the instrument fails.

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

Note

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

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

- The technicians of KaVo branches throughout the world
- Special technicians especially trained by KaVo

To ensure proper function, the medical device must be set up according to the methods described in the KaVo instructions for use, and the care products and methods 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 should take into account the frequency of use.

Service may only be provided by repair shops that have undergone training by KaVo and that use original KaVo replacement parts.

3 Product description

INTRA surgical handpiece 3610 N3 (**Mat. no. 0.524.5620**)

3.1 Technical data

Drive speed	max. 40,000 rpm
Identification	1 blue ring
Transmission	1:1
Maximum speed	max. 40,000 rpm^{-1}

The INTRA surgical handpiece 3610 N3 can be disassembled.

See also: 4 First use, Page 22

Handpiece cutters or grinders can be inserted.
After conversion, short handpiece cutters or grinders can be inserted.

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

3.2 Transportation and storage conditions

⚠ CAUTION

Starting up the medical device can be hazardous after it has been stored in an excessively cold location.
The medical device can malfunction.

- Prior to start-up, very cold products must be heated to a temperature of 20°C (68°F) to 25°C (77°F).

	Temperature: -20°C (-4°F) to 50°C (122°F)
	Relative humidity: Non-condensing

	Air pressure: 700 hPa (10 psi) to 1060 hPa (15 psi)
	Protect from moisture.

4 First use

⚠ WARNING

Hazard from nonsterile products.
Infection danger to the care provider and patient.

- ▶ Before first use and after each use, sterilise the medical device.

4.1 Cooling medium supply

⚠ CAUTION

Hazard of air embolism and skin emphysema
The insufflation of spray in open wounds in the surgical area can cause air embolisms and skin emphysema.

- ▶ Avoid the insufflation of spray in open wounds in surgical area!

- Turn off the spray air and spray water supply on the treatment unit.
- Cool the cutter or grinder using an external supply.
- During surgery, observed the necessary guidelines concerning cooling.
- Use physiological sterile cooling liquid.
- Make sure that the coolant supply is free of air.
- Do not use a different coolant.

5 Operation

5.1 Attach the medical device

⚠ CAUTION

Connection with the drive motor.
Lock the handpiece.

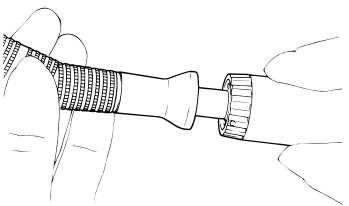
- Only start the hand piece when the chuck is closed.

⚠ CAUTION

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

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

	⚠ WARNING
	Release of the medical device during treatment. A medical device that is not properly locked in place can release from the supply hose. ▸ Carefully pull on it before each treatment to ensure that the medical device is securely locked on the supply hose.



▸ Place the medical device on the motor coupling and lock it into place.

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

5.2 Remove the medical device

- Unlock the medical device from the motor coupling and remove it, or pull it off by twisting it slightly on its axis.

5.3 Insert the milling cutters or diamond grinders

Note

Only use carbide cutters or diamond grinders that correspond to ISO 1797-1 type 3, are made of steel or hard metal and meet the following criteria:
- Shank diameter: 2.334 to 2.350 mm without drill stop
- Overall length: max. 70 mm
- Shank clamping length: min. 56 mm
- Cutting diameter: max. 3 mm

⚠ WARNING

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

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

⚠ CAUTION

Injury from using worn cutters or grinders.
Cutters or grinders can fall out during treatment and injure the patient.

- Never use cutters or grinders 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 can fall out and cause damage.

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

- Rotate the grip sleeve all the way in the direction of the arrow, and insert the handpiece cutter or grinder into the chuck.
- Turn the grip sleeve back into its initial position.
- Check that the cutter or grinder is seated by pulling on it.

5.4 Removing the milling tool or diamond grinder

⚠ WARNING

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

- Do not touch rotating cutters or grinders!
- Never press the pushbutton while the cutter or grinder is rotating!
- Do not touch soft tissue with the head/tip that can heat and burn the soft tissue.
- Remove the cutter/grinder from the contra-angle handpiece after treatment to avoid injury and infection when putting it away.

- After the cutter or grinder has stopped rotating, turn the grip sleeve all the way in the direction of the arrow, and remove the cutter or grinder.
- Turn the grip sleeve back into its initial position.

5.5 Conversion for short handpiece cutters or grinders

Note

The handpiece must be converted when short cutters or grinders are used.

- Open the handpiece chuck.
- Insert the accompanying drill stop into the chuck.
- Insert the handpiece cutter or grinder, and push it in all the way.

- Remove the drill stop using the accompanying hook.

6 Preparation methods according to ISO 17664

6.1 Preparations at the site of use

⚠ CAUTION

Hazard from nonsterile products.
An infection hazard exists from contaminated medical devices.

- Observe suitable personal protective measures.

Note

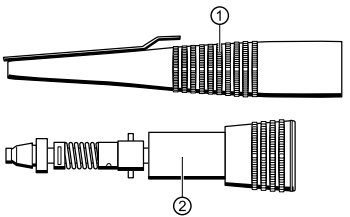
After each operation, immediately disassemble the medical device and clean it thoroughly to prevent malfunctions.

- Remove residual cement, composite or blood at the site of use .

- The medical device must be dry when transporting it to be prepared. (Do not place it in a solution or the like).
- Prepare the medical device directly before treatment.
- Remove cutters or burs from the medical device.

6.2 Disassemble the medical device

- Remove cutters or burs from the medical device.



- Grip the sleeve ② and remove the grip sleeve ① by pulling it forward.

6.3 Assembling the medical device

- Place the grip sleeve ① on the sleeve ② and snap it into place.

6.4 Cleaning

⚠ CAUTION

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

- Only clean manually or in the thermodesinfector!

6.4.1 Cleaning: Manual cleaning - external

Required accessories:
- Tap water 30°C ±5 °C (86 °F ± 10 °F) or a 60 to 70% alcohol solution
- Brush such as a medium hard toothbrush

6.4.2 Cleaning: Automated external cleaning

KaVo recommends thermodisinfectors in accordance with ISO 15883-1, e.g. Miele G 7781 / G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear") and only refers to material compatibility with KaVo products.)

- The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermodisinfector.

6.4.3 Cleaning: Manual cleaning of the inside

For a medical device with KaVo CLEANspray and KaVo DRYspray.

- Cover the medical device with the KaVo CLEANpac bag, and place it on the corresponding care adapter. Press the spray button three times for 2 seconds each time. Remove the medical device from the spray attachment and let the cleaner work for one minute.
- Then rinse for 3-5 seconds with KaVo DRYspray.

See also: Instructions for use for the KaVo CLEANspray/KaVo DRYspray.

Note

KaVo CLEANspray and KaVo DRYspray for manual interior cleaning are only available in the following countries:
Germany, Austria, Switzerland, Italy, Spain, Portugal, France, Luxembourg, Belgium, Netherlands, United Kingdom, Denmark, Sweden, Finland and Norway.
In other countries,only automated interior cleaning with thermodisinfectors in accordance with ISO 15883-1.

6.4.4 Cleaning: Automated internal cleaning

KaVo recommends thermodisinfectors in accordance with ISO 15883-1, e.g. Miele G 7781 / G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear") and only refers to material compatibility with KaVo products.)

- The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermodisinfector.
- Directly after automated cleaning, treat the medical device with the care products and systems provided by KaVo.

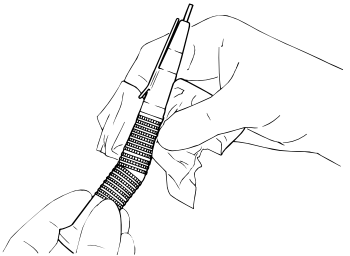
6.5 Disinfection

⚠ CAUTION

Malfunctions from using a disinfectant bath or chlorine-containing disinfectant.
Defects to the product.

- Only clean manually or in the thermodesinfector!

6.5.1 Disinfection: Manual disinfection - external



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

- Microcide AF by Schülke&Mayr (liquid or cloths)
- FD 322 by Dürr

- CaviCide by Metrex

Required tools:

- Cloths for wiping down the medical device.

▸ Spray the disinfectant on a cloth, then thoroughly wipe down the medical device and leave the disinfectant to soak in according to the instructions from the disinfectant manufacturer. disinfectant manufacturer. .

Note

Observe the instruction for use for the disinfectant.

6.5.2 Disinfection: Manual disinfection - internal

To effectively set up, the inside of the machine must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1. (The inside of this product should not be disinfected manually.)

6.5.3 Disinfection: Machine disinfection - external and internal

KaVo recommends thermodisinfectors in accordance with ISO 15883-1, e.g. Miele G 7781 / G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear") and only refers to material compatibility with KaVo products.)

- The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermodisinfector.

- Directly after automated cleaning, treat the medical device with the care products and systems provided by KaVo.

6.6 Drying

Manual drying

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

Machine drying

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

6.7 Care products and systems - Servicing

⚠ CAUTION

Sharp cutters or grinders in the medical device.
Injury hazard from sharp and/or pointed cutters or grinders.

- Remove the cutter or grinder.

⚠ CAUTION

Premature wear and malfunction from improper service and care.
Shortened product service life.

- Regularly service the device properly!

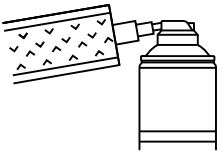
Note

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

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

KaVo recommends servicing the project twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilisation.

- ▸ Remove the cutter or grinder and close the chuck.

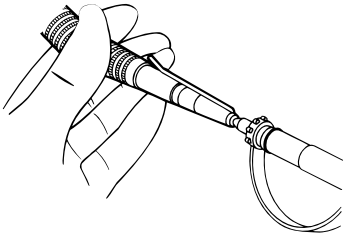


- Cover the product with the Cleanpac bag.

- Place the product on the cannula, and press the spray button for one second.

Chuck care

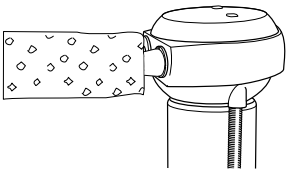
KaVo recommends cleaning and maintaining the chucking system every evening.



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

Note

For the care procedure, see the section "Care with KAVOspray."



6.7.2 Care products and systems - Servicing: Care of the KaVo SPRAYrotor

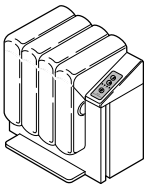
KaVo recommends servicing the project twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilisation.

- ▸ Place the product on the appropriate coupling on the **KaVo SPRAYrotor** , and cover the product with the Cleanpac bag.
- ▸ Servicing the product.

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

6.7.3 Care products and systems - Servicing: Care with KaVo QUATTROcare

Cleaning and care unit with expansion pressure for thorough cleaning and care.



KaVo recommends servicing the project twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilisation.

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

Chuck care

KaVo recommends cleaning and maintaining the chucking system once a week.

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

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

- Subsequently treat with the care products and systems listed below.

6.8 Packaging

Note

The sterilisation bag must be large enough for the instrument so that the bag is not stretched.
The quality and use of the packaging of the items to be sterilised must satisfy the applicable standards and be appropriate for sterilising.

- Individually weld the medical device in the sterilised item packaging (such as KaVoSTERIclave bags **Mat. no. 0.411.9912**.

6.9 Sterilisation

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

⚠ CAUTION

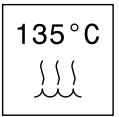
Premature weary and malfunctions from improper servicing and care.
Reduced production time.

- Before each sterilisation cycle, treat the medical device with KaVo care products.

⚠ CAUTION

Contact corrosion as a result of moisture.
Damage to the product.

- ▶ After the sterilisation cycle, immediately remove the product from the steam steriliser .



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

KaVo recommends for example
- STERIclave B 2200/ 2200P by KaVo
- Citomat/ K-series by Getinge

Autoclave with a triple prevacuum for at least 4 minutes at 134°C ± 1°C (273°F ± 1.8°F)
Autoclave using the gravitation method for at least 10 minutes at 134°C ± 1°C (273°F ± 1.8°F)
Autoclave using the gravitation method for at least 60 minutes at 121 °C ± 1°C (250 °F ± 1.8°F)
Follow the manufacturer's instructions for use.

6.10 Storage

Prepared products should be stored protected germ-free from dust in a dry, dark and cool room.

Note

Observe the expiration date of the sterilised item.

7 Tools

Available from dental and medical 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	0.410.0931
Spray hose, sterilisable	0.065.5188
Drill stop	0.524.0892
Hook	0.410.1963
KaVo CLEANspray	1.007.0579
KaVo DRYspray	1.007.0580

Material summary	Mat. no.
KAVOspray 2112 A	0.411.9640
ROTAspray 2142 A	0.411.7520
QUATTROcare plus Spray 2108 P	1.005.4525

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