Instructions for use
INTRA Chirurgie Handstück 3610 N1 - REF 0.524.5600

KaVo. Dental Excellence.

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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

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

	Disinfectable by heat
135°C	Steriliseable in steam up to 135°C (275°F)
CE	CE mark (European Community). A product with this mark meets the requirements of the applicable EC directive.
▶	Call to Action

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 date of 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 cannot be held liable for defects and their consequences that have arisen or may arise from to 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 ac-

cordance with KaVo's instructions for use or other manufacturer's instructions.
No liability is assumed when defects or their consequences are derived 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, 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 illustrates the potential consequences of non-observance. ▶ The optional step covers necessary measures for avoiding hazards.

Description of danger 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 or moderate physical harm.

	⚠ WARNING
	WARNING indicates a hazardous situation that can cause death or serious injury.

	⚠ DANGER **DANGER** indicates the maximum hazard level. indicates a hazardous situation that can directly cause death or serious injury.

2.2 Purpose – Proper use

This medical device is

- Only intended for dental treatment. All other types of use or alterations to the product are not permitted and can be hazardous. The medical product is designed to be used with the corresponding shanks in the following application areas: setting an implant, bone augmentation, sinuslifts, dental extraction, implantology and maxillary-facial surgery.
- A medical device according to relevant national statutory regulations.

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, the user is required 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..

2.3 Safety instructions

	⚠ WARNING **Hazard to the care provider and patient.** In the case of damage, irregular running noise, excessive vibration, untypical warming, excessive drill impact or when the cutter or grinder is not held securely. ▶ Stop working and contact service support.

	⚠ 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 nonuse.

Note

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

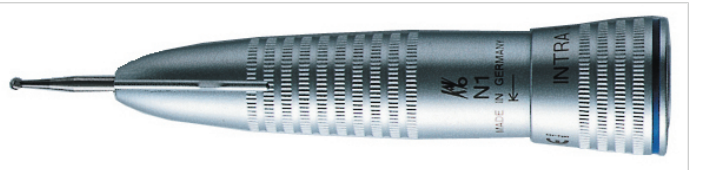
The following individuals are authorized to repair and service KaVo products:

- 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 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 N1 (**Mat. no. 0.524.5600**)

3.1 Technical Specification

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

Transmission	1 : 1
Maximum speed	max. 40,000 rpm

The INTRA surgical handpiece 3610 N1 can be disassembled.

See also: 4 First use, Page 20

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.

3.2 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. ▶ Products that are very cold must be warmed to 20 °C to 25 °C (68 °F to 77 °F) before use.

	Temperature: -20°C to +70°C (-4°F to +158°F)
	Relative humidity 5% RH to 95% RH

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

4 First use

	⚠ WARNING **Hazard from non-sterile 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.** There is a danger that 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!

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

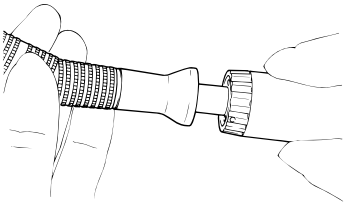
5 Operation

5.1 Attach the medical device

	⚠ WARNING
	**Loosening 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!



- 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 (LUX) motor coupling by twisting it slightly and then pulling it along 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:
- Shaft diameter: 2.334 to 2.350 mm

with a drill bit stop
- Overall length: max. 22 mm
- Shaft clamping length: min. 12 mm
- Edge diameter: max. 3 mm

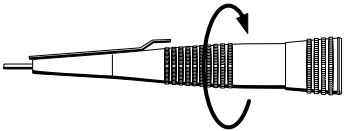
without a drill bit stop
- Overall length: max. 44.5 mm
- Shaft clamping length: min. 30 mm
- Edge diameter: max. 3 mm

	⚠ 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.

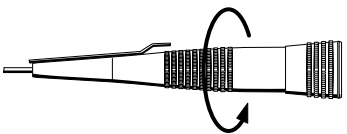


- Rotate the gripping sleeve in the direction of the arrow to the stop and insert the handpiece cutter or polisher in the chuck.

- Rotate the gripping sleeve back to its original position.
- Check that the cutter or grinder is securely attached by pulling on it.

5.4 Removing the milling tool or diamond grinder

	⚠ 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.



► Once the cutter or polisher has stopped rotating, rotate the gripping sleeve in the direction of the arrow to the stop and remove the cutter or polisher.

- Rotate the gripping sleeve back to its original 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

	⚠ **WARNING**
	Hazard from non-sterile products. There is a risk of infection from contaminated medical devices. ▸ Observe suitable personal protective measures.

Note

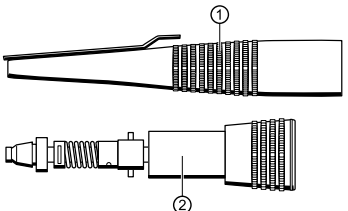
Immediately disassemble and thoroughly clean the medical device after each surgical intervention since malfunctions could otherwise occur.

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

- Dry the medical device to prepare it for transportation. (Do not place it in a solution, etc.).
- Prepare the medical device directly after treatment.
- Remove the cutter or grinder 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 an ultrasonic unit.** Defects in the product. ▸ Only clean manually or in a thermodisinfector.

6.4.1 Cleaning: Manual cleaning - external

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

- Brush off under flowing tap water.

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 detergent "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear" and only refers to the 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.

6.4.3 Cleaning: Manual cleaning of the inside

Can only be done with KaVo CLEANspray or 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.
- Afterwards, rinse for 3-5 seconds with KaVo DRYspray.

See also: KaVo CLEANspray / KaVo DRYspray Instructions for Use

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 detergent "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodish-

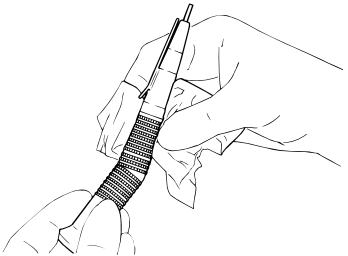
er® mielclear" and only refers to the material compatibility with KaVo products.)

- 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
	Malfunctioning from using a disinfectant bath or disinfectant containing chlorine. Defects in the product. ► Only disinfect in a thermodisinfector or manually.

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 from Schülke&Mayr (liquid or cloths)
- FD 322 from Dürr

- CaviCide from Metrex

Tools required:
- 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.

Note

Observe the instructions for use for the disinfectant.

6.5.2 Disinfection: Manual disinfection - internal

For the effective re-preparation, the inside of the device must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1.
The interior of this product is not designed for manual disinfection.

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 detergent "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear" and only refers to the 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 with compressed air until water drops are no longer visible.

Machine drying

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

Note

Please observe the instructions for use of the thermodisinfector.

6.7 Care products and systems - Servicing

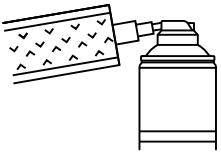
	⚠ CAUTION
	Sharp cutters or grinders in the medical device. Injury hazard from sharp or pointed cutters or grinders. ▶ Remove cutter or grinder.

⚠	⚠ 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.

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



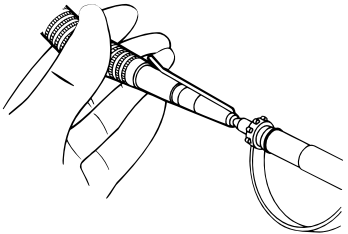
KaVo recommends servicing the project after each time it used, i.e. after each automatic cleaning and before each sterilisation.

- Remove cutter or grinder.

- 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 servicing the chuck system once a week.

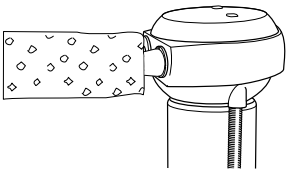


- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

Note

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

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



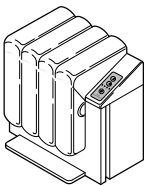
KaVo recommends servicing the project after each time it used, i.e. after each automatic cleaning and before each sterilisation.

- 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**

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

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



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

- Remove cutter or grinder.
- Service the product.

Chuck care

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

See the KaVo **QUATTROcare** instructions for use

- 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: Care with KaVo QUATTROcare

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 sterilised product packaging must satisfy applicable standards and be suitable for the sterilisation procedure.

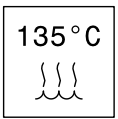
- Individually weld the medical device in the sterilised item packaging (such as KaVo STERIclave bags **Mat. no. 0.411.9912**)!

6.9 Sterilisation

Sterilisation in a steam steriliser (Autoclave) 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 medical device is resistant to temperatures up to 138℃ (280.4°F).

KaVo recommends e.g.
- STERIclave B 2200/ 2200P from KaVo
Citomat / K series from Getinge

Depending on the device, select a suitable process from the following sterilisation processes.

Autoclave with a triple pre-vacuum for least four minutes at 134°C ± 1°C (273°F ± 1.8°F)
Autoclave with gravitation process for least ten minutes at 134°C ± 1°C (273°F ± 1.8°F)
Autoclave with gravitation process 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 must be stored, protected from germs (as far as possible) and dust, in a dry, dark, cool room.

Note

Observe the expiration date of the sterilised item.

7 Tools

Obtainable 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	0.410.1633

Material summary	Mat. no.
KaVo CLEANspray	1.007.0579
KaVo DRYspray	1.007.0580

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

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