

Instructions for use

INTRA LUX head 22 LA - REF

0.549.3640 INTRA LUX head 22

LB - REF 0.549.3650



KaVo. Dental Excellence.

**Distributed by:**

KaVo Dental GmbH

Bismarckring 39

D-88400 Biberach

Tel. +49 7351 56-0

Fax +49 7351 56-1488

**Manufacturer:**

Kaltenbach & Voigt GmbH

Bismarckring 39

D-88400 Biberach

[www.kavo.com](http://www.kavo.com)



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# 1 User instructions





Dear user,



Congratulations for purchasing this KaVo quality product. Following the instructions below will allow you to work smoothly, economically and safely.

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## Symbols

	Refer to chapter Safety/Warning
	Important information for users and technicians
	Thermodisinfectable
	Sterilisable 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 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 accordance with KaVo's instructions for use or other manufacturer's instructions. The warranty does not usually cover lamps, light conductors made of glass and glass fibres, glassware, rubber parts and the colourfastness of plastic parts.

Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party not authorised by KaVo are excluded from the warranty.

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 portrays the possible consequences of non-observance.

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

## Description of danger levels

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

	 <b>CAUTION</b>
	<b>CAUTION</b> 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 directly hazardous situation that can cause death or serious injury.

## 2.2 Purpose – Proper use

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: Microsurgery.
- 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 equipment that is operating correctly
- 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 malfunctioning from improper storage during long periods of nonuse. Reduced production time.**

- ▶ The instrument must be cleaned, serviced and stored dry if it has not been used for a long period.

**WARNING****Hazard to the care provider and patient**

Damage, irregular noise during operation, excessive vibration, unusual build-up of heat or if the bud bur or cone bur cannot be firmly held.

- Stop work and seek service support.

**CAUTION**

**Hazard from improperly putting away instruments.**

Injury and infection caused by chucked bud bur or cone bur.

- ▶ After treatment, properly put away the instrument in the holder without a bud bur or cone bur.

**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.



Authorized to repair and service KaVo products:

- Technicians at the 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 LUX Kopf 22 LA (Mat. no. 0.549.3640)**



**INTRA LUX head 22 LB (Mat. no. 0.549.3650)**

## 3.1 Technical data 22 LA

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Drive speed	max. 20,000 rpm
Transmission	1 : 1

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Bud burs can be inserted.

Use the special key to change the drill bit.

The head can be inserted in all KaVo reducing shanks.

## 3.2 Technical data on the 22 LB

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Drive speed	max. 20,000 rpm
Transmission	1 : 1

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Inverted cone burs can be inserted.

Use the special key to change the drill bit.

The head can be inserted in all KaVo reducing shanks.

### 3.3 Transportation and storage conditions







#### CAUTION

**It is hazardous to start up the medical device after it has been stored 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% - 95% non-condensing
	Air pressure: 700 hPa to 1060 hPa (10 psi to 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.



## 5 Operation

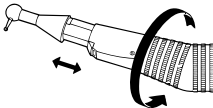
### 5.1 Attach the medical device



#### CAUTION

**Release 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 rotating. Before each treatment, check if the head is firmly seated and if the clamping ring is tight.



- ▶ Rotate the clamping ring in the direction of the arrow to the stop.
- ▶ Insert the medical device to the stop. Make sure that the catches are properly seated.

- ▶ Rotate the clamping ring in the opposite direction and tighten it.

## **5.2 Remove the medical device**

- ▶ Rotate the clamping ring in the direction of the arrow to the stop.
- ▶ Pull the medical device off while twisting slightly.
- ▶ Release the clamping ring.

## 5.3 Insert the bud bur or inverted cone bur.



### Note

Only use bud burs or cone burs meeting the following requirements:

- Size 02 edge diameter: max. 1.1 mm

**(Mat. no. 0.549.0032)**

- Size 0 edge diameter: max. 0.9 mm

**(Mat. no. 0.549.0042)**

Cone burs:

- Size 02 edge diameter: max. 1.1 mm  
**(Mat. no. 0.549.0062)**
- Size 0 edge diameter: max. 0.9 mm  
**(Mat. no. 0.549.0072)**



**WARNING****Use of impermissible bud burs or cone burs.**

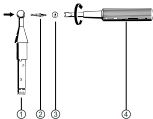
Injury to the patient or damage to the medical device.

- ▶ Only use bud burs or cone burs that do not deviate from the indicated data.

**CAUTION**

**Injury hazard from bud burs or cone burs.  
Infections or cuts.**

- ▶ Wear gloves or fingerstalls.



- ▶ Insert the bud bur or cone bur ② in the head housing.
- ▶ Mount bearing cover ③ and screw tight with special wrench ④ in the direction of the arrow.
- ▶ Check the function by turning the driver ①.



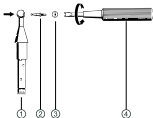
## 5.4 Remove bud bur or cone bur



### **WARNING**

**Hazard from rotating bud bur or cone bur.  
Lacerations.**



- ▶ Do not touch the bud bur or cone bur when it is rotating!
- ▶ Do not touch soft tissue with the head/tip that can heat and burn the soft tissue.



- ▶ Unscrew the bearing cover ③ with the special wrench ④ in the direction of the arrow.
- ▶ Remove the bud bur or cone bur ② from the head housing in the direction of the arrow while slightly turning the drive ①.

## 6 Preparation methods according to ISO 17664

### 6.1 Preparations at the site of use

	<div data-bbox="487 420 1822 536"> <b>WARNING</b></div> <div data-bbox="496 550 1822 881"><p><b>Hazard from nonsterile products.</b> An infection hazard exists from contaminated medical devices.</p><ul style="list-style-type: none"><li>► Observe suitable personal protective measures.</li></ul></div>
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**Note**

The bud bur or cone bur remains in the head during preparation. All of the following preparation steps refer to both the head as well as the bud bur and cone bur.

- ▶ 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.

## 6.2 Cleaning



### CAUTION

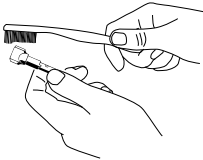
**Malfunctions from cleaning in the ultrasonic unit.**  
Defects in the product.

- ▶ Only clean in a thermodisinfecteur or manually.

## **6.2.1 Cleaning: Manual cleaning - external**

Required accessories:

- Tap water  $30^{\circ}\text{C} \pm 5^{\circ}\text{C}$  ( $86^{\circ}\text{F} \pm 10^{\circ}\text{F}$ ) or a 60 to 70% alcohol solution
- Brush such as a medium hard toothbrush



- Brush off under flowing tap water, or clean with a 60-70% alcohol solution.

### **6.2.2 Cleaning: Manual cleaning - 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 interior of this product is not to be cleaned manually).

### **6.2.3 Cleaning: Machine cleaning - 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 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 thermodisinfectant.
- ▶ Directly after automated cleaning, treat the medical device with the care products and systems provided by KaVo.

## 6.3 Disinfection

	<div data-bbox="653 305 1060 388"> <b>CAUTION</b></div> <p data-bbox="500 422 1810 564"><b>Malfunctioning from using a disinfectant bath or chlorine-containing disinfectant.</b></p> <p data-bbox="500 578 1129 640">Defects in the product.</p> <ul data-bbox="563 699 1804 751" style="list-style-type: none"><li>▶ Only disinfect in a thermodisinfecter or manually.</li></ul>
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### 6.3.1 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 off 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 instruction for use for the disinfectant.

### **6.3.2 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.)

### **6.3.3 Disinfection: Automated disinfection of the inside and outside**

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 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 thermodisinfectors.

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

## **6.4 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 thermidisinfector.

**Note**

Please observe the instructions for use of the thermidisinfector.



## 6.5 Care products and systems - Servicing



### **Note**

Remove the bud bur or cone bur to care for the product.

**CAUTION**

**Sharp bud bur or cone bur in the medical device.**  
Injury hazard from sharp and/or pointed bud bur or cone bur.

- ▶ Take special care when caring for the medical device.

**CAUTION**

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

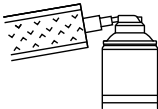
- ▶ Regularly perform proper care.

**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.

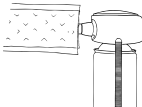
## 6.5.1 Care products and systems - Servicing: Care with KaVo SPRAY

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.



- ▶ Cover the product with the Cleanpac bag.
- ▶ Place the product on the cannula, and press the spray button for one second.

### **6.5.2 Care products and systems - Servicing: Care with 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 of the **KaVo SPRAYrotor** and cover it with a Cleanpac bag.
- ▶ Servicing the product.

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

### **6.5.3 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 twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilisation.

- ▶ Servicing the product.

## 6.6 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 sterilisation 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 STERlclave bags **Mat. no. 0.411.9912**)!

## 6.7 Sterilisation

### Sterilise in a steam steriliser (Autoclave) EN 13060/ISO 17665-1

	<div data-bbox="476 409 1824 533"> <b>CAUTION</b></div> <div data-bbox="476 533 1824 954"><p><b>Premature weary and malfunctions from improper servicing and care.</b> Reduced production time.</p><ul style="list-style-type: none"><li>▶ Before each sterilisation cycle, treat the medical device with KaVo care products.</li></ul></div>
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	<div data-bbox="649 174 1060 252"> <b>CAUTION</b></div> <div data-bbox="496 291 1410 353"><b>Contact corrosion from moisture.</b></div> <div data-bbox="496 368 1039 430">Damage to product</div> <div data-bbox="559 487 1797 607"><ul style="list-style-type: none"><li>▶ Immediately remove the product from the steam steriliser after the sterilisation cycle!</li></ul></div>
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The medical device is temperature resistant up to 138°C (280.4°F).

KaVo recommends for example

- STERlclave B 2200/ 2200P by KaVo
- Citomat/ K-series by Getinge

Depending on the device, select a suitable method from the following gravitation methods.

Autoclave with a triple pre-vacuum for least four minutes at  $134^{\circ}\text{C} \pm 1^{\circ}\text{C}$  ( $273^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$ )

Autoclave using the gravitational method: sterilise for at least 10 min. at  $134^{\circ}\text{C} \pm 1^{\circ}\text{C}$  ( $273^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$ )

Autoclave using the gravitational for at least 60 min. at  $121^{\circ}\text{C} \pm 1^{\circ}\text{C}$  ( $250^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$ )

Follow the manufacturer's instructions for use.

## 6.8 Storage

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



### Note

Observe the expiration date of the sterilized item.

## 7 Tools

Obtainable from dental and medical suppliers

Material summary	Mat. no,
Special wrench	0.411.0731
Instrument stand 2151	0.411.9501
Cleanpac 10 units	0.411.9691
Cellulose pad 100 units	0.411.9862

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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