

# Instructions for use

## COMFORTdrive 200 XDR - REF 1.007.3570



**Distributed by:**  
KaVo Dental - Charlotte  
11729 Fruehauf Drive  
Charlotte, NC 28273 USA  
Tel. 847-550-6800  
Fax 847-550-6825

**Manufacturer:**  
Kaltenbach & Voigt GmbH  
Bismarckring 39  
D-88400 Biberach  
www.kavo.com

Table of contents

1

### Table of contents

|   |           |
|---|-----------|
| <b>1 User instructions</b> .....  | <b>5</b>  |
| <b>2 Safety</b> .....   | <b>7</b>  |
| 2.1 Description of safety instructions .....                            | 7         |
| 2.2 Safety instructions .....   | 9         |
| <b>3 Product description</b> .....                                      | <b>19</b> |
| 3.1 Purpose – Proper use .....  | 20        |
| 3.2 Technical Specifications .....                                      | 22        |
| 3.2.1 Technical Specifications: Operation with high-pressure lamp ..... | 24        |
| 3.3 Transportation and storage conditions .....                         | 25        |
| <b>4 First use</b> .....  | <b>27</b> |
| 4.1 Checking the amount of water .....                                  | 28        |

Table of contents

2

|   |           |
|---|-----------|
| <b>5 Operation</b> .....  | <b>29</b> |
| 5.1 Attach the medical device .....                                   | 29        |
| 5.2 Remove the medical device .....                                   | 31        |
| 5.3 Insert the milling cutters or diamond grinders .....              | 32        |
| 5.4 Removing the milling tool or diamond grinder .....                | 36        |
| 5.5 Attaching GENTLEcap .....   | 38        |
| 5.6 Removing GENTLEcap .....  | 39        |
| <b>6 Troubleshooting</b> .....  | <b>40</b> |
| 6.1 Check for malfunctions .....                                      | 40        |
| 6.2 Troubleshooting .....   | 42        |
| 6.2.1 Troubleshooting: Replacing the O-rings on the supply hose ..... | 42        |
| 6.2.2 Troubleshooting: Cleaning the spray nozzle. ....                | 43        |
| 6.2.3 Troubleshooting: Change the water filter .....                  | 45        |
| 6.2.4 Troubleshooting: Changing the high-pressure lamp .....          | 47        |

|   |           |
|---|-----------|
| <b>7 Preparation methods according to ISO 17664</b> .....               | <b>49</b> |
| 7.1 Preparations at the site of use .....                               | 49        |
| 7.2 Cleaning .....  | 50        |
| 7.2.1 Cleaning: Manual cleaning - external .....                        | 51        |
| 7.2.2 Cleaning: Automated external cleaning .....                       | 52        |
| 7.2.3 Cleaning: Manual cleaning - internal .....                        | 53        |
| 7.2.4 Cleaning: Automated internal cleaning .....                       | 53        |
| 7.3 Disinfection .....  | 54        |
| 7.3.1 Disinfection: Manual disinfection - external .....                | 55        |
| 7.3.2 Disinfection: Manual disinfection - internal .....                | 56        |
| 7.3.3 Disinfection: Machine disinfection - external and internal .....  | 57        |
| 7.4 Drying .....  | 58        |
| 7.5 Care products and systems - Servicing .....                         | 59        |
| 7.5.1 Care products and systems - Servicing: Care with KaVo Spray ..... | 60        |

|   |           |
|---|-----------|
| 7.5.2 Care products and systems - Servicing: Care with KaVo QUATTROcare ..... | 62        |
| 7.6 Packaging .....   | 64        |
| 7.7 Sterilisation .....   | 65        |
| 7.8 Storage .....   | 69        |
| <b>8 Tools</b> .....  | <b>70</b> |
| <b>9 Warranty terms and conditions</b> .....                                  | <b>73</b> |



## 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.

© Copyright by KaVo Dental GmbH

### Symbols

|   |   |
|---|---|
|  | Refer to the section Safety/warning symbols             |
|  | Important information for users and service technicians |

|   |   |
|---|---|
|  | Action request  |
|  | Steam sterilisable 134 °C -1 °C / +4 °C (273 F -1.6 F / +7.4 F) |
|  | Thermoisinfectable  |

### 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



|   |   |
|---|---|
|  |  <b>DANGER</b>   |
|   | <p><b>The introduction describes the type and source of the hazard.</b><br/>This section describes the potential consequences of non-observance.</p> <ul style="list-style-type: none"> <li>▶ The optional step includes necessary measures for hazard prevention.</li> </ul> |

### Description of danger levels



The safety instructions listed here, together with the three levels of danger will help avert property damage and injury.



|   |   |
|---|---|
|  |  <b>CAUTION</b>                          |
|   | <p><b>CAUTION</b><br/>indicates a hazardous situation that can cause damage to property or mild to moderate injuries.</p> |



|  |   |
|--|---|
|  |  <b>WARNING</b>  |
|  | <p><b>WARNING</b><br/>indicates a hazardous situation that can cause death or serious injury.</p> |



|   |   |
|---|---|
|  |  <b>DANGER</b>         |
|   | <p><b>DANGER</b><br/>indicates a hazardous situation that can directly cause death or serious injury.</p> |

### 2.2 Safety instructions


|   |  |
|---|--|
|  |  <b>WARNING</b>   |
|   | <p><b>Hazards for the care provider and the patient.</b><br/>In the case of damage, irregular running noise, excessive vibration, untypical warming or when the cutter or grinder cannot be held.</p> <ul style="list-style-type: none"> <li>▶ Do not use further and notify Service.</li> </ul> |


|   |   |
|---|---|
|  |  <b>CAUTION</b>  |
|   | <p><b>Risks due to lack of control equipment.</b><br/>Hazards can arise if control equipment is not available for changing the speed and the direction of rotation.</p> <ul style="list-style-type: none"> <li>▶ The dental treatment unit connected must have control equipment for changing the speed and direction of rotation.</li> <li>▶ A note is to be included in the documents accompanying the dental treatment unit, referring to responsibilities arising from safety, reliability and performance.</li> <li>▶ The medical device may only be combined with a treatment unit released by KaVo.</li> </ul> |

|   |   |
|---|---|
|  | <b>⚠ CAUTION</b>  |
|   | <p><b>Premature wear and malfunctioning from improper storage during long periods of nonuse.</b><br/>Reduced product life.</p> <ul style="list-style-type: none"> <li>▶ The medical device should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of nonuse.</li> </ul>             |
|  | <b>⚠ CAUTION</b>  |
|   | <p><b>Risk due to incorrectly stored instrument.</b><br/>Injury and infection caused by chucked cutters or grinders.<br/>Damage to clamping system from dropping the instrument.</p> <ul style="list-style-type: none"> <li>▶ After treatment, place the instrument properly in the cradle, without the cutter or grinder.</li> </ul> |

|   |  |
|---|--|
|  | <b>⚠ CAUTION</b>   |
|   | <p><b>Burning hazard from hot instrument head or hot instruments cover.</b><br/>If the instrument overheats, burns may arise in the oral area.</p> <ul style="list-style-type: none"> <li>▶ Never contact soft tissue with the instrument head or instrument cover.</li> </ul>   |
|  | <b>⚠ CAUTION</b>   |
|   | <p><b>Hazard from use as a light probe.</b><br/>Do not use the device as a light probe since the rotating cutter grinder can cause injury.</p> <ul style="list-style-type: none"> <li>▶ For additional illumination of the oral cavity or preparation site, use a suitable light probe such as the KaVo DIALux 2300L.</li> </ul> |

#### Risks from electromagnetic fields (pacemakers)

|   |   |
|---|---|
|  | <b>⚠ WARNING</b>  |
|   | <p><b>Risks from electromagnetic fields.</b><br/>The functions of implanted systems (such as pacemakers) can be influenced by electromagnetic fields.</p> <ul style="list-style-type: none"> <li>▶ Ask patients before treatment and counsel them about the risks.</li> </ul> |

|   |   |
|---|---|
|  | <b>⚠ WARNING</b>  |
|   | <p><b>Electrical power</b><br/>Electrical shock from incorrectly connecting a non-KaVo system to the medical device.</p> <ul style="list-style-type: none"> <li>▶ When installing and operating the medical device on treatment equipment and furnishings from other manufacturers, observe the provisions of "Protection from electrical shock," "Leakage current," and "Not grounding the application part" in accordance with DIN EN IEC 60601-1.</li> <li>▶ Make sure that the medical device is combined only with a treatment unit that has been released by KaVo.</li> </ul> |



**Note**  
 This medical device in conjunction with the dental treatment unit meets the requirements of DIN EN IEC 60601-1-2.

|  |   |
|--|---|
|  | <b>CAUTION</b>  |
|  | <p><b>Hazard from the use of handpieces equipped with electronic micromotors.</b> Electronic micromotors generate much more energy than conventional pneumatic turbines and motors. Given the higher torque and speed, handpieces that are poorly serviced, damaged or used improperly can overheat which can cause serious burn injuries to the patient.</p> <ul style="list-style-type: none"> <li>▶ Observe the following points.</li> </ul> |

The following guidelines must be observed to ensure safe use of the electrically driven handpieces:

- The service instructions for handpieces must be precisely followed when using KAVO spray or QUATTROcare care systems.
- Before each use, the handpiece must be checked for external damage.
- Before each use, perform a test run with the handpiece, and watch for atypical heating and unusual noise and vibration.
- Immediately stop using handpieces that act unusual.
- Never press the pushbutton during operation. This also includes lifting the cheek or tongue!

We recommend returning the handpieces to KaVo at regular intervals for testing, setup and servicing. The frequency of the care depends on the instruments used. The contra-angle handpieces must be setup according to the KaVo instructions to ensure proper functioning.

|  |  |
|--|--|
|  | <b>CAUTION</b>   |
|  | <p><b>Swallowing or aspiration of the GENTLEcap by the patient.</b></p> <ul style="list-style-type: none"> <li>▶ Place a rubber dam before each treatment involving the GENTLEcap.</li> <li>▶ Replace the GENTLEcap no later than after 250 sterilisation cycles.</li> </ul> |



**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



COMFORTdrive 200 XDR (Mat. no. 1.007.3570)

#### 3.1 Purpose – Proper use

##### Purpose:

This medical device is

- intended for dental treatment only. Any other type of use or alteration to the product is impermissible and can be hazardous. The medical device is intended for the following applications: cavity and crown preparations, removal of fillings, processing of tooth and restoration surfaces, cutting off of crowns and bridges.
- A medical device according to relevant national statutory regulations.

This medical device

- contains a dental electrical low voltage motor according to DIN EN ISO 11498 type 3.
- and is not permitted for use in explosive areas.

##### 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, 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..

#### 3.2 Technical Specifications

With integrated electric motor.

|                                 |   |
|---------------------------------|---|
| Identification                  | Red colour marking  |
| Motor speed                     | min. 30,000 min <sup>-1</sup> to max. 200,000 min <sup>-1</sup> |
| Motor power                     | 30 Watt   |
| COMFORTtronic motor electronics | Mat. no. 1.005.0169   |
| Max. motor voltage              | 18 V AC   |
| Max. output torque              | 0.45 Ncm  |

Can be placed on the COMFORTbase (Mat. no. 1.004.9811) supply hose.

Information about the connected loads on the device side should be obtained from the manufacturer.

|  |  |
|--|--|
| Operating time                           | Intermittent operation 0.5 min. on, 9 min. off |
| Air outlet at the coupling (cooling air) | 7 to 10 NL/min.                                |
| Spray air                                | 1.0 to 2.5 bar (15 to 36 psi)                  |
| Spray water                              | 0.8 to 2.0 bar (12 to 29 psi)                  |

The GENTLEcap A (**Mat. no. 1.007.6757**) can be placed on the COMFORTdrive 200 XDR. The package of the GENTLEcap A (**Mat. no. 1.007.6757**) contains 4 GENTLEcap A units.



#### Note

The GENTLEcap produces heat insulation between the instrument head and the patient's mucous membranes. This reduces the probability of mucosal burn significantly if an error is made (e.g. overheating of the instrument head due to storage defect).

#### 3.2.1 Technical Specifications: Operation with high-pressure lamp

|   |               |
|---|---------------|
| Operating voltage of the high-pressure lamp | max. 3.2 V DC |
| High-pressure lamp power                    | max. 2.5 Watt |



### 3.3 Transportation and storage conditions

|  |  |
|--|--|
|  | <b>⚠ CAUTION</b>   |
|  | <p><b>It is hazardous to start up the medical device after it has been stored strongly refrigerated.</b><br/>This can cause the medical device to malfunction.</p> <ul style="list-style-type: none"> <li>▶ Prior to start-up, very cold products must be heated to a temperature of 20°C to 25°C (68°F to 77°F).</li> </ul> |


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

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

#### 4 First use


|   |  |
|---|--|
|  | <b>⚠ WARNING</b>   |
|   | <p><b>Hazard from non-sterile products.</b><br/>Infection danger to the care provider and patient.</p> <ul style="list-style-type: none"> <li>▶ Before first use and after each use, sterilise the medical device.</li> </ul>  |
|  | <b>⚠ CAUTION</b>   |
|   | <p><b>Damage from soiled and moist cooling air.</b><br/>Contaminated and moist cooling air can cause malfunctions and lead to premature bearing wear.</p> <ul style="list-style-type: none"> <li>▶ Make sure that the supply of cooling air is dry, clean and uncontaminated according to ISO 7494-2.</li> </ul> |


#### 4.1 Checking the amount of water

|   |   |
|---|---|
|  | <b>⚠ CAUTION</b>  |
|   | <p><b>Overheating of the tooth due to insufficient amount of cooling water.</b><br/>Insufficient spray water can cause the medical device to overheat and damage the pulp and tooth.</p> <ul style="list-style-type: none"> <li>▶ Adjust the water amount for the spray cooling to a minimum of 50 cm<sup>3</sup>/min (3.1 inch<sup>3</sup>).</li> <li>▶ Check spray water channels and if necessary clean spray nozzles with the nozzle needle (<b>Mat. no. 0.410.0921</b>).</li> <li>▶ Check water filter and replace, if necessary.</li> </ul> |

#### 5 Operation

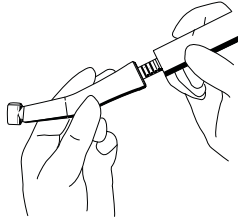
##### 5.1 Attach the medical device

|   |   |
|---|---|
|  | <b>⚠ WARNING</b>  |
|   | <p><b>Release of the medical device during treatment.</b><br/>A medical device that is not properly locked in place can release from the supply hose.</p> <ul style="list-style-type: none"> <li>▶ Carefully pull on it before each treatment to ensure that the medical device is securely locked on the supply hose.</li> </ul> |

|   |   |
|---|---|
|  | <b>⚠ CAUTION</b>  |
|   | <p><b>Press the foot control while attaching or detaching the medical device.</b><br/>Loss of function and damage to the medical device and supply hose.</p> <ul style="list-style-type: none"> <li>▶ Do not connect or remove the medical device while pressing the foot control.</li> </ul> |

- ▶ Slightly wet the O-rings on the supply hose with KAVO spray.





- ▶ Connect the medical device with the supply hose until it locks into place and twist it until the catch audibly locks in place.

**5.2 Remove the medical device**

- ▶ Remove the medical device from the supply hose in an axial direction.

**5.3 Insert the milling cutters or diamond grinders**



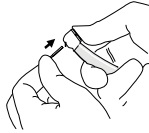
**Note**

Only use cutters or grinders that correspond to ISO 1797-1 type 3, are made of steel or hard metal and meet the following criteria:

- Shaft diameter: 1.59 to 1.60 mm
- Overall length: max. 25 mm
- Shaft clamping length: 11 mm
- Edge diameter: max. 2 mm


|  |   |
|--|---|
|  | <p><b>⚠ WARNING</b></p>   |
|  | <p><b>Use of unauthorised cutters or grinders.</b><br/>Injury to the patient or damage to the medical device.</p> <ul style="list-style-type: none"> <li>▶ Observe the instructions for use and use the cutter or grinder properly.</li> <li>▶ Only use cutters or grinders that do not deviate from the specified data.</li> </ul> |
|  | <p><b>⚠ CAUTION</b></p>   |
|  | <p><b>Injury from using worn drill bits or burs.</b><br/>Drill bits or burs could fall out during treatment and injure the patient.</p> <ul style="list-style-type: none"> <li>▶ Never use drill bits or burs with worn shafts.</li> </ul>  |

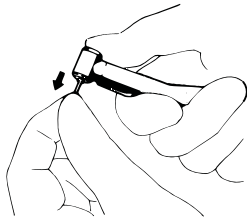
|  |   |
|--|---|
|  | <p><b>⚠ CAUTION</b></p>   |
|  | <p><b>Danger of injury from cutters or grinders.</b><br/>Infections or cuts.</p> <ul style="list-style-type: none"> <li>▶ Wear gloves or fingerstalls.</li> </ul>   |
|  | <p><b>⚠ CAUTION</b></p>   |
|  | <p><b>Hazard from defective chucking system.</b><br/>The cutter or grinder could fall out and cause injury.</p> <ul style="list-style-type: none"> <li>▶ 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.</li> </ul> |



- ▶ Forcefully press the push button with your thumb and simultaneously insert the cutter or grinder all the way.
- ▶ Check that the cutter or grinder is seated by pulling on it.

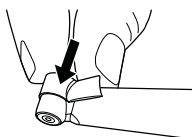
#### 5.4 Removing the milling tool or diamond grinder

|   |  |
|---|--|
|  | <b>⚠ WARNING</b>   |
|   | <p><b>Hazard from rotating cutter or grinder.</b><br/>Lacerations and damage to the chucking system.</p> <ul style="list-style-type: none"> <li>▶ Do not touch rotating cutter or grinder.!</li> <li>▶ Never press the press-button while the cutter or grinder is rotating!</li> <li>▶ Remove the cutter or grinder from the contra-angle handpiece after treatment to avoid injury or infection while storing it.</li> </ul> |



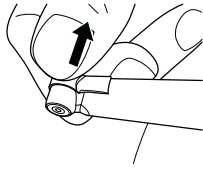
- ▶ After the cutter or grinder has stopped rotating, press the press-button with your thumb and simultaneously pull out the drill bit or bur.

#### 5.5 Attaching GENTLEcap



- ▶ Push the GENTLEcap onto the head until the GENTLEcap locks into place noticeably. Ensure that the GENTLEcap rests against the instrument evenly.
- ▶ Pull lightly in the pull-off direction to check the secure seating of the GENTLEcap on the instrument.

### 5.6 Removing GENTLEcap



- ▶ Pull the GENTLEcap off the instrument.

## 6 Troubleshooting

### 6.1 Check for malfunctions

|  |   |
|--|---|
|  | <b>CAUTION</b>  |
|  | <p><b>Missing or damaged O-rings.</b><br/>Malfunctions and premature failure.</p> <ul style="list-style-type: none"> <li>▶ Make sure that all O-rings are on the coupling and undamaged.</li> </ul> |

Number of available O-rings: 3

|  |   |
|--|---|
|  | <b>CAUTION</b>  |
|  | <p><b>Heating of the product.</b><br/>Burns or product damage from overheating.</p> <ul style="list-style-type: none"> <li>▶ Do not use the product if it is irregularly heated.</li> </ul> |

- ▶ The medical device is too hot while idling:  
Check the amount of cooling air.
- ▶ The medical device is too hot while working:  
Caring for the medical device.
- ▶ When the speed drops or is uneven:  
Caring for the medical device.
- ▶ An O-ring is missing on the motor coupling:  
Replace O-ring.

#### 6.2.1 Troubleshooting: Replacing the O-rings on the supply hose

|  |   |
|--|---|
|  | <b>CAUTION</b>  |
|  | <p><b>Hazard from improper care of the O-rings.</b><br/>Malfunctions or complete failure of the medical device.</p> <ul style="list-style-type: none"> <li>▶ Do not use Vaseline or other grease or oil.</li> </ul> |




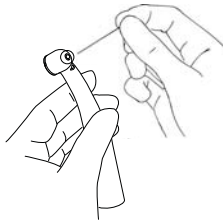
**Note**

The O-ring on the supply hose may only be lubricated with cotton ball wet with KAVO Spray.

- ▶ Press the O-ring between your fingers to form a loop.
- ▶ Shove the O-ring to the front, and remove it.
- ▶ Insert new O-rings into the grooves.


6.2.2 Troubleshooting: Cleaning the spray nozzle.

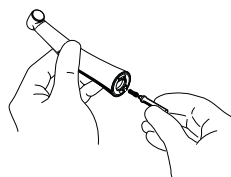
|   |  |
|---|--|
|  | <p><b>⚠ CAUTION</b></p>  |
|   | <p><b>Hazard from insufficient spray water.</b><br/>Overheating of the medical device and damage to the tooth.</p> <ul style="list-style-type: none"> <li>▶ Check the spray water channels and clean the spray nozzles with the nozzle needle <b>Mat. no. 0.410.0921</b> if necessary.</li> <li>▶ Check the water filter and exchange if necessary.</li> </ul> |



- ▶ Clean the water passage in the spray nozzles by using the nozzle needle (**Mat. no. 0.410.0921**).


6.2.3 Troubleshooting: Change the water filter

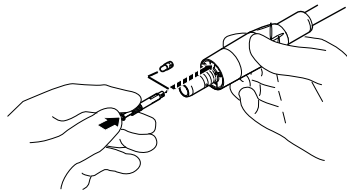
|   |  |
|---|--|
|  | <p><b>⚠ CAUTION</b></p>  |
|   | <p><b>Hazard from insufficient spray water.</b><br/>Overheating of the medical device and damage to the tooth.</p> <ul style="list-style-type: none"> <li>▶ Check the spray water channels and clean the spray nozzles with the nozzle needle <b>Mat. no. 0.410.0921</b> if necessary.</li> <li>▶ Check the water filter and exchange if necessary.</li> </ul> |



- ▶ Screw out and remove the filter with the wrench (**Mat. no. 1.002.0321**).
- ▶ Insert the new filter (**Mat. no. 1.002.0271**) and screw it in with the wrench.

**6.2.4 Troubleshooting: Changing the high-pressure lamp**

|   |  |
|---|--|
|  | <b>⚠ CAUTION</b>   |
|   | <p><b>Danger due to hot high-pressure bulb.</b><br/>Burning hazard.</p> <ul style="list-style-type: none"> <li>▶ After it has been used, do not touch the high-pressure lamp until it has cooled.</li> </ul> |



- ▶ Shove the included lamp changer on the high pressure lamp, and pull the lamp out axially.

- ▶ Insert the new lamp into the lamp changer, and introduce it into the hole in the face of the supply hose. Carefully shove the lamp into the socket by twisting slightly.
- ▶ Simultaneously turn the lamp changer and pull it out axially.


**7 Preparation methods according to ISO 17664**



**Note**

The following setup procedures apply to the COMFORTdrive 200 XDR, the nozzle needles and the GENTLEcap.


**7.1 Preparations at the site of use**

|   |  |
|---|--|
|  | <b>⚠ WARNING</b>   |
|   | <p><b>Hazard from non-sterile products.</b><br/>There is a risk of infection from contaminated medical devices.</p> <ul style="list-style-type: none"> <li>▶ Observe suitable personal protective measures.</li> </ul> |

- ▶ Remove all residual cement, composite or blood without delay.
- ▶ Recondition the medical device as soon as possible after treatment.

- ▶ Remove the cutter or grinder from the medical device.
- ▶ The medical device must be dry when transported for reconditioning.
- ▶ Do not place it in a solution or similar.

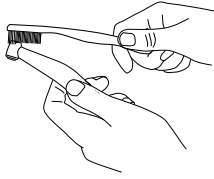
**7.2 Cleaning**

|   |   |
|---|---|
|  | <b>⚠ CAUTION</b>  |
|   | <p><b>Malfunctions from cleaning in an ultrasonic unit.</b><br/>Defects in the product.</p> <ul style="list-style-type: none"> <li>▶ Only clean manually or in a thermodisinfectior.</li> </ul> |

### 7.2.1 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.

### 7.2.2 Cleaning: Automated external cleaning



KaVo recommends thermodisinfectors in accordance with EN ISO 15883 that are operated with alkaline cleaning agents at a pH of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the ""VARIO-TD" programme, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent, and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfectant (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, and then lubricate immediately with care agents from the KaVo care system.

### 7.2.3 Cleaning: Manual cleaning - internal

Not applicable.

### 7.2.4 Cleaning: Automated internal cleaning



KaVo recommends thermodisinfectors in accordance with EN ISO 15883 that are operated with alkaline cleaning agents at a pH of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the ""VARIO-TD" programme, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent, and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

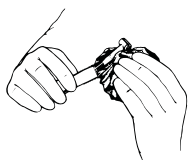
- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfectant (complying with max. pH value of 10).

- ▶ In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry, and then lubricate immediately with care agents from the KaVo care system.

### 7.3 Disinfection

|  |  |
|--|--|
|  | <b>⚠ CAUTION</b>   |
|  | <p><b>Malfunctioning from using a disinfectant bath or disinfectant containing chlorine.</b><br/>Defects in the product.</p> <ul style="list-style-type: none"> <li>▶ Only disinfect in a thermodisinfectant or manually.</li> </ul> |

### 7.3.1 Disinfection: Manual disinfection - external



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

- 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.
- ▶ Observe the instructions for use for the disinfectant.

### 7.3.2 Disinfection: Manual disinfection - internal

The efficacy of manual internal disinfection must be demonstrated by the manufacturer of the disinfection agent. With KaVo products, use only disinfection agents that have been released by KaVo with respect to the compatibility of materials (e.g. WL-cid / made by ALPRO).

- ▶ Immediately after internal disinfection, lubricate the KaVo medical device immediately with care agents from the KaVo care system.

- ▶ Observe the instructions for use for the disinfectant.

### 7.3.3 Disinfection: Machine disinfection - external and internal



KaVo recommends thermosdisinfectors in accordance with EN ISO 15883 that are operated with alkaline cleaning agents at a pH of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" programme, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent, and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermosdisinfector (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, and then lubricate immediately with care agents from the KaVo care system.

## 7.4 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 disinfection program of the thermosdisinfector.

- ▶ Please observe the instructions for use of the thermosdisinfector.

## 7.5 Care products and systems - Servicing

|   |  |
|---|--|
|  | <b>⚠ WARNING</b>   |
|   | <b>Sharp cutters or grinders in the medical device.</b><br>Risk of injury from sharp or pointed cutters or grinders. <ul style="list-style-type: none"> <li>▶ Remove cutter or grinder.</li> </ul> |
|  | <b>⚠ CAUTION</b>   |
|   | <b>Premature wear and malfunctions from improper servicing and care.</b><br>Reduced product life. <ul style="list-style-type: none"> <li>▶ Perform proper care regularly!</li> </ul>               |

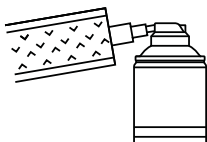
**Note**

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.

**Note**

Do not use cleaning agents and cleaning systems for the GENTLEcap.

## 7.5.1 Care products and systems - Servicing: Care with KaVo Spray



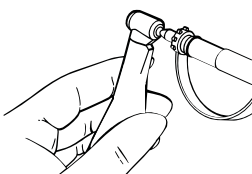
KaVo recommends servicing the product after each time it is used, i.e. after each automatic cleaning and before each sterilisation.

- ▶ Remove cutter or grinder and close 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 servicing the chuck system once a week.

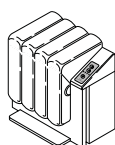


- ▶ Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

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

## 7.5.2 Care products and systems - Servicing: Care with KaVo QUAT-TROcare

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



KaVo recommends servicing the product after each time it is 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

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

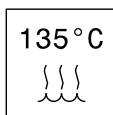
- ▶ Individually seal the medical device in the sterilised item packaging.

#### 7.7 Sterilisation

**Sterilisation in a steam steriliser (autoclave) in accordance with EN 13060/ISO 17665-1 (e.g. KaVo STERiClave B 2200 / 2200 P)**

|  |  |
|--|--|
|  | <b>CAUTION</b>   |
|  | <p><b>Premature wear and malfunctions from improper servicing and care.</b><br/>Reduced product life.</p> <ul style="list-style-type: none"> <li>▶ Before each sterilisation cycle, service the medical device with KaVo care products.</li> </ul> |

|  |   |
|--|---|
|  | <b>CAUTION</b>  |
|  | <p><b>Contact corrosion due to moisture.</b><br/>Damage to product.</p> <ul style="list-style-type: none"> <li>▶ Immediately remove the product from the steam steriliser after the sterilisation cycle!</li> </ul> |
|  | <b>CAUTION</b>  |
|  | <p><b>Defects in the product.</b><br/>Comply with cooling time.</p> <ul style="list-style-type: none"> <li>▶ Do not rinse the product with cold water after sterilisation. Allow product to cool.</li> </ul>        |

**Note**

Only sterilise the GENTLEcap when it is removed.

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

(Depending on the available autoclave,) select a suitable procedure from the following sterilisation processes:

- Autoclave with three times initial vacuum:
    - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)  
Drying time: 20 min.
  - Autoclave using the gravitation method:
    - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F) or alternatively  
Drying time: 30 min.
    - at least 60 minutes at 121 °C -1 °C / +4 °C (250 °F -1.6 °F / +7.4 °F)  
Drying time: 30 min.
- Use according to the manufacturer's Instructions for Use.

**7.8 Storage**

- Reconditioned products should be stored protected from dust with minimum exposure to germs in a dry, dark and cool space.
- Comply with the expiry date of the sterilised item.

**8 Tools**

Available from dental suppliers.

| Material summary                       | Mat. no.   |
|--|------------|
| Airflow measuring tube                 | 0.411.4441 |
| Adapter for the airflow measuring tube | 1.005.1702 |
| Nozzle needle                          | 0.410.0921 |
| Bulb changer                           | 1.005.1773 |
| Replacement filter                     | 1.002.0271 |
| COMFORTdrive service coupling          | 1.005.1707 |
| Wrench for filter                      | 1.002.0321 |
| COMFORTdrive spray head                | 1.005.3154 |
| High-pressure lamp                     | 1.002.2928 |
| O-ring                                 | 1.005.0327 |

| Material summary        | Mat. no.   |
|-------------------------|------------|
| GENTLEcap A 4 pcs.      | 1.007.6757 |
| Cellulose pad 100 units | 0.411.9862 |
| Cleanpac 10 units       | 0.411.9691 |

**Only for the USA**

| Material summary                      | Mat. no.   |
|---------------------------------------|------------|
| KaVo Spray America 2113 A             | 0.411.9660 |
| QUATTROcare plus Spray America 2141 P | 1.005.4524 |

**Only for Canada**

| Material summary                     | Mat. no.   |
|--------------------------------------|------------|
| KaVo Spray Canada 2114 A             | 0.411.9680 |
| QUATTROcare plus Spray Canada 2149 P | 1.005.4523 |

**9 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 24 months from data 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 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. 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 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, device number or type and factory number or serial number must be clearly visible on this document.

