

Instructions for use
CORONAflex 2005 - REF 0.579.1000



KaVo. Dental Excellence.

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1 User instructions




Dear User

Congratulations on purchasing this KaVo quality product. By following the instructions below you will be able to work smoothly, economically and safely.

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Symbols

	Refer to the chapter on Safety/Warning symbol
	Important information for users and service technicians

	Action request
	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
	Can be steam sterilizes at 134 °C -1 °C / +4 °C (273 °F -1,6 °F / +7,4 °F)

Target group

This document is intended for dentists and their assistants. The section on starting up is also intended for service technicians.

2 Safety

2.1.1 Description of safety instructions: Warning symbol



Warning symbol

2.1.2 Description of safety instructions: Structure



DANGER

The introduction describes the type and source of the hazard.

This section describes the potential consequences of non-observance.

- ▶ The optional step includes necessary measures for hazard prevention.

2.1.3 Description of safety instructions: 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 to moderate injuries.



WARNING

WARNING

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

**⚠ DANGER****DANGER**

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

2.2 Safety instructions

**⚠ WARNING**

**Swallowing or aspiration of the loose parts or substances by the patient.
Danger of suffocation.**

- Before each treatment, insert a dental dam for safety reasons.

**⚠ WARNING****Removal of an entire dental prosthesis.**

Damage to the dental prosthesis and corresponding hard, soft, and anchoring tissues of the body.

- ▶ Always use the CORONAfex by means of an intervening medium (pliers, adhesion clamp or loop).
- ▶ Never place the hammer directly at the crown or bridge.
- ▶ Follow the instructions for use.

**⚠ WARNING**

Hazard to the care provider and patient.

In case of damage, irregular noises, excessive vibrations.

- ▶ Stop working and contact service support.

**⚠ CAUTION**

Premature wear and malfunctioning from improper storage during long periods of nonuse.

Reduced production time.

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

**Note**

Protective goggles must be worn (user).

**Note**

The CORONAFlex must be subjected to a safety check after 5,000 strikes or every 2 years (whichever occurs first). Send the CORONAFlex to KaVo Customer Service Centre Warthausen or a test centre approved by KaVo.

**Note**

CORONAFlex aids and appliances are subject to wear and tear.

- For this reason, both the pliers and the loop holder must be subjected to a safety check after 1,500 strikes. The loops may not be used any longer after 50 strikes.

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

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

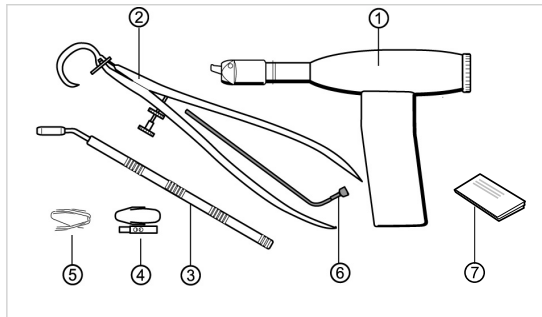
To ensure proper function, the medical device must be set up according to the methods described in the KaVo instructions for use. KaVo recommends specifying a service interval at the dental office for a licensed shop to clean, service and check the functioning of the medical device. This service interval 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



CORONAflex 2005 (**Mat. no. 0.579.1000**)

3.1 Scope of delivery



The CORONAflex 2005 Set includes:

- CORONAflex ①
- Crown pliers ②
- Loop holder ③
- Clamp, small ④
- Clamp, large ④
- Loops ⑤
- Cleaning attachment ⑥
- Instructions for Use ⑦

3.2 Purpose – Intended use

Purpose:

This medical device is

- intended for dental treatment only. All other types of use or alterations to the product are not permitted and can be hazardous. This medical product is intended for the following applications: removal of single or partial crowns, primary telescopes or bridge abutments in the region of the frontal or lateral teeth. Please refer also to the Instructions for Use.
- A medical device according to relevant national statutory regulations.

Proper use:

According to these regulations, this medical device may only be used for the described application by a knowledgeable user. The following must be observed:

- the applicable health and safety regulations
- the applicable accident prevention regulations
- these instructions for use

According to these regulations, it is the responsibility of the user to:

- only use equipment that is operating correctly,
- use the equipment for the proper purpose,
- protect him or herself, the patient and third parties from danger, and
- avoid contamination from the product.

3.3 Technical Specifications

Drive pressure	2.5 to 3.5 bar (36 to 51 psi)
Air consumption	9 to 18 NL/min.
Impact force, max.	4,000 N
Impact duration	8 μ s

Can be attached to all MULTiflex (LUX) / MULTiflex LED couplings.

3.4 Transportation and storage conditions



CAUTION

It is hazardous to start up the medical device after it has been stored strongly refrigerated.

This can cause the medical device to malfunction.



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



Temperature: -20°C to +70°C (-4°F to +158°F)



Relative humidity: 5% RH to 95% RH absence of condensation

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

4 Start up and shut down



WARNING

Hazard from nonsterile products.

Infection danger to the care provider and patient.

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



WARNING

Disposal of the product in the appropriate manner.

Prior to disposal, the product must be appropriately prepared or sterilised if this is necessary.

4.1 Mounting the MULTiflex (LUX) / MULTiflex LED coupling

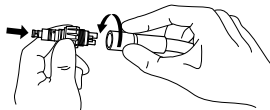


WARNING

Release of the medical device during treatment.

A medical device that is not properly locked in place can release from the MULTiflex (LUX) / MULTiflex LED coupling during treatment.

- ▶ Before each use, check if the medical device is securely locked on-to the MULTiflex (LUX) / MULTiflex LED coupling by pulling on it.



- ▶ Screw the **MULTiflex (LUX) / MULTiflex LED coupling** onto the turbine hose and tighten with the wrench.

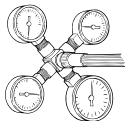
**Note**

As the CORONAFlex 2005 does not require any light, spray water or spray air, these functions need to be disabled.

4.2 Check the pressure**⚠ CAUTION****Compressed air connection on devices.**

Contaminated and humid compressed air leads to premature wear and tear.

- ▶ Supply dry, clean and uncontaminated compressed air according to ISO 7494-2 only.



A minimum drive pressure of 2.5 bar (36 psi) is required to operate the **CORONAflex**.

- Place the test gauge (**Mat. no. 0.411.8731**) between the **MULTiflex (LUX) / MULTiflex LED coupling** and the CORONAflex and test the following pressure:

Drive air: 2.5 - 3.5 bar (36 - 51 psi)

5 Operation

5.1 Mount the medical device

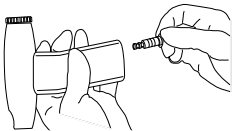


WARNING

Release of the medical device during treatment.

A medical device that is not properly locked in place can release from the MULTiflex (LUX) / MULTiflex LED coupling during treatment.

- ▶ Before each use, check if the medical device is securely locked on-to the MULTiflex (LUX) / MULTiflex LED coupling by pulling on it.



- ▶ Mount the medical device accurately on the MULTiflex (LUX) / MULTiflex LED coupling and push it backward until the coupling audibly locks in the medical device.
- ▶ Pull on the medical device to make sure that it is securely affixed to the coupling.

5.2 Remove the medical device

- ▶ Hold the coupling tight, and pull the medical device off while twisting slightly.

5.3 Setting the impact force



CAUTION

Irregularities at the knurled screw.
Injury hazard and product damage.

- ▶ Discontinue working with the device and submit the CORONAflex for inspection.

Requirement

In order to be able to set the impact force, the handpiece must be free of pressure, i.e. the foot control must not be pressed.



- ▶ Turn the knurled screw to set the impact force.

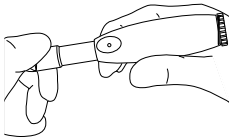
Rotate clockwise: the impact force increases.

Rotate counterclockwise: the impact force decreases.

Examples of settings:

- five-unit bridge in the region of the lateral teeth: start with an intermediate impact force setting.
- crowns in the region of the frontal teeth: always start with the lowest setting and increase up to max. 50 %.
- The maximal impact force setting should be reserved for large bridges and/or restorations with healthy stumps of a large cross-section.

5.4 Setting the percussion head position



- ▶ Rotate the percussion head to situate the trigger in the optimal working position in the upper or lower jaw.

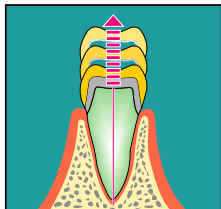
5.5 Generation of impact



⚠ CAUTION

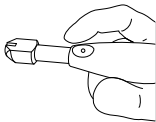
The CORONAFlex is subject to increased wear and tear if operated without load.

- ▶ Do not operate the CORONAFlex without load.



The CORONAFlex and the aiding tool must both be situated in axial pull. If there is insufficient pull, the impact is ineffective.

For the removal of bridges, the aiding tool should always be placed on the weakest abutment first to allow the strongest abutment to still bear the bridge.



- ▶ Actuate drive air on the foot control in order to keep the handpiece ready for impact.
- ▶ Close the nozzle with a finger to trigger the impact.
- ▶ To render the handpiece ready for impact again, take your finger off the nozzle and wait for 2 to 3 seconds.

5.6 Application



CAUTION

Placing the CORONAfex directly at the crown or bridge.

Damage to the corresponding hard, soft, and anchoring tissues of the body.

- ▶ Always use the CORONAfex by means of an intervening medium (pliers, adhesion clamp or loop).
- ▶ Never place the hammer directly at the crown or bridge.

**⚠ CAUTION**

Previous periodontal damage to the tooth to be treated.

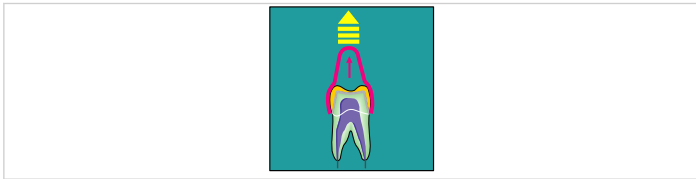
Possible extraction cannot be excluded fully if the damage is extensive.

- ▶ Make sure that the stability of the root is not compromised by advanced previous periodontitis prior to using the CORONAfex.

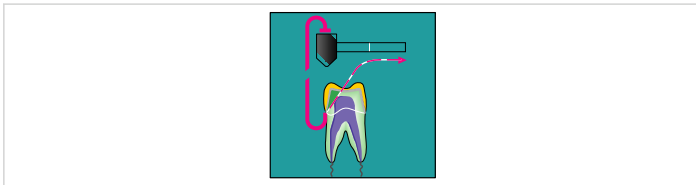
Permanent dental prostheses, such as crowns and bridges, are usually means to be permanent, i.e. irreversibly attached, restorations. However, there may arise the need to remove the dental prosthesis, for example in order to be able to carry out endodontic treatment.

The KaVo CORONAfex can now be used to remove most types of permanent dental prostheses without difficulty.

Pneumatic removal of dental prostheses eases the of the dentists significantly as compared to conventional methods of removal. The brief impact pulse destroys the cement structure. Attained through "grasping" action from vestibular and oral, the axial pull is associated with the crucial advantage in that the dental prostheses can no longer become lodged upon removal. This is a gentle means of handling to tooth stump and the dental prosthesis.



Favourable conditions for removal of the dental prosthesis.



Unfavourable conditions for removal of the dental prosthesis.

In most cases, the removed restoration remains undamaged and may be therefore be re-used. This is important especially for temporary restorations.

The best outcomes are attained using the KaVo CORONAflex in combination with the following types of cement:

- Zinc-phosphate cement
- Zinc-eugenol cement
- Carboxylate cement

Dental prostheses may be difficult to remove if they are attached using the following cements:

- Glass ionomer cement
- Dual-curing attachment cement

The adhesion of these cements to the dentine may cause substantial difficulties during removal. However, if the dental prosthesis has been in place for a number of years, the CORONAflex may be successful even with these cements, since experience tells that the adhesive power of these cements decreases over time.

**Note**

The scope of delivery of the CORONAflex includes comprehensive accessories order to cover a broad range of indications.

See also:

5 Operation: 5.6.1 Pliers, Page 39

5 Operation: 5.6.2 Adhesive clamp, Page 41

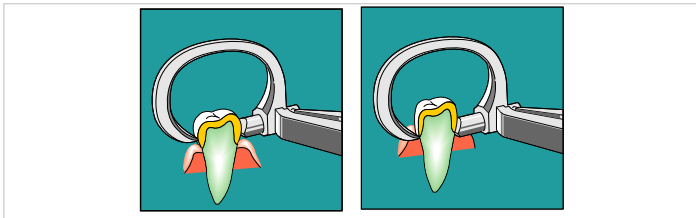
5 Operation: 5.6.3 Loop, Page 48

5.6.1 Application: Pliers



Single crowns in the region of the premolars and molars can be removed with the pliers. For this purpose, the pliers need to be placed below the equator or on the edge of the crown. The pliers are suitable for use in all four quadrants. Turn down the pliers arc accordingly.

- ▶ Place the pliers below the equator or on the edge of the crown.



- ▶ Close the pliers until there is substantial pre-tensioning, then screw down with the knurled wheel using the other hand.
- ▶ Place the **CORONAflex** at the jaw of the pliers and situate the pliers and the **CORONAflex** in axial pull.
- ▶ Trigger impact pulse.

5.6.2 Application: Adhesive clamp



**⚠ WARNING**

Swallowing or aspiration of the clamp or an adhesive approved for use in human medicine by the patient.

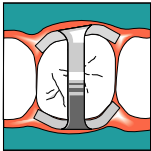
- ▶ Before you work with an adhesive approved for use in human medicine, you need to insert a dental dam for safety purposes.
- ▶ While working with the adhesive, any vapours should be minimised by suction, and suction should be continued for another approx. 2 minutes after the work is completed.

**Note**

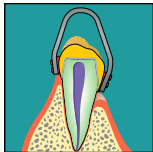
Only adhesives approved for use in human medicine are permissible.

Single crowns, partial crowns, primary telescopes or bridge-units in the region of the frontal or lateral teeth, which do not have an equator and do

not permit the application of the pliers, cannot be removed with the adhesive clamp.



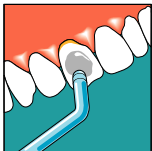
- Prior to application, adapt the adhesive clamp to the shape of the tooth using three-jaw pliers (Aderer pliers).



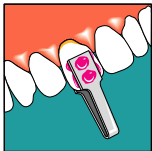
- The clamp should reach all the way to the gingival edge in vestibular and oral positions.



- ▶ Mark the vestibular side, since this may be difficult to recognise later when the adhesive is present.
- ▶ Then clean the crown or bridge-unit thoroughly, ideally with pumice paste or a rubber cup. Stir the pumice powder in water, apply it and clean for approx. 1 minute. The cleaning paste should not contain any fluorides as there may otherwise be saturation effects at the surface of the dental prosthesis which reduce the adhesive effect and may limit the success of removal.
- ▶ Thoroughly rinse off the paste until all of the cleaning agent is removed.
- ▶ Dry the cleaned surface and keep it dry. This is necessary to allow the adhesive that is approved for use in human medicine to penetrate into and bond to the minimal surface roughness of the surface of the dental prosthesis.



- ▶ After cleaning and drying, apply the adhesive that is approved for use in human medicine, e.g., with a thick ball-shaped plugger, to the dental prosthesis.
- ▶ Simultaneously, mix some low viscosity Duroplast or composite material. Avoid using too much liquid. Using much liquid means more shrinkage during the curing process and therefore a poorer adhesive bond to the dental prosthesis.
- ▶ Apply the plastic material to both jaw of the pliers. Do not spread an excessive amount of plastic material into the clamps that are adapted to the shape of the tooth. Otherwise, too much dampening of the impact of the strike is prevented.



- ▶ Place the clamp on the dental prosthesis to which adhesive has been applied. The plastic material that is used must emanate from the holes of the clamp and extend to the gingival edge. In order to preserve the veneering in the case of crowns and frontal tooth crowns with ceramic veneers, it is recommended not to grasp the occlusal surface or cutting edge with plastic material.
- ▶ Excess material in approximal position needs to be removed before it cures (in order to protect adjacent teeth). Firm bonding of adhesive clamp to the dental prosthesis is thus attained.
- ▶ Once the adhesive and the plastic material dried somewhat and are cured, apply the CORONAFlex in axial position and trigger the impact pulse.

- Soften the modelling wax over a white spirit or gas flame and remove it from the removed dental prosthesis. For reasons of adhesive effect and visual appearance, it is recommended to have the adhesive clamp blasted at the dental lab in regular intervals.

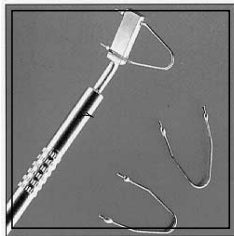
**Note**

Comply with the notes of the manufacturer of the adhesive.

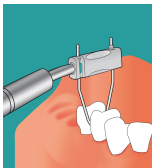
**Note**

Proper use of the adhesive clamp takes some practice. However, the rate of success achieved with the adhesive clamp, if applied properly, is several-fold higher than with the pliers (less mass needs to be accelerated, better transmission of the impact). Experience has shown that dental prostheses that cannot be removed with the pliers can be removed easily using the clamp.

5.6.3 Application: Loop



The loops are suitable for removal of bridge-units in the region of the frontal and lateral teeth.



- ▶ Pass the loop through under the bridge as close as possible to the abutment tooth.
- ▶ Fix the loop with the loop holder.
- ▶ If seated firmly, check pull and direction of removal.
- ▶ Place the **CORONAFlex** and trigger the impact pulse.



Note

For removal of a bridge in the region of the lateral teeth with premolars and molars as abutment tooth, the loop should first be placed near the weakest premolar.

**Note**

If the loop cannot be passed through between crowns that are situated too close to each other, the two retention buttons on the loop can be ground down to some degree. Alternatively, use a surgical wire with a diameter of 0.4 mm. Pass-through the wire three to four times and make several knots (just twisting the wire is not enough). Make sure the loops are equal in length. Place the impact lever of the CORONAFlex at the loops and situate in axial pull. Trigger impact pulse.

5.7 Incorrect usage

As any tooth removal system, the application of the CORONAFlex may be associated with problems.

**⚠ CAUTION**

A stump fracture may occur in rare cases.

In order to prevent this, please note the following:

- ▶ seek axial pulling direction only
- ▶ in the case of frontal teeth (CAUTION: large crown-cement surface relative to small stump cross-section), start with lowest impact force and increase up to max. 50 %.
- ▶ if there is any sign of secondary caries, the risk of fracture is known to be larger than if the dentine is healthy.

**⚠ CAUTION**

The CORONAflex must not be used in case the tooth holder apparatus shows strong previous periodontal damage (deep gingival pockets with a clear loss of bone).

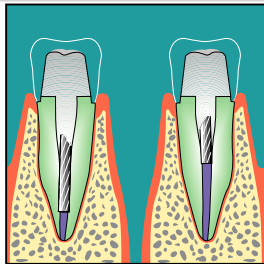


**⚠ CAUTION**

Root fracture due to inadvertent lodging while removing the crown or bridge.

In the case of pin superstructures, the length of the root canal pin should be equal to two-thirds of the length of the root canal.

- ▶ If the patient experiences pain during application, this could be evidence of inflammation of the periodontium due to advanced pulpitis.



6 Reconditioning methods according to ISO 17664



Note

The reconditioning methods described in the following apply to the CORONAFlex, pliers, loop, loop holder, and cleaning attachment.

6.1 Preparation at the site of use



WARNING

Hazard from nonsterile products.

There is a risk of infection from contaminated medical devices.

- ▶ Take suitable personal protective measures.
- ▶ Remove all residual cement or blood without delay.

- ▶ The medical device must be dry when transported for reconditioning. Do not place it in a solution or similar.
- ▶ Recondition the medical device as soon as possible after treatment.

6.2 Cleaning



CAUTION

Malfunctions from cleaning in the ultrasonic unit.

Defects in the product.

- ▶ The CORONAFlex 2005 may be cleaned manually only!
- ▶ Clean the pliers, loop, loop holder, and cleaning attachment in the thermodisinfectior or manually.

**Note**

After manual or automatic cleaning, the pliers holder needs to be serviced with KaVo spray.

6.2.1 Cleaning: Manual cleaning - external

Accessories required:

- Tap water $30\text{ °C} \pm 5\text{ °C}$ ($86\text{ °F} \pm 10\text{ °F}$)
 - Brush, e.g. medium-hard toothbrush
- Brush off under flowing tap water.

**Note**

No potable water must enter into the inside of the handpiece.

6.2.2 Cleaning: Automated external cleaning



Note

Not applicable for the CORONAflex 2005.



Note

Applicable only for pliers, loop, loop holder, and cleaning attachment.



KaVo recommends thermodisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781 / G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® miel-clear" and only applies to the material compatibility with KaVo products).

- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfectant (complying with max. pH value of 10).
- ▶ In order to prevent impairment of the KaVo medical device, make sure that the inside and outside of the device is dry after the end of the cycle.

6.2.3 Cleaning: Manual cleaning of the inside



Note

Manual cleaning of the interior should be carried out over a basin or a covered surface.

Can only be done with KaVo CLEANspray.

**Note**

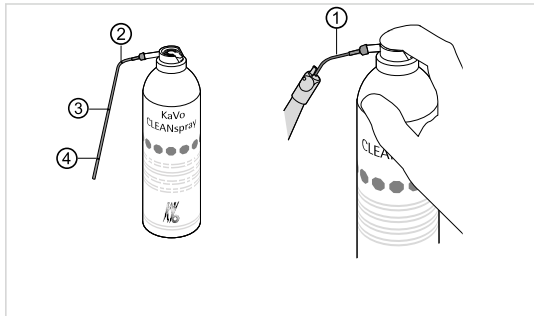
KaVo CLEANspray for manual interior cleaning is only available in the following countries:

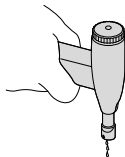
Germany, Austria, Switzerland, Italy, Spain, Portugal, France, Luxembourg, Belgium, Netherlands, United Kingdom, Denmark, Sweden, Finland and Norway.

In other countries interior cleaning can only be carried out with thermosinfectors in accordance with ISO 15883-1.

- Pull the CORONAFlex off the coupling while twisting slightly.

- Guide the tube of the cleaning attachment ① through one of the two bore holes of the CORONAfex to the upper marking ② on the tube of the CORONAfex. Keep the CLEANSpray can vertical.





- ▶ Spray one spray puff through the CORONAFlex until foam exits from the openings of the CORONAFlex (at least for 4 seconds). Wait for the foam to become liquid.
- ▶ Repeat this procedure three times while each time pulling the tube further out to the next marking ③ and ④.
- ▶ Take the CORONAFlex off the cleaning attachment, place it in the holder with its tube facing vertically upward and allow the cleaning agent to act for 3 minutes.
- ▶ Let CLEANSpray drain from the bore holes of the CORONAFlex.
- ▶ Rinse the CORONAFlex with deionised water (10 ml).

- ▶ Let the deionised water drain from the bore holes of the CORONAFlex.

**Note**

In order to keep the CORONAFlex 2005 functional, the following additional steps are required during reconditioning.

**Note**

As the CORONAFlex 2005 does not require any light, spray water or spray air, these functions need to be disabled.

**⚠ WARNING****Detachment of the medical device during reconditioning.**

A medical device that is not properly locked in place can become detached from the MULTIflex (LUX) / MULTIflex LED coupling during reconditioning.

- ▶ Before each reconditioning, check if the medical device is securely locked onto the MULTIflex (LUX) / MULTIflex LED coupling by pulling on it.
- ▶ Mount the CORONAfex accurately on the MULTIflex (LUX) / MULTIflex LED coupling and push it backward until the coupling audibly locks in the CORONAfex.
- ▶ Pull on the CORONAfex to make sure that it is securely affixed to the coupling.

- ▶ Set the CORONAFlex to a medium impact force with the knurled screw.

Requirement

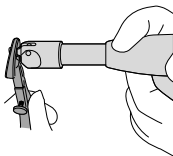
In order to be able to set the impact force, the handpiece must be free of pressure, i.e. the foot control must not be pressed.

- ▶ Actuate drive air on the foot control in order to keep the handpiece ready for impact.

**⚠ CAUTION**

The CORONAFlex is subject to increased wear and tear if operated without load.

- ▶ Do not operate the CORONAFlex without load.



- ▶ Apply the crown pliers for this purpose, since the CORONAFlex must not be actuated without load. Trigger the CORONAFlex 6x by closing the nozzle with a finger. To render the handpiece ready for impact again, take your finger off the nozzle between triggered impacts and wait for 2 to 3 seconds.
- ▶ Pull the CORONAFlex off the coupling while twisting slightly.
- ▶ Set the CORONAFlex to lowest impact force with the knurled screw.

6.2.4 Cleaning: Automated internal cleaning

Not applicable.

6.3 Disinfection



CAUTION

Malfunctioning from using the disinfectant bath or chlorine-containing disinfectants.

Defects in the product.

- ▶ The CORONAFlex 2005 may be disinfected manually only!

6.3.1 Disinfection: Manual disinfection of the exterior



CAUTION

Malfunction may be caused by disinfectant entering the interior of the CORONAflex.
Malfunctions.

- ▶ Avoid spraying into the air openings directly from the front.

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

- Mikrozyd AF Liquid made by Schülke & Mayr
- FD 322 made by Dür

- CaviCide made by Metrex

Consumables required:

- 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.
- ▶ Follow the instructions for use of the disinfectant.

6.3.2 Disinfection: Manual disinfection of the interior

Not applicable.

6.3.3 Disinfection: Mechanical disinfection of the exterior and interior

**Note**

Not applicable for the CORONAflex 2005.

**Note**

Applicable only for pliers, loop, loop holder, and cleaning attachment.



KaVo recommends thermosdisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781 / G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® miel-clear" and only applies to the material compatibility with KaVo products).

- ▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfectant (complying with max. pH value of 10).
- ▶ In order to prevent impairment of the KaVo medical device, make sure that the inside and outside of the device is dry after the end of the cycle.

6.4 Drying

Manual Drying

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

Automatic Drying



Note

Not applicable for the CORONAFlex 2005.



Note

Applicable only for pliers, loop, loop holder, and cleaning attachment.

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

- Follow the instructions for use of the thermodisinfectors.

6.5 Care products and systems - Servicing



CAUTION

Do not clean the CORONAFlex with oil or care spray.

Malfunction or damage to the product.

- ▶ The CORONAFlex must not be lubricated with oil or care spray.

6.6 Packaging



Note

The sterilisation bag must be large enough for the goods to be sterilised without stretching the packaging.

The quality and use of the sterilisation packaging must comply with applicable standards and be suitable for the sterilisation procedure!

- ▶ Seal each product to be sterilised individually in a sterilised item package!

6.7 Sterilisation

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



CAUTION

Contact corrosion due to moisture.
Damage to product.

- ▶ Immediately remove the product from the steam steriliser after the sterilisation cycle!



The 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)
 - 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
 - at least 60 minutes at 121 °C -1 °C / +4 °C (250 °F -1.6 °F / +7.4 °F)
- Use according to the manufacturer's Instructions for Use.

6.8 Storage

- ▶ Reprocessed 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 items.

7 Tools and consumables

Available from dental suppliers.

Material summary	Mat. no.
Crown pliers	0.579.0111
Clamp, small	0.579.0392
Clamp, large	0.579.0402
Loop holder	0.579.0412
Loop	0.579.0422
Cleaning attachment	1.005.9618

Material summary	Mat. no.
KaVo CLEANspray 2110 P	1.007.0579
KaVo Spray 2112 A	0.411.9640

8 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 the date of the invoice, subject to the following conditions:

In case of justified complaints, KaVo will honour its warranty with a free replacement or repair. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.

KaVo shall not be liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies

or chemical or electrical factors deemed abnormal or impermissible in accordance with KaVo's instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to lamps, light conductors made of glass and glass fibres, glassware, rubber parts, and the colourfastness of plastic parts.

All liability is excluded if defects or their consequences originate from manipulations or changes to the product made by the customer or a third party that is not authorised by KaVo.

Warranty claims will only be accepted if the product is submitted along with proof of purchase in the form of a copy of the invoice or note of delivery. The dealer, purchase date, type, and serial number must be clearly evident from this document.



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