

Instructions for use

PROPHYflex 4 Perio Kit

- 1.011.9403

Refill PROPHYflex perio tip

- 1.010.0287



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1 User instructions

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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**KaVo Technical Service**

If you have any questions or complaints, please contact the KaVo Technical Service:

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KaVo Repair Service

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Target group





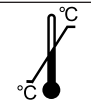





This document is intended for dentists and their assistants. The startup section is also intended for service technicians.

General marks and 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-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermoisinfectable

Information on the packaging

	Material number
	Serial number
	Legal Manufacturer
	CE mark according to Medical Devices Directive EC 93/42

	Please note the electronic instructions for use
	Note: observe accompanying documents
	EAC conformity mark (Eurasian Conformity)
	GOST R certification
	Transportation and storage conditions (Temperature range)
	Transportation and storage conditions (Air pressure)
	Transportation and storage conditions (Humidity)
	Protect from moisture
	Protect from impact
	HIBC Code

Hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and material damage. The warning notes are designated as shown below:



DANGER

In cases which – if not prevented – directly lead to death or severe injury.



WARNING

In cases which – if not prevented – could lead to death or severe injury.



CAUTION

In cases which – if not prevented – could lead to minor or moderate injury.

NOTICE

In cases which – if not prevented – could lead to material damage.

2 Safety

The instructions for use are a component of the product and must be read carefully prior to use and be accessible at all times.

The device may only be used in accordance with the intended use, any other type of use is not permitted.

2.1 Infection hazard

Patients, users or third parties could be infected by contaminated medical devices.

- ▶ Take suitable personal protective measures.
- ▶ Follow the instructions for using the components.
- ▶ Before initial startup and after each use, reprocess the product and accessories appropriately.
- ▶ Carry out the reprocessing as described in the instructions for use. The procedure has been validated by the manufacturer.
- ▶ If you deviate from this procedure, it is essential to make sure that the reprocessing is effective.
- ▶ Reprocess the product and accessories appropriately before disposal.

2.2 Air embolism and skin emphysema

There is a danger that the insufflation of spray can cause air embolisms and skin emphysema.

- ▶ Avoid the insufflation of spray in open wounds.

The improper use of the product might lead to emphysema. Emphysema may arise in extreme individual cases, especially in the presence of pathological gingival pockets (> 3 mm), mucosal lesions, direct skin contact or contact with soft tissue and/or improper handling.

- ▶ The powder jet device must be used as briefly as possible.
- ▶ The PROPHYflex perio tip may be re-used for up to 10 times.
- ▶ After the treatment, unscrew the empty powder container and rinse the PROPHYFLEX perio tip with air and water for approx. 10 seconds.
- ▶ For safety reasons, the torque wrench should be placed on the perio tip as protection against injuries when the is PROPHYflex in the holder.

2.3 Technical condition

A damaged device or components could injure patients, users and third parties.

- ▶ Only operate devices or components if they are undamaged on the outside.
- ▶ Check that the device is working properly and is in satisfactory condition before each use.
- ▶ Have parts with sites of breakage or surface changes checked by the Service.

Observe the following instructions in order to guarantee optimum functioning and prevent material damage:

- ▶ The device should be cleaned, serviced and stored in a dry location, according to instructions, if it will not be used for a longer period.

2.4 Accessories and combination with other equipment

Use of un-authorised accessories or un-authorised modifications of the device could lead to injury.

- ▶ Only use accessories that have been approved for combination with the product by the manufacturer.
- ▶ Only use consumables that have been approved for combination with the product by the manufacturer.
- ▶ Do not make any modifications to the device unless these have been approved by the manufacturer of the product.

2.5 Qualification of personnel

Application of the product by users without the appropriate medical training could injure the patients, the users or third parties.

- ▶ Make sure that the user has read and understood the instructions for use.
- ▶ Only employ the device if the user has the appropriate medical training.
- ▶ Observe national and regional regulations.

2.6 Protective equipment

PROPHYflex Powder and other powders may get in the eyes or mouth of the user or patient during treatment.

- ▶ Both patient and user have to wear protective goggles during the treatment.
- ▶ KaVo recommends the use of dust extraction equipment and mouth protection during the treatment with PROPHYflex.

3 Product Description

PROPHYflex 4 perio Kit - REF 1.011.9403



Index

- | | |
|--|-------------------------------|
| ① 3x perio tip | ② 1x Adapter |
| ③ 1x Wrench | ④ 1x Nozzle pin |
| ⑤ 2x Powder container
20g. Perio Powder | ⑥ 2x Rubber cover subgingival |

PROPHYflex perio tip Refill - REF 1.010.0287



Index

- | | |
|-----------------|-------------|
| ① 10x perio tip | ② 1x Wrench |
| ③ 1x Nozzle pin | |



The markings of the PROPHYflex perio tip are based on the WHO index.

3.1 Intended use

Indications for use:

This medical device is

- intended for dental treatment only. All other types of use or modifications of the product are not permitted and can be hazardous.
- The PROPHYflex perio tip is designed for use in combination with PROPHYflex Perio Powder for the removal of sub- and supragingival plaque.

Proper use:

According to these provisions, the medical device is only for the described use in conformance with:

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

According to these regulations, the user is required to:

- only use properly operating equipment,
- to comply with the specified intended use.
- to protect himself, the patient and third parties from danger,
- to avoid contamination by the product.





3.2 Transportation and storage conditions

NOTICE

Startup after refrigerated storage.

Malfunction.

- Prior to startup, very cold products must be heated up 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 85% RH absence of condensation
	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
	Protect from moisture

4 Startup and shut down



WARNING

Hazard from non-sterile products.

Infection hazard for dentist and patient.

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

See also:

 6 Reprocessing steps in accordance with ISO 17664, Page 15



WARNING

Dispose of the product in appropriate manner.

Infection hazard.

- ▶ Before disposal, reprocess and sterilise the product and accessories appropriately.
- ▶ Dispose of the perio tip like injection needles in a closed container.

See also:

 6 Reprocessing steps in accordance with ISO 17664, Page 15

4.1 Inserting the adaptor into the PROPHYflex



CAUTION

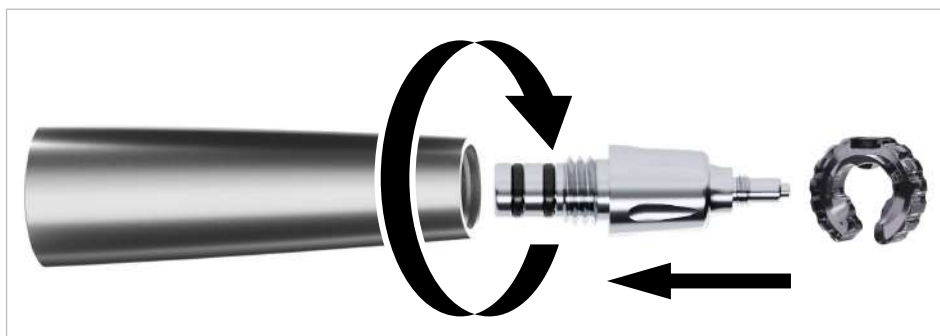
Adapter falling off during the treatment.

The adapter falling off is a hazard for patient and user.

Visual inspection each time the adapter is inserted.

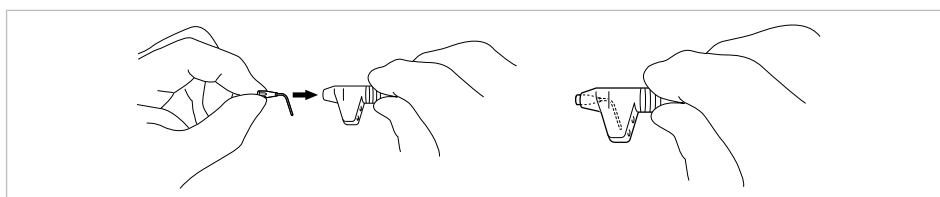
Before commencing the treatment, check that there is no gap between the adapter and the gripping sleeve.

- ▶ Insert the adapter in the gripping sleeve and use the wrench for the cannula (**Mat. no. 3.004.6351**) to tighten it in clockwise direction while holding on to the gripping sleeve.



4.2 Inserting the PROPHYflex perio tip into the wrench

- ▶ Slide the PROPHYflex perio tip into the wrench until it locks into place.



4.3 Screwing the PROPHYflex perio tip onto the adaptor using the wrench



⚠ CAUTION

Hazard from detachment of the perio tip during the treatment.

This can lead to a significant hazard for user and patient.

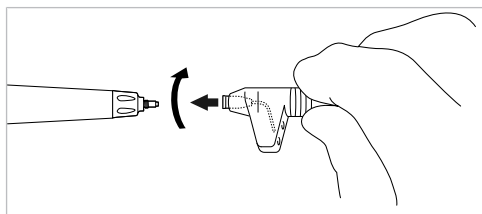
- ▶ Pull on the perio tip before each treatment and check if it is seated firmly.
- ▶ Before each treatment, make sure that the perio tip works properly.



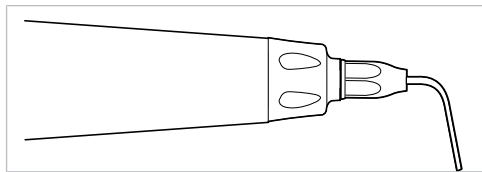
Note

In order to screw it on, hold the wrench with 2 fingers in the round grasping area (not at the cover for the perio tip).

- ▶ Screw the PROPHYflex perio tip onto the adaptor in clockwise direction holding the wrench with 2 fingers.

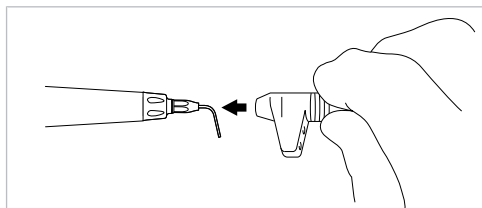


- ▶ Pull the wrench off and check if the perio tip is seated firmly by pulling on it.



4.4 Removing the PROPHYflex perio tip

- ▶ Slide the wrench onto the PROPHYflex perio tip.

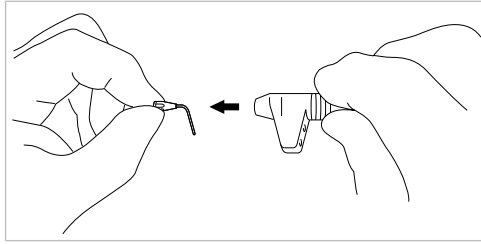


- ▶ Unscrew the PROPHYflex perio tip using the wrench in counter-clockwise direction.



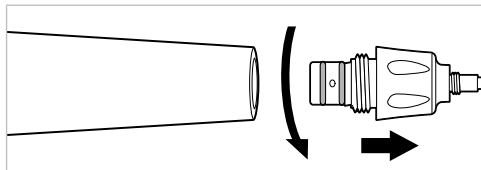
4 Startup and shut down | 4.4 Removing the PROPHYflex perio tip

- Carefully pull the PROPHYflex perio tip out of the wrench.



Take the adapter off

- Unscrew the adapter in counterclockwise direction using the wrench for the cannula (**Mat. no. 3.004.6351**).



5 Operation

Preparation

CAUTION

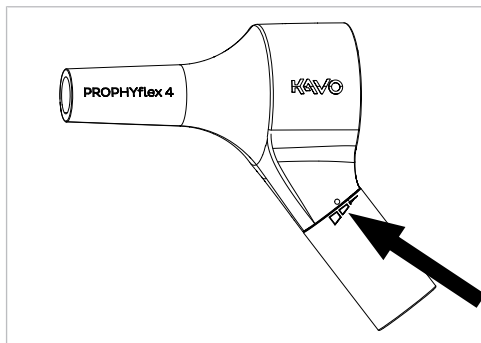
Risk of increased development of emphysema.

If the pressure is too high during the treatment, there is an increased risk of emphysema developing.

- ▶ Do not select the highest level for the treatment.

- ▶ The powder quantity can be controlled at three levels using the adjusting ring on the PROPHYflex 4.

⇒ Select the middle level for the treatment.



Add the powder

- ▶ Shake the bottle before adding powder.
- ▶ Add PROPHYflex Perio Powder to the marked level of the powder container. Add the powder slowly to avoid the formation of dust.
- ▶ Screw the container filled with the PROPHYflex Perio Powder onto the PROPHYflex 4.

Settings on the powder jet unit

- ▶ Aim the jet nozzle at a wet washbasin from a distance of approx. 20 cm.
- ▶ Set the quantities of water and air/powder for treatment as described in the Instructions for Use of the unit. Never use the powder jet device without water since this would render the mixture of air/powder more difficult to aspirate.
- ▶ Direct the jet into a washbasin until a homogeneous powder/water mixture is produced.

Getting the patient ready

- ▶ Apply some Vaseline® ointment to the patient's lips. This prevents the lips from becoming dry and cracking.
- ▶ Hook the small saliva ejector in the corner of the patient's mouth such that the saliva is extracted from under the tongue. Use a large suction cannula for aspiration of the water/powder mixture bouncing off the tooth.

Treating the patient



CAUTION

Hazard from overly frequent use or dropping of the handpiece.

The PROPHYflex perio tip can fracture or be contaminated.

- Re-use the PROPHYflex perio tip for up to 10 times.

Indication

- Pockets with a probing depth of up to 5 mm
- Use 1-3 weeks after initial treatment with sonic, ultrasonic or hand-held instruments
- Root tip with at least 3 mm bony periodontium comprises
- Record X-ray image for clarification

Contraindication

- Apical focus
- Root caries

Treatment procedure:

1. Introduce the perio tip to the floor of the pocket, then pull the perio tip out by 1-2 mm.
2. Start-up the PROPHYflex with the foot control.
3. Using slight swinging motions, pull the perio tip out of the pocket and deactivate the foot control.
4. Spray the treated sites with anti-inflammatory agent twice daily for 1 to 4 weeks.



Note

The PROPHYflex perio tip must not be used in combination with powder for supragingival plaque.



Note

Please advise your patients that the intake of foods (tea, coffee or food items) in the first 2-3 hours after the treatment may lead to discoloration of the teeth.



Note

The abrasion can be varied on devices in which the drive air can be adjusted with a foot switch.

6 Reprocessing steps in accordance with ISO 17664



WARNING

Hazard from non-sterile products.

Infection hazard for dentist and patient.

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



Note

The reprocessing procedures described in the following apply to the PROPHYflex perio tip, adaptor and wrench.

6.1 Preparations at the site of use



WARNING

Hazard from contaminated products.

Contaminated products are associated with an infection hazard.

- ▶ Take suitable personal protective measures.



Note

Do not place the perio tip in the drill bit bath since the fine capillaries will not be able to be rinsed under running water any longer and strong corrosion occurs.

- ▶ Use the wrench to remove the PROPHYflex perio tip from the adaptor.

See also:

 4.4 Removing the PROPHYflex perio tip, Page 11



Note

Hardened or damaged adaptor O-rings need to be replaced.

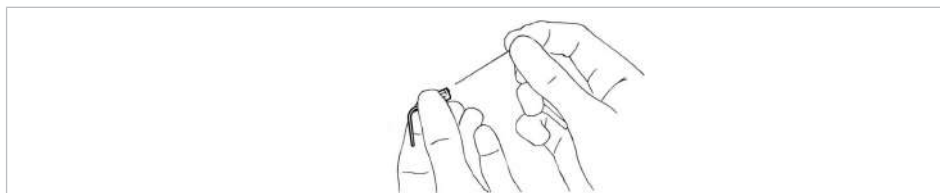
- ▶ Reprocess the medical device as soon as possible after treatment.
- ▶ The medical device must be dry when transported to reprocessing.
- ▶ To minimise the risk of infection during reprocessing, always wear protective gloves.
- ▶ Remove all residual cement, composite or blood immediately.
- ▶ Do not place in solutions or similar substance.

6.2 Non-fixing pre-cleaning of the PROPHYflex perio tip

Accessories required:

- Demineralised water 30 °C ± 2 °C (86 °F +/- 4 °F)
- Nozzle pin
- Brush, e.g. medium-hard toothbrush
- Disposable syringe
- ▶ Brush the PROPHYflex perio tip with a medium-hard toothbrush under demineralised water.
- ▶ Check the patency of the PROPHYflex perio tip and if necessary clean it with the nozzle pin (**Mat. no. 0.410.0911**).
- ▶ Rinse the PROPHYflex perio tip with at least 20 ml demineralised water using a disposable syringe.

- ▶ If the PROPHYflex perio tip cannot be determined to be patent after the manual rinsing procedure or once 10 reprocessing cycles have been completed, the medical device must be replaced.



6.3 Manual Reprocessing



WARNING

Sharp tool in the medical device.

Injury hazard from sharp and/or pointed tool.

- ▶ Remove the tool.

NOTICE

Never reprocess this medical device in an ultrasonic device.

Malfunction and material damage.

- ▶ Clean it in a washer disinfectant only.

6.3.1 Manual external cleaning

Manual external cleaning of the PROPHYflex 4 perio tip is not applicable. For effective reprocessing after non-fixating pre-cleaning, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with ISO 15883-1.

6.3.2 Manual internal cleaning

Manual internal cleaning of the PROPHYflex 4 perio tip is not applicable. For effective reprocessing after non-fixating pre-cleaning, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with ISO 15883-1.

6.3.3 Manual external disinfection

WARNING

Incomplete disinfection.

Infection hazard.

- ▶ Only use disinfection procedures that are verified to be bactericidal, fungicidal and virucidal.
- ▶ If the disinfectants used do not meet these requirements, the process must be concluded by disinfection of the unit(s) without packaging using a steam steriliser.



NOTICE

Never disinfect the medical device with chloride-containing products.

Malfunction and material damage.

- ▶ Only disinfect in a washer disinfectant or manually.

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

Approved disinfectants:

- Mikrozid AF made by Schülke & Mayr (liquid or cloths)
- FD 322 made by Dürr
- CaviCide made by Metrex

Consumables required:

- Cloths for wiping the medical device.
- ▶ Spray the disinfectant on a cloth, then wipe down the medical device and allow the disinfectant to act according to the instructions of the disinfectant manufacturer.
- ▶ Follow the instructions for use of the disinfectant.



6.3.4 Manual disinfection - internal

Manual internal disinfection of the PROPHYflex 4 perio tip is not applicable. For effective reprocessing, the inside of the device must be subjected to automated cleaning in a cleaning and disinfection unit in accordance with ISO 15883-1.

6.3.5 Manual drying

Use KaVo DRYspray for subsequent drying of the air, water and gear unit ducts.

- ▶ Cover the medical device with the KaVo CLEANpac bag, and place it on the corresponding care adapter.
- ▶ Hold the can vertically.
- ▶ Press the spray key for at least 3 seconds.

See also:

 KaVo DRYspray Instructions for Use



Note

KaVo CLEANSpray and KaVo DRYspray for manual interior cleaning are only available in the following countries:

Belgium, Denmark, Germany, Finland, France, United Kingdom, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Austria, Poland, Portugal, Sweden, Switzerland, Spain and the Czech Republic.

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

6.4 Automated reprocessing



⚠ WARNING

Incomplete disinfection.

Infection hazard.

- ▶ Only use disinfection procedures that are verified to be bactericidal, fungicidal and virucidal.
- ▶ If the disinfectants used do not meet these requirements, the process must be concluded by disinfection of the unit(s) without packaging using a steam steriliser.



⚠ WARNING

Sharp tool in the medical device.

Injury hazard from sharp and/or pointed tool.

- ▶ Remove the tool.

NOTICE

Never disinfect the medical device with chloride-containing products.

Malfunction and material damage.

- ▶ Only disinfect in a washer disinfector or manually.

NOTICE

Never reprocess this medical device in an ultrasonic device.

Malfunction and material damage.

- ▶ Clean manually or in a washer disinfector only.

6.4.1 Preparation for automated internal and external cleaning as well as internal and external disinfection



Note

For reprocessing, attach the PROPHYflex perio tip ③ with adapter ② to the cleaning adapter PROPHYflex 4 long (**Mat. no. 3.004.6640**) ①.

- ▶ Slide the PROPHYflex perio tip into the wrench until it locks into place.
- ▶ Screw the PROPHYflex perio tip onto the adapter in clockwise direction holding the wrench with 2 fingers.
- ▶ Pull the wrench off.
- ▶ Attach the PROPHYflex perio tip to the cleaning adapter PROPHYflex 4 long (**Mat. no. 3.004.6640**).



- ① PROPHYflex perio tip
- ② Adaptor
- ③ Cleaning adapter PROPHYflex 4 long

- ▶ Place the cleaning adapter PROPHYflex 4 long (**Mat. no. 3.004.6640**) on the receptacle for INTRA connectors.

6.4.2 Automated internal and external cleaning and internal and external disinfection



KaVo recommends washer disinfectors according to EN ISO 15883-1, which are operated using alkaline cleaning agents having a maximum pH value of 10. The validation was conducted with a Miele washer disinfector using the "VARIO-TD" programme, the "neodisher® mediClean" cleaning agent, the neodisher® Z" neutralisation agent and the "neodisher® mielclear" rinsing agent.

- ▶ For programme settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the washer disinfector.

6.4.3 Automated Drying

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



Note

Please observe the instructions for use of the thermodisinfectors.

- ▶ 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.
- ▶ Remove any residual liquids with KaVo DRYspray.

See also:

📖 6.3.5 Manual drying, Page 17

6.5 Visual inspection and functional check



Note

Plug the adaptor with the PROPHYflex perio tip onto the PROPHYflex with an empty powder container, and check it.

6.6 Care products and systems - Servicing

NOTICE

Improper care.

Malfunction or property damage.

- ▶ Do not service the PROPHYflex perio tip and adapter with oils or care spray.

6.7 Packaging



Note

The sterilisation bag must be large enough to accommodate the perio tip without stretching the bag.

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

- ▶ The medical device must be packed before sterilisation.

6.8 Sterilisation

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

NOTICE

Contact corrosion due to moisture.

Damage to product.

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



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

Select a suitable procedure (depending on the available autoclave) from the following sterilisation processes:

- Steriliser with triple pre-vacuum:
 - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Steriliser using the gravity method:
 - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- ▶ Use according to the manufacturer's Instructions for Use.

6.9 Storage

Reprocessed products must be stored appropriately such that they are protected from germs (as far as possible) and dust, in a dry, dark, cool room.



Note

Comply with the expiry date of the sterilised items.

7 Tools

Available from dental suppliers.

Adapter perio tip		1.011.9400
Key		2.000.0901
Wrench for cannula		3.004.6351
Nozzle pin		0.410.0911
PROPHYflex perio tip Refill (10 pcs)		1.010.0287
Cleaning adapter PROPHYflex 4 long		3.004.6640
Powder container		3.002.8136
Rubber cover subgingival		3.004.4709
PROPHYflex Perio Powder (4x 100g)		1.009.3732

8 Terms and conditions of warranty

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 10 reprocessing cycles / applications or 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, optical fibres 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.

